# 1NC

## Offs

### 1

#### Interp – reductions are permanent

Reynolds 59. Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway. The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency. Aside from the practical aspect indicating permanency other indicia point to the same conclusion. From 1924 (L. 1924, ch. 619) to 1947 (L. 1947, ch. 841) a provision appeared in the Civil Service Law which read substantially as follows: "If the pension of a beneficiary is reduced for any reason, the amount of such reduction shall be transferred from the pension reserve fund to the pension accumulation fund during that period that such reduction is in effect." (See L. 1924, ch. 619, § 2 [Civil Service Law, § 58, subd. 4]; L. 1947, ch. 841 [Civil Service Law, § 66, subd. e].) This provision reappears in the 1955 Retirement and Social Security Law as subdivision f of section 24. This provision is useful for interpretative purposes. Since it prescribes that moneys not paid because of reduction should be transferred back to the accumulation fund the conclusion is inescapable that such reductions were meant to be permanent. If temporary suspensions were intended this bookkeeping device would result in a false picture of the funds, i.e., the reserve fund would be depleted when it would contain adequate funds to meet eventual payments 57\*57 to present pensioners. Likewise, the accumulation fund would be improperly inflated with respect to the present pensioners. Section 64 of the Retirement and Social Security Law (§ 85 under the 1947 act) provides that any disability pension must be reduced by the amount payable pursuant to the Workmen's Compensation Law if applicable. In Matter of Dalton v. City of Yonkers (262 App. Div. 321, 323 [1941]) this court interpreted "reduce" to mean "offset" in holding that under then section 67 (relating to Workmen's Compensation benefits as do its successors sections 85 and 64), pensions were to be offset by compensation benefits. This is merely another indication that "reduce" means a diminishing of the pension pursuant to a given formula rather than a mere recoverable, temporary suspension during the time other benefits or salaries are being received by the pensioner. (Also, cf., Retirement and Social Security Law, § 101 [§ 84 under the 1947 act].)

#### Violation – cx

#### Negate –

#### Limits and topic lit – their model allows adding on infinite random suspensions to IP protections, anything from conditioning IP protections on human rights to monopolistic tendencies – the core of the debate is reducing IP protections, not temporarily suspending them

### 2

#### Interp – “medicines” treat or cure, whereas vaccines prevent – o/w on specificity since it’s about the COVID vaccine

Vecchio 7/22 (Christopher Vecchio, [CFA, Senior Strategist,], 7-22-2021, “Delta Variant Concerns Won't Cripple Markets, US Economy“, DailyFX, accessed: 8-9-2021, https://www.dailyfx.com/forex/video/daily\_news\_report/2021/07/22/market-minutes-delta-variant-concerns-wont-cripple-markets-us-economy.html) ajs

Let’s stick to the facts. The COVID-19 vaccines are not medicines, which by definition “treat or cure diseases.” Vaccines “help prevent diseases,” an important distinction. Why does this matter? Because data coming out of some of the world’s developed economies with high adult vaccination rates suggest that the vaccines are working as intended: tail-risks have been reduced, with hospitalizations and deaths falling relative to the recent spike in infections (which have been occurring primarily among the unvaccinated at this point). Put another way, vaccines are like a Kevlar vest for the immune system; while they don’t make you bulletproof, they dramatically increase the odds of surviving an adverse event.

#### Violation – j vaccines

#### Negate –

#### 1] Limits – expanding the topic to preventative treatment or medical interventions allows anything from surgery to medical devices to education strategies or mosquito repellent to prevent malaria. Destroys core generics like innovation which are exclusive to disease curing – core of the topic is about proprietary information.

#### Voters:

#### Drop the debater – they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to,

#### Use competing interps reasonability invites arbitrary judge intervention since we don’t know your bs meter,

#### No RVIs –illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance,

#### Evaluate T before 1AR theory – norms – we only have a couple months to set T norms but can set 1AR theory norms anytime,

### 3

#### CP: The United States of America should declare covid a national emergency on the basis of <> and issue compulsory licenses for COVID-19 vaccines. Member nations should offer regulatory and legal assistance to nations filing a compulsory license.

#### Compulsory licensing solves access- empirics and past precedent

**Zhuang 2017** (Wei, PhD from the University of Geneva, is currently an associate in the Geneva Office of Van Bael & Bellis. She assists governments in WTO dispute settlement proceedings and advises companies and governments in trade remedy investigations. Prior to joining Van Bael & Bellis, Wei worked in the Legal Affairs Division of the WTO as part of a Secretariat Team on a trade remedy dispute from beginning to end. In addition, she assisted the WTO Secretariat Team in an IP-related dispute, including by contributing to the preliminary rulings. Wei has also gained practical experience as a legal consultant at the United Nations (2010 – 2011), as a legal intern at the International Tribunal for the Law of the Sea (2009) and as an associate judicial officer at the Commission for Discipline Inspection (Muchuan Branch) in China. Wei was also a Marie Curie Fellow with the DISSETTLE (Dispute Settlement in Trade: Training in Law and Economics) Programme; a Visiting Fellow at the Lauterpacht Centre for International Law, University of Cambridge, and a Research Fellow at the Max Planck Institute for IP and Competition Law. Interpreting Patent-Related Flexibilities in the TRIIPS Agreement for Facilitating Innovation and Transfer of ESTs, chapter 6 of *Intellectual Property Rights and Climate Change* Cambridge University Press Pg. 298-304)DR 21

\*\*\*Note: EST= Environmentally Sound Technologies\*\*\*

Even though there are limits to their effectiveness, compulsory licences are considered a valuable tool for governments to facilitate access to medicines through the prevention of patent abuses as well as the “encouragement of domestic capacities for manufacturing pharmaceuticals”. 289 According to the UNDP Human Development Report (2001), after the adoption of the TRIPS Agreement, compulsory licences were initially mainly used in Canada, Japan, the UK and the United States for products such as pharmaceuticals – particularly as a remedy to address anti-competitive practices and prevent higher prices – while no compulsory licence was issued then in developing countries largely due to pressure from Europe and the United States and the fear of long and expensive litigation against the pharmaceutical industry.290 As demonstrated in Section 5.4.1.2, in order to address developing countries’ concern, the 2001 Doha Declaration explicitly reaffirmed the right of countries to issue compulsory licences where necessary, in the interests of public health.

In order to enable countries with insufficient manufacturing capacity in the pharmaceutical sector to benefit from the compulsory licensing system, the WTO General Council adopted the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (the so-called paragraph 6 system).291 This decision essentially expanded the TRIPS flexibilities, involving two waivers: (1) with respect to the exporting country, a “waiver” of obligations to use the authorised compulsory licence predominantly for the supply of the domestic market under Article 31(f); and (2) with regard to the importing country, a waiver of the adequate remuneration requirement under Article 31(h) when remuneration is paid in the exporting Member. “Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorised in the exporting Member”. 292

In 2005, WTO Members agreed to make the waivers permanent by amending the TRIPS Agreement.293 With the approval of two-thirds of the WTO Members, the amendment entered into force on 23 January 2017. As the very first legal amendment to a WTO multilateral agreement, it was said to have shown that “[M]embers are determined to ensure the WTO’s trading system contributes to humanitarian and development goals”. 294 Likewise, such amendment could be extended to address other global concerns such as climate change in accordance with the WTO’s sustainable development objective and Articles 7 and 8 of the TRIPS Agreement.

In effect, the compulsory licensing system established within the WTO framework is not a panacea, but rather a legal guarantee of rights and ability to make effective use of compulsory licences. Since the adoption of the Doha Declaration, a number of developing countries (e.g., Thailand, Brazil, Ecuador, India and Indonesia) have issued compulsory licences to lower the price of patented medicines such as HIV/AIDS drugs.295 Additionally, in 2007, Rwanda became the first country without sufficient manufacturing capacities to use the WTO “paragraph 6 system” to import Apo-TriAvir from Apotex, a Canadian firm.296 Commentators note that since the Doha Declaration was adopted in 2001, the threat of compulsory licenceshas motivated multinational companies to “voluntarily make proactive efforts to realistically make their drugs accessible**”** either through dramatically lowering the price or by offering voluntary licences on favourable terms.297 Meanwhile, many countries have successfully used the threat of compulsory licences as leverage in drug price negotiations with pharmaceutical companies.298

#### It’s goldilocks - protects patents while allowing urgent access – the perm or the aff shatters IP protections which crushes innovation while the CP strikes an accepted balance

**Bacchus 2020** (James, Adjunct Fellow, Cato Institute, former U.S. Representative (D-FL), and former Chairman, World Trade Organization’s Appellate Body. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” *Cato* <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#balancing-ip-rights-access-medicines-not-new-wto> December 16, 2020)DR 21

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”[7](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref7) But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.[8](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref8)

After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”[9](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref9) In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.[10](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref10) In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.[11](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref11)

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance **struck by the members of the WTO** between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

Does a Novel Virus Present Novel Issues?

Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”[12](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref12)

The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”[13](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref13)

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines.

In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”[14](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref14)

India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”[15](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref15) But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market.

Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. **Subordinating IP rights temporarily** to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth **in the 21st century is increasingly** ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus **preventing** the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules **recognize that “intellectual property rights are private rights”** and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### Biotech industry strong now – new innovation and R&D coming

Cancherini et al. 4/30 [Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company] “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide> //ajs

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### COVID exceptions erode IP policies broadly – plus their Jecker card spots us spillover

PRMA 21 The Pharmaceutical Research and Manufacturers of America SPECIAL 301 SUBMISSION 2021 <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf> SM

Moreover, some countries are using the COVID-19 pandemic opportunistically to advance longstanding industrial policies to further erode intellectual property policies. India and South Africa are key sponsors of a proposal at the WTO TRIPS Council calling to eliminate for an indefinite term certain WTO obligations to grant IP on a wide range of technologies related to COVID-19. The proposal marks a significant escalation in anti-IP global activism and will further polarize legitimate conversations on countries’ engagement to combat the pandemic. The proposal will do nothing to address the production and distribution challenges for making COVID-19 vaccines globally available. If anything the proposals threaten to undermine the ability to respond to another pandemic, and will inevitably affect IP discussions in countries around the world.

#### Undermines R&D and innovation

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

1. An IP waiver would undermine R&D and innovation The IP system is designed to encourage and reward creativity and innovation while benefiting society as a whole. The idea is that IPRs stimulate innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.” 23 Therefore, while in the short term waiving IPRs may arguably accelerate the distribution of goods and services – i.e. access to COVID-19 vaccines – in the long term undermining IPRs would eliminate the incentives that spark innovation, thus hindering the discovery and development of knowledge for new products or technologies that the world needs.24

An example that illustrates the significance of IP protection is the technology of synthetic mRNA, a genetic technology behind the COVID-19 vaccines of both Pfizer and Moderna. Synthetic mRNA is a genetic technology that has long held huge promise but has so far run into biological roadblocks. The concept of tweaking specific strands in synthetic mRNA to deliver desired results was first introduced in the 1990s, but at that time while it made sense in theory it often failed in the real world as synthetic RNA was notoriously vulnerable to the body’s natural defences and the synthetic RNA was very often destroyed before reaching its target cells. In some situations, the foreign materials even elicited an immune response that poses health risks for some patients. The solution, substituting one of the nucleosides (building blocks of mRNA) for a slightly tweaked version to bypass the body’s defence, was not discovered until 2005 and did not reach commercialization stage for another 15 years.

Without the prospect of IP protection, it is simply unimaginable that scientists would devote the human and monetary resources into such R&D as there would have been no incentive to spend the time and effort on a promising but extremely challenging technology. Likewise, venture capitalists would refuse to invest billions of dollars into any research effort knowing that any other company could simply take the successful result and produce a medicine without paying for the R&D costs; in such a scenario, it would be virtually impossible to recoup the initial investment. Thus, without the promise of IP protection the technology underpinning the most advanced and promising COVID-19 vaccines would likely never have been developed. This point is of such importance that it is worth stating the obvious: IPRs have played a large role in the response to COVID-19; a response which has led to an incredible feat of humanity – the identification of the genome of a new pathogen and development of several treatments and promising vaccines within the space of a year. Without the promise of financial gain, the level of R&D into the novel coronavirus would have been greatly reduced and innovation hampered and delayed. In short, the IP system encouraged a robust response to the threat from innovator companies and worked as designed. It would be unwise (if not reckless) to place the innovation system which has delivered results in record time in jeopardy only in exchange for what is at best short-term benefits.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

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

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### COVID incentivizes engineered bioterror- extinction

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

#### 1AR theory is skewed towards the aff – a) the 2NR must cover substance and over-cover theory, since they get the collapse and persuasive spin advantage of the 3min 2AR, b) their responses to my counter interp will be new, which means 1AR theory necessitates intervention. Implications – a) reject 1AR theory since it can’t be a legitimate check for abuse, b) drop the arg to minimize the chance the round is decided unfairly,

### 4

#### The United States federal government should:

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

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

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

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

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

### 5

#### The United States, using a strictly limited constitutional convention ratified by at least thirty-eight of the States, should pass an amendment to the constitution that prohibits the usage of intellectual property protections for COVID-19 vaccines.

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### 6

#### Infrastructure is making halting progress via reconciliation – bipartisanship is key for Manchin and Republicans to not nuke it

Litvan 9/2 [Laura] “Manchin Jolts Democrats by Urging ‘Pause’ on $3.5 Trillion Bill,” Bloomberg, September 2, 2021, <https://www.bloomberg.com/news/articles/2021-09-02/manchin-tells-democrats-to-pause-on-biden-s-3-5-trillion-plan> TG

Senator Joe Manchin is demanding a “strategic pause” in action on President Joe Biden’s economic agenda, potentially imperiling the $3.5 trillion tax and spending package that Democratic leaders plan to push through Congress this fall.

The West Virginia Democrat, a linchpin vote in the evenly divided Senate, said at an event in his home state on Wednesday and in a Thursday Wall Street Journal op-ed that rising inflation and a soaring national debt necessitate a go-slow approach and a “significantly” smaller plan than the one Democratic leaders and the White House have endorsed.

“By placing a strategic pause on this budgetary proposal, by significantly reducing the size of any possible reconciliation bill to only what America can afford and needs to spend, we can and will build a better and stronger nation for all our families,” Manchin said in the op-ed.

Manchin’s resistance to the core of Biden’s economic plan caps a politically painful month for a White House that has grappled with a chaotic withdrawal from Afghanistan, a resurgent pandemic and a massive hurricane that cut a path of death and damage from Louisiana to New York.

In comments Wednesday at an event hosted by the West Virginia Chamber of Commerce, the moderate Democrat said his party should “hit the pause button.” Lawmakers, he said, have too many other pressing issues before them, including heightening national security concerns after the Taliban takeover of Afghanistan.

“Let’s sit back. Let’s see what happens. We have so much on our plate,” he said.

Manchin’s comments come as Democratic leaders and committee chairs in the Senate and House work out the specifics of the economic package, with a goal of moving it through Congress soon after lawmakers return from a recess later this month. All members of the Senate Democratic caucus would have to back the measure for it to get the 51 votes needed to pass, with Vice President Kamala Harris providing the tie-breaking vote.

A spokesman for Senate Majority Leader Chuck Schumer didn’t immediately respond to a request for comment about Manchin’s request, and White House Press Secretary Jen Psaki did not immediately provide a comment.

The chair of the Congressional Progressive Caucus, Representative Pramila Jayapal, replied “Absolutely not” on Twitter to Manchin’s idea of a pause.

The spending package also is facing obstacles in the House. Democrats can only afford three defections in that chamber if Republicans are united in opposition, and some moderate Democrats also are balking at the size of the package being drawn up.

Manchin also called on the House to pass within a few weeks a Senate-passed $550 billion bipartisan infrastructure bill. House Speaker Nancy Pelosi has promised progressives in the chamber that she will marry that legislation with the much bigger Democrat-only tax-and-spending package, although moderates have been promised an infrastructure vote by late September.

#### General bipartisanship could spark compromise but the plan’s partisan nature tanks any shot

Montanari 21 “Biden’s Undermining Of U.S. Intellectual Property Rights Is Dangerous And Will Hurt Pandemic Response,” Lorenzo Montanari [executive director of Property Rights Alliance, an advocacy policy group in charge of publishing the International Property Rights Index], May 12, 2021 <https://www.forbes.com/sites/lorenzomontanari/2021/05/12/bidens-undermining-of-us-intellectual-property-rights-is-dangerous-and-will-hurt-pandemic-response/?sh=4a74c5004890> SM

Republican Congressman Byron Donalds (R-Fla.) is working on a new piece of legislation titled "Preventing Foreign Attempts to Erode Healthcare Innovation Act” to block the White House IP waiver position and to "prevent the Biden Administration from senselessly giving away America's intellectual property to countries like China”. IP rights are enshrined in Article 1, Section 8, Clause 8 of the U.S. Constitution of 1787, “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” As a central pillar to American history and constitutionalism for 244 years, IP converges tradition and progress to enrich the lives of citizens and society.

Waiving IP rights not only goes directly against America’s core values and threatens public health but wanes potential for bipartisan efforts. “Congress has spent decades wrangling over the contours of patent protections,” WSJ’s Kimberley A. Strassel says, “producing bipartisan legislation from the Bayh-Dole Act of 1980 and the Hatch-Waxman Act of 1984 to the Leahy-Smith Act of 2011.” All these bipartisan efforts to defend American inventors with a strong and fair IP system risk being seriously damaged with this Biden move.

#### Infrastructure investment beats China in the tech-race

Anderson 2/22 [(Norman, Chairman & CEO of CG/LA Infrastructure, a firm focused on global infrastructure project development, driving productivity across countries, and maximizing the benefits of infrastructure for people in the U.S. and around the world) “The Biden Infrastructure Plan - 5 Actions To Jolt Us Awake, Now,” *Forbes*, 2-22-2021, <https://www.forbes.com/sites/normananderson/2021/02/22/the-biden-infrastructure-plan5-actions-to-jolt-us-awake-now/?sh=1d72f17b2ebd>] TDI

The Focus Needs to be on Creating Project Results. Producing immediate results is necessary for our political system - how does this work, when the average highway project takes 9.5 years to move through the approval process, and 4.5 years after that for results - say cars, or autonomous trucks, zipping down the freeway? Lucky for us we are not starting from scratch - we have an enormous pent-up backlog of projects that can start showing results… this year.

By results I don’t just mean creating new and well-paying jobs, or saving the thousands of struggling professional service firms that are in danger of turning off their computers, rather what I mean is addressing the Administration’s priorities in the way that infrastructure professionals think about investment (yes, these people exist - and they are as smart as economists!):

* Brownfield projects - you can revitalize Army Corps reservoirs, or put 5G on interstate highways, or authorize the Gateway tunnel, or make rural broadband really fast, right now, tomorrow,
* Greenfield projects - infrastructure is a ‘thinking short, thinking long’ business, so while you are speeding up investment in ultra high voltage transmission lines, you can also get moving on the Brent Spence Bridge, and by the end of 2024 you can get butts in seats on the Dallas/Houston high speed rail project, and the Great Lakes Basin highway project, and
* New Infrastructure - this is the low-hanging fruit, and the battlefield between China and the U.S. for global influence, period. Largely private, and almost wholly environmentally friendly, this is where our economy has tremendous strengths that we are not seeing. It’s also the battlefield - AI, Machine Learning, 5G, Autonomy, High Voltage Transmission, along with high speed rail - that is critical to the achievement of every single goal that our country can set for the future.

Every infrastructure person - and every citizen - across the country can tell you the five projects that they’d like to see happen. The map above is a 500 project stimulus map that my firm, CG/LA infrastructure, created by polling people around the country. Why not engage citizens now, and show results this year, picking up steam in 2022 and in 2023? Infrastructure is 5G/AI and Electrification, and it Needs a Budget. The infrastructure of the future is going to be as different as cellular is from fixed line telephony, and that future is coming at us extremely fast… The 2020’s will be a decade of disruption - the greatest period of disruption in 100 years or more. We can either continue our course, and try and weather the storm, or we can make the kind of strategic investments that will allow us to lead - with enormous environmental and equity benefits, coupled with the kind of productivity increases that come from rapid innovation. There couldn’t be a bigger difference between the way that China is going about new infrastructure creation, with their top down, devil may care about the individual approach, and our celebration of the individual. The problem - in democracies around the world - is that we are absent, and so China is winning. Leaders Set Goals, Achieve Goals - and Create Trust. Who is in charge of infrastructure? Without an infrastructure office it is hard to tell, and this is a fatal flaw problem. The presidency needs to to bring everyone together to discuss what world we want to create, what our infrastructure vision going forward will look like. This needs to happen fast - and then we need to set goals that we all agree to: projects completed, time to project approvals, life expectancy, reduction of traffic congestion, reduction in carbon by sector, even increases in infrastructure equity. I am a business guy - everything is opportunity. Then we (all of us) need to row hard in the same direction, and achieve those goals. Action This Day. If we can get this right, the results for all of us will be extraordinary - domestic growth, environmental leadership and an injection of strength into the global democratic model. Unimaginable things can quickly be envisioned, and developed, including the return of manufacturing (advanced and distributed manufacturing) to our newly digitized and electrified heartland. Infrastructure can bring us together, but it is a very heavy lift - as in war, the first thing a president things about in the morning, and the last thing he thinks about before going to bed at night.

#### Chinese tech leadership leads to nuclear war

Kroenig 18 (Matthew, Deputy Director for Strategy, Scowcroft Center for Strategy and Security Associate Professor of Government and Foreign Service, Georgetown University) “Will disruptive technology cause nuclear war?” *BAS*, Nov 12, 2018, <https://thebulletin.org/2018/11/will-disruptive-technology-cause-nuclear-war>

Recently, analysts have argued that emerging technologies with military applications may undermine nuclear stability (see here, here, and here), but the logic of these arguments is debatable and overlooks a more straightforward reason why new technology might cause nuclear conflict: by upending the existing balance of power among nuclear-armed states. This latter concern is more probable and dangerous and demands an immediate policy response. For more than 70 years, the world has avoided major power conflict, and many attribute this era of peace to nuclear weapons. In situations of mutually assured destruction (MAD), neither side has an incentive to start a conflict because doing so will only result in its own annihilation. The key to this model of deterrence is the maintenance of secure second-strike capabilities—the ability to absorb an enemy nuclear attack and respond with a devastating counterattack. Recently analysts have begun to worry, however, that new strategic military technologies may make it possible for a state to conduct a successful first strike on an enemy. For example, Chinese colleagues have complained to me in Track II dialogues that the United States may decide to launch a sophisticated cyberattack against Chinese nuclear command and control, essentially turning off China’s nuclear forces. Then, Washington will follow up with a massive strike with conventional cruise and hypersonic missiles to destroy China’s nuclear weapons. Finally, if any Chinese forces happen to survive, the United States can simply mop up China’s ragged retaliatory strike with advanced missile defenses. China will be disarmed and US nuclear weapons will still be sitting on the shelf, untouched. If the United States, or any other state acquires such a first-strike capability, then the logic of MAD would be undermined. Washington may be tempted to launch a nuclear first strike. Or China may choose instead to use its nuclear weapons early in a conflict before they can be wiped out—the so-called “use ‘em or lose ‘em” problem. According to this logic, therefore, the appropriate policy response would be to ban outright or control any new weapon systems that might threaten second-strike capabilities. This way of thinking about new technology and stability, however, is open to question. Would any US president truly decide to launch a massive, bolt-out-of-the-blue nuclear attack because he or she thought s/he could get away with it? And why does it make sense for the country in the inferior position, in this case China, to intentionally start a nuclear war that it will almost certainly lose? More important, this conceptualization of how new technology affects stability is too narrow, focused exclusively on how new military technologies might be used against nuclear forces directly. Rather, we should think more broadly about how new technology might affect global politics, and, for this, it is helpful to turn to scholarly international relations theory. The dominant theory of the causes of war in the academy is the “bargaining model of war.” This theory identifies rapid shifts in the balance of power as a primary cause of conflict. International politics often presents states with conflicts that they can settle through peaceful bargaining, but when bargaining breaks down, war results. Shifts in the balance of power are problematic because they undermine effective bargaining. After all, why agree to a deal today if your bargaining position will be stronger tomorrow? And, a clear understanding of the military balance of power can contribute to peace. (Why start a war you are likely to lose?) But shifts in the balance of power muddy understandings of which states have the advantage. You may see where this is going. New technologies threaten to create potentially destabilizing shifts in the balance of power. For decades, stability in Europe and Asia has been supported by US military power. In recent years, however, the balance of power in Asia has begun to shift, as China has increased its military capabilities. Already, Beijing has become more assertive in the region, claiming contested territory in the South China Sea. And the results of Russia’s military modernization have been on full display in its ongoing intervention in Ukraine. Moreover, China may have the lead over the United States in emerging technologies that could be decisive for the future of military acquisitions and warfare, including 3D printing, hypersonic missiles, quantum computing, 5G wireless connectivity, and artificial intelligence (AI). And Russian President Vladimir Putin is building new unmanned vehicles while ominously declaring, “Whoever leads in AI will rule the world.” If China or Russia are able to incorporate new technologies into their militaries before the United States, then this could lead to the kind of rapid shift in the balance of power that often causes war. If Beijing believes emerging technologies provide it with a newfound, local military advantage over the United States, for example, it may be more willing than previously to initiate conflict over Taiwan. And if Putin thinks new tech has strengthened his hand, he may be more tempted to launch a Ukraine-style invasion of a NATO member. Either scenario could bring these nuclear powers into direct conflict with the United States, and once nuclear armed states are at war, there is an inherent risk of nuclear conflict through limited nuclear war strategies, nuclear brinkmanship, or simple accident or inadvertent escalation. This framing of the problem leads to a different set of policy implications. The concern is not simply technologies that threaten to undermine nuclear second-strike capabilities directly, but, rather, any technologies that can result in a meaningful shift in the broader balance of power. And the solution is not to preserve second-strike capabilities, but to preserve prevailing power balances more broadly. When it comes to new technology, this means that the United States should seek to maintain an innovation edge. Washington should also work with other states, including its nuclear-armed rivals, to develop a new set of arms control and nonproliferation agreements and export controls to deny these newer and potentially destabilizing technologies to potentially hostile states. These are no easy tasks, but the consequences of Washington losing the race for technological superiority to its autocratic challengers just might mean nuclear Armageddon.

## Case

### Disease

#### Squo solves – plan increases price of scarce materials and results in costly, ineffective facilities

Mcmurry-Heath 8/18 (Michelle Mcmurry-Heath, [physician-scientist and president and CEO of the Biotechnology Innovation Organization.], 8-18-2021, “Waiving intellectual property rights would harm global vaccination“, STAT, accessed: 8-19-2021, https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/) ajs

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](https://www.barrons.com/articles/a-plan-to-break-the-vaccine-manufacturing-bottleneck-51621952245) of various vaccines every year. Now the world needs an additional [11 billion doses](https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-g7-summit---12-june-2021) — 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](https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/) 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](https://launchandscalefaster.org/covid-19/vaccinemanufacturing), 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](https://www.timesofisrael.com/israel-said-to-be-paying-average-of-47-per-person-for-pfizer-moderna-vaccines/) 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](https://www.bmj.com/content/372/bmj.n281) 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](https://www.who.int/initiatives/act-accelerator/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.”](https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/05/17/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-4/) 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](https://www.npr.org/sections/goatsandsoda/2021/08/03/1023822839/biden-is-sending-110-million-vaccines-to-nations-in-need-thats-just-a-first-step) by the end of summer. Other countries are following the administration’s leadership and ramping up their donations.

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

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

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### Waivers fail – license agreements are key to access and scaling up vaccines

Crosby et al 21 [[Daniel Crosby](https://www.jdsupra.com/authors/daniel-crosby/), [Evan Diamond](https://www.jdsupra.com/authors/evan-diamond/), [Isabel Fernandez de la Cuesta](https://www.jdsupra.com/authors/isabel-fernandez-de-la-cuesta/), [Jamieson Greer](https://www.jdsupra.com/authors/jamieson-greer/), [Jeffrey Telep](https://www.jdsupra.com/authors/jeffrey-telep/), [Brian White](https://www.jdsupra.com/authors/brian-white/)] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### Squo solves – voluntary licensing and other initiatives

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3. Voluntary licensing and other initiatives are supporting access to COVID-19 vaccines Contrary to assertions the sponsors made at the TRIPS Council, pharmaceutical companies have been actively signing voluntary licensing agreements with various generic drug manufacturers to scale up the production of COVID-19 medication. For instance, Gilead’s antiviral drug named Remdesivir was approved for emergency use for COVID-19 treatment by the US Food and Drug Administration (FDA) and the European Medicines Agency in May 2020.35 As demand surged following the approvals for use in COVID-19, Gilead issued nonexclusive voluntary licences to generic producers based in India, Egypt and Pakistan in order to meet the growing demand for the product. Under the voluntary licensing agreements, these manufacturers receive the technology necessary to manufacture Remdesivir, as well as set their own prices for the generic drugs they produce. The arrangement allows the distribution of the drug in 127 countries, covering nearly all low-income and lower-middle-income countries.36 Another example of industry cooperation is the COVID-19 vaccine co-developed by AstraZeneca and University of Oxford. AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicence agreements with several generic drugs producers to increase the supply of future vaccine, including with the Serum Institute of India (one of the world’s largest vaccine producers),37 Fiocruz in Brazil,38 BioKangtai in China39 and R-Pharm in Russia,40 enabling the massive production of cheap generic vaccines and supply of over two billion doses to lower-middle-income countries once the vaccine is approved for sale in those countries.

Other initiatives set up in response to IP issues related to COVID-19 treatments and vaccines include the World Health Organization’s (WHO) COVID-19 Technology Access Pool (CTAP), launched to gather COVID-19 technology related patents and other kinds of intellectual properties, such as data, know-how and software.41 This Pool, similar to Medicines Patent Pool (MPP) – established to pool and distribute generic licences for HIV/AIDS-related treatments – aims to accelerate the scale-up of production of medical inventions to fight against COVID-19 and ensure they are available globally and equitably.42 To date, 39 WHO member states and 4 intergovernmental bodies have indicated their support43 and a coalition of 18 generic drugs manufacturers located in India, China, Bangladesh and South Africa have pledged to work together to accelerate access to millions of doses of new interventions for COVID-19 for lowand middle-income countries.

Another effort, the Access to Covid-19 Tools (ACT) Accelerator, has raised $5.8 billion from nearly forty countries and over 40 private and non-governmental sources for the deployment tests, treatments and vaccines. 44 COVAX, convened by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, is the vaccine pillar of the ACT and acts as a global initiative to pool procurement of safe and effective COVID-19 vaccines. The objective of this accelerator collaboration is to guarantee rapid and fair access to COVID-19 vaccines for every country in the world. As of January 2021, COVAX has agreements in place to access 2 billion doses of promising COVID-19 vaccine candidates, implying that all 190 participating economies are eligible to access effective and approved vaccines in the first half of 2021.45 At least 1.3 billion donor-funded doses will be made available to 92 low- and middle-income economies.46

With the advance of reasonably priced patented treatments and vaccines, as well as the widespread and growing use of non-exclusive voluntary licence agreements and several newly established global initiatives, it is not only unnecessary to waive IPRs to ensure access to affordable medicines for all populations around the world during the pandemic but also unwise as the waiver would stifle cooperative efforts and potentially lead to less availability of needed treatments and vaccines.

#### Existing mechanisms solve – domestic not international policy is the problem

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4. Existing mechanisms effectively safeguard public health

The international system was designed to deal with all circumstances – including global pandemics like COVID-19 – providing both incentives to industry to spend large amounts of time and money on research and development and tools for developing countries to leverage in their fight against COVID-19.

The rights and protections granted by the TRIPS Agreement must be read in the context of the objectives and principles of the agreement as set out in Article 7 and 8: Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights [shall be] in a manner conducive to social and economic welfare” while Article 8 states that WTO Members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” Read together, these two provisions should allow for a wide range of policy choices and health measures taken during a health crisis or emergency, such as the COVID-19 pandemic.47

Moreover, in the wake of the HIV/AIDS crisis, developing countries secured a major victory when WTO Members agreed to adopt the Doha Declaration on TRIPS and Public Health as part of the Doha Ministerial Declaration in November 2001. 48 The Doha Declaration, inter alia, reiterated that every WTO Member “has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” 49 Members could not agree, however, on how to resolve the issue of how Members with insufficient or no manufacturing capability could make use of the compulsory licensing provision set out in Article 31 of the TRIPS Agreement.50 This issue was resolved in August 2003, when Members adopted a waiver allowing such Members to import generic drugs under a compulsory licence from another country even if the required drugs are protected by patent in that third country. 51 In such a case, licences are required to be issued in both the importing and exporting countries. In 2017, the waiver became the first (and to date only) amendment to any WTO Agreement in the form of Article 31bis of the TRIPS Agreement. 52

Despite repeated assertions by leading non-governmental organizations (NGOs) that the TRIPS flexibilities such as the aforementioned compulsory licence regime are too complicated to use or that threats from developed countries restrict their use, a study by leading public health advocates found that the flexibilities “been used more frequently than commonly assumed and proven effective for procuring generic versions of essential medicines”. 53 More specifically, the study found extensive use of TRIPS flexibilities between 2001 and 2016, with the four leading flexibilities being (i) compulsory licensing (including public non-commercial use licensing); (ii) least-developed countries (LDCs) making use of the pharmaceutical transition measure54; (iii) parallel importation55; and (iv) the research exception.56 In total, the study identified 176 occurrences of possible use of TRIPS flexibilities by 89 countries,

of which around 60% engaged in the use of compulsory or government use licences and over one-fifth involved the LDC pharmaceutical transition measure.57

The flexibilities described above have been proven effective in reducing the price of medicines by promoting generic competition and effectively ensuring equitable access to medical products for all. 58 This is especially the case with regards to compulsory licensing. For example, Malaysia’s use of compulsory licences in 2002 reduced the price of antiretrovirals to treat HIV/AIDS by up to 83% while Thailand’s granting of compulsory licences on five medicines (including antiretrovirals and medicines to treat cancer and coronary disease) between 2006 and 2008 contributed to a reduction in prices of up to 98 percent.59

Thus, while the sponsors to the proposal may argue a waiver is urgently needed given that the TRIPS flexibilities are not being fully utilized, the reality is that several developing countries and LDCs have made good use of the flexibilities and those that have not done so lack explicit provisions in their domestic legislation.6

Where available flexibilities have not been utilised, it is often the complicated and unworkable domestic framework which proves to be the stumbling block and not the international system. This point is perhaps illustrated best by reference to compulsory licensing. In Zimbabwe, for example, the institutional framework and capacity to effectively implement and take advantage of the TRIPS flexibility has been severely curtailed since the local regulations establish that a compulsory licence decision requires the approval of two government agencies: the Ministry of Health for medicines procurement and the Patent office for enquiry on the patent status of medicines. The lack of clarity and overlapping in roles and responsibilities leads to delayed access and, worse, a standstill.61 Even the Indian representative to the WTO placed some responsibility on the Members when he admitted that “many smaller countries were not able to fulfil the formalities required” to make use of available flexibilities.62

A final flexibility contained in the TRIPS Agreement is Article 73, which in relevant part allows a Member to take “any action which it considers necessary for the protection of its essential security interests… taken in time of war or other emergency in international relations.” Following precedent established in the Russia–Transit dispute,63 the WTO panel in Saudi Arabia–IPRs found that Article 73 is not self-judging.64 More specifically, the panel held that the mere invocation of Article 73 is justiciable and that it could proceed to assess:

a. whether the existence of a “war or other emergency in international relations” has been established…;

b. whether the relevant actions were “taken in time of” that war or other emergency in international relations; c. whether the invoking member has articulated its relevant “essential security interests” sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and d. whether the relevant actions are so remote from, or unrelated to, the “emergency in international relations” as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.65

While we cannot say for certain whether the COVID-19 pandemic would constitute an emergency in international relations, whether measures taken by WTO members to override IPRs may be considered necessary to protect their essential security interests, or if the presence of other provisions in the TRIPS Agreement addressing emergencies preclude Members from invoking Article 73, there is scholarly support that the provision could be used to justifiably override IPRs in this time of global health pandemic.66 The debate may indeed be academic as it extremely unlikely that any Member would file a WTO complaint and initiate dispute settlement against a developing country Member invoking Article 73.

What is clear is that instead of calling for an IP waiver a better way to ensure equitable distribution of vaccines during the pandemic and a more lasting sustainable and prodevelopment solution would be for developing countries to revise their domestic laws to allow better use of the flexibilities existing within the TRIPS Agreement.

### WTO

#### The US has structurally undermined WTO legitimacy

Baschuk 2/22 [(Bryce, reporter for Bloomberg Economics based in Geneva, Switzerland, has been published in Bloomberg, the Washington Times, United Press International and National Public Radio) “Biden Picks Up Where Trump Left Off in Hard-Line Stances at WTO,” Bloomberg, 2/22/2021] TDI

President Joe Biden’s administration dashed hopes for a softer approach to the World Trade Organization by pursuing a pair of his predecessor’s strategies that critics say risk undermining the international trading system.

The U.S. delegation to the WTO, in a statement Monday obtained by Bloomberg, backed the Trump administration’s decision to label Hong Kong exports as “[Made in China](https://www.bloomberg.com/news/articles/2020-10-30/hong-kong-takes-formal-wto-action-on-u-s-made-in-china-order)” and said the WTO had no right to mediate the matter because the organization’s rules permit countries to take any action to protect their “essential security interests.”

“The situation with respect to Hong Kong, China, constitutes a threat to the national security of the United States,” the U.S. delegation said. “Issues of national security are not matters appropriate for adjudication in the WTO dispute-settlement system.”

Prior to 2016, WTO members generally steered clear of defending their trade actions on the basis of national security because doing so could encourage other nations to pursue protectionist policies that have little or nothing to do with hostile threats.

That changed in 2018, when the Trump administration triggered a cold war-era law to justify tariffs on foreign imports of steel and aluminum. In response, a handful of U.S. trade partners, including Canada, the EU, and China filed disputes at the WTO and a ruling in those cases is expected later this year.

Since then, more nations -- including Saudi Arabia, India, Russia and others -- have cited the WTO’s national-security exemption in regional trade fights, leading trade experts to warn that such cases could erode the organization’s ability to mediate disputes.

The Biden administration on Monday said the U.S. has consistently argued that national-security disputes are not subject to WTO review because it would infringe on a member’s right to determine what is in its own security interests.

In spite of the U.S. objection, the WTO granted Hong Kong’s dispute inquiry and will establish a panel of experts to deliberate the matter and render a decision, which could take two to three years.

At the same meeting, the Biden administration said it would not agree to appoint new members to the WTO’s appellate body, a seven-member panel of experts who until 2019 had the final say on trade disputes involving billions of dollars worth of international commerce.

The Biden administration said it could not do so because the U.S. “continues to have systemic concerns” with the functioning of the appellate body as have all previous administrations over the past 16 years.

Though the statement was not entirely unexpected, it confirms America’s bipartisan frustration with the functioning of the WTO appellate body and the new administration’s willingness to block new panelists until changes can be agreed.

Once Katherine Tai is confirmed as the U.S. Trade Representative, her office “looks forward to working with” WTO Director-General Ngozi Okonjo-Iweala to tackle the problems with WTO dispute settlement, including the unresolved issues over appellate-body overreach, USTR spokesman Adam Hodge said in an email. “These are long-standing, bipartisan concerns that we hope our trading partners will work with us to address,” he said.

The Trump administration broke precedent when it refused to consider any nominees to fill vacancies on the panel until there weren’t enough to sign off on new rulings. As a result, the WTO’s dispute-settlement system has been critically damaged because WTO members are now free to veto any adverse dispute rulings by appealing them into a legal void created by the appellate body’s paralysis.

#### Trade is irrelevant for war

Katherine Barbieri 13, Associate Professor of If the Biden administration wants to achieve its stated goals, it will remove Trump’s protectionist measures, work multilaterally, strengthen US infrastructure, invest in workforce skills and education, and expand America’s research capabilities. Political Science at the University of South Carolina, Ph.D. in Political Science from Binghamton University, “Economic Interdependence: A Path to Peace or Source of Interstate Conflict?” Chapter 10 in Conflict, War, and Peace: An Introduction to Scientific Research, google books

How does interdependence affect war, the most intense form of conflict? Table 2 gives the empirical results. The rarity of wars makes any analysis of their causes quite difficult, for variations in interdependence will seldom result in the occurrence of war. As in the case of MIDs, the log-likelihood ratio tests for each model suggest that the inclusion of the various measures of interdependence and the control variables improves our understanding of the factors affecting the occurrence of war over that obtained from the null model. However, the individual interdependence variables, alone, are not statistically significant. This is not the case with contiguity and relative capabilities, which are both statistically significant. Again, we see that contiguous dyads are more conflict-prone and that dyads composed of states with unequal power are more pacific than those with highly equal power. Surprisingly, no evidence is provided to support the commonly held proposition that democratic states are less likely to engage in wars with other democratic states.¶ The evidence from the pre-WWII period provides support for those arguing that economic factors have little, if any, influence on affecting leaders’ decisions to engage in war, but many of the control variables are also statistically insignificant. These results should be interpreted with caution, since the sample does not contain a sufficient number wars to allow us to capture great variations across different types of relationships. Many observations of war are excluded from the sample by virtue of not having the corresponding explanatory measures. A variable would have to have an extremely strong influence on conflict—as does contiguity—to find significant results. ¶ 7. Conclusions This study provides little empirical support for the liberal proposition that trade provides a path to interstate peace. Even after controlling for the influence of contiguity, joint democracy, alliance ties, and relative capabilities, the evidence suggests that in most instances trade fails to deter conflict. Instead, extensive economic interdependence increases the likelihood that dyads engage in militarized dispute; however, it appears to have little influence on the incidence of war.

#### Also empirics flow neg, WW2 proves where countries abandened econ allies ie Japan