### T - Intellectual property

#### INTERPRETATION: "Intellectual property", in the context of medicines, refers to patents.

**Oxfam no date** [Oxfam is a global organization working to end the injustice of poverty. "Intellectual property and access to medicine" Accessed 8/11/2021 https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/]

Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents. Patents are a public policy instrument aimed at stimulating innovation. By providing a monopoly through a patent—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement.

#### VIOLATION: The aff defends waiving copyright and trade secrets as well – their aff literally is those 4 areas

Dhar, Biswajit and KM Gopakumar (2020). Dhar is a Professor of Economics, Jawaharlal Nehru University, New Delhi, India and adviser to ARTNeT and Gopakumar is a Legal Advisor, Third World Network, Penang, Malaysia, “Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS”, ARTNeT Working Paper Series No. 200, November 2020, Bangkok: ESCAP, <https://www.unescap.org/sites/default/d8files/knowledge-products/AWP200_Dhar.pdf>

The COVID-19 pandemic has once again brought a similar response from India and South Africa. The two countries have tabled a joint proposal, which was discussed by the TRIPS Council, seeking waiver from certain obligations under the TRIPS Agreement for the “prevention, containment, and treatment of COVID-19” (World Trade Organization 2020a). Kenya and Eswatini have also supported this Proposal. Using the provisions of Article IX of the Marrakesh Agreement Establishing the WTO, the proposal makes a request to the General Council of the WTO, to waive the implementation, application, and enforcement of four forms of IPRs covered by the TRIPS Agreement for some years for the prevention, containment, and treatment of COVID-19. The scope of waiver includes the following: copyright and related rights, industrial designs, patents, and trade secrets. It should be noted here that the waiver of legal obligations under WTO agreement is not new. Since 1995, of the waivers that were granted, three were from TRIPS obligations (World Trade Organization 2016).3

#### Trade secrets protect the process to develop medicines, not the medicine itself.

**Edelson et al. 20** [Rebecca Edelson, Kazim Naqvi & Dylan Turner (Intellectual Property attorneys at SheppardMullin) "Admonition To Members Of The Healthcare Industry: Don’t Give Trade Secret Protection The Short Shrift!" SheppardMullin Healthcare Law Blog (Sheppard Mullin’s Healthcare Law Blog is designed to provide breaking industry news, legal analysis, and updates on emerging issues involving a variety of related topics.) July 8, 2020 https://www.sheppardhealthlaw.com/2020/07/articles/healthcare/trade-secret-patent-protection/]

While the definition may vary somewhat across jurisdictions, a trade secret generally is information that derives independent economic value from not being known; and is subject to reasonable efforts to maintain its secrecy. In the healthcare industry, potential trade secrets include formulas or techniques to develop pharmaceuticals, biosimilars, drugs, vaccines, or medical devices; code for a medical technology software; testing results; and patient analyses.

#### STANDARDS:

#### 1. Precision: my evidence defines IP in the context of medicine and is comparative. Precision is a side-constraint on all standards because the resolution determines legitimate division of predictable ground -- deviations are arbitrary and self-serving.

#### 2. Ground: fiating changes other than to patents lets the neg spike out of DAs and solvency takeouts related to supply chains or logistics. Aff justifies "waive IP for computer chips" if computer chips are a bottleneck of vaccine production – kills clash.

#### That’s key to education – allows for the best clash, and limits on an already huge and aff biased topic – limits allow for better, in depth rounds where both sides can engage – its about the model of the topic that they set

#### Drop the debater:

#### a) necessary to compensate the time spent running T or else allows infinite affs with no aff ability to check back

#### b) its incoherent – you have to drop the advocacy first

### CP - Buyout

#### CP Text: The United States should buy COVID-19 vaccine patents from American companies and release them into the public domain as described by Watney -- solves the aff and avoids the link to innovation

Caleb **Watney 6/15** [Caleb Watney is Director of Innovation Policy at PPI. "A Marshall Plan to Solve the Global Vaccine Shortfall" A16Z, June 15, 2021 https://future.a16z.com/marshall-plan-to-solve-global-vaccine-shortfall/]

The economist Michael Kremer wrote a paper in 1997 formalizing the idea of using patent buyouts as a way of maintaining strong incentives for innovation, while still getting crucial information into the public domain as soon as possible. Essentially, a government could offer to pay the present value of the expected future revenue stream that would result from the temporary monopoly that a patent sometimes grants. While the patent-owning company or individual should be indifferent to the outcome, the general public could receive more value from having unabridged access to the information and the ability to modify it without permission before the patent expired. In these cases, a patent buyout can clearly improve outcomes for everyone, and Kremer notes that pharmaceuticals may be a particularly appropriate case. Patent buyouts maximize the number of players that can legally produce vaccines while maintaining strong incentives for future innovation. Of course, in this situation it’s only partly about the intellectual property, and partly about the manufacturing know-how that has to be transferred, which means we need a broader conception here — a more full-stack “technology buyout” that includes both the IP and the process knowledge transfer. Essentially, the U.S. government (or even a set of governments) could offer a lump sum payment to the accepting firm(s) to make explicit the scientific and production process as much as possible and then also make it publicly available. We could offer a secondary payment for sharing on-the-ground technical expertise to aid in setting up manufacturing operations — either on an individual factory level, or on the basis of vaccine doses administered. A per-vaccine-dose-administered basis properly aligns incentives for the firm(s) sharing technology, maximizing their impact by transferring to partners that can actually get shots into arms as quickly as possible and to make sure they do a good job. To put some back-of-the-envelope numbers on this, the initial lump sum payment to make the IP public would be in the range of $10-20 billion per firm, and the additional per-dose-administered prize would be in the realm of $0.50-$2. Assuming this program was able to administer vaccines for an additional 4 billion people (8 billion doses) across the developing world, we are talking in the range of $36-56 billion. And we should overpay. In a situation like this, we should err on the side of overcompensating, and risking some economic rents, rather than inadvertently undercompensating and hurting the long-term incentives for innovation. The key is to not kill the goose that lays the golden egg. In any event, we should be willing to pay an order of magnitude more than $36 billion to definitively end COVID, so this program is a bargain under a wide range of potential cost assumptions. One estimate from a group of economists and public health officials ballpark the global monthly cost of the pandemic at around $1 trillion per month.

#### Competes: it's mutually exclusive and uses a different mechanism than the aff. It's impossible to simultaneously purchase IP rights and also waive them because if they're waived no one can buy them

#### A buyout is preferable to IP suspension -- speed and incentive to innovate -- solves future variants which turns case.

Caleb **Watney 6/15** [Caleb Watney is Director of Innovation Policy at PPI. "A Marshall Plan to Solve the Global Vaccine Shortfall" A16Z, June 15, 2021 https://future.a16z.com/marshall-plan-to-solve-global-vaccine-shortfall/]

A buyout also presents several key advantages when compared to IP suspension as well, even putting the incentive issues aside: First, speed. Even with the U.S. reversing course and supporting the WTO proposal, it will take quite a bit of time to negotiate and wrangle all the other countries to the table. Remember, the proposal has to be supported unanimously, so there is no guarantee that all other opposed nations will reverse course just because the U.S. did. A buyout, in contrast, can be done unilaterally by the U.S. (at least for the U.S.-based vaccine firms). Second, in the unfortunate event that a new variant requires a booster shot, a buyout ensures the incentive to quickly create a solution so that the new booster shot can also get bought out. Under the WTO petition, the IP suspension would remain in play for the duration of the crisis, which would reduce the urgency and resources pharma companies are willing to throw at the problem, given fewer opportunities to recoup their costs.

#### The counterplan boosts US soft power -- unilateralism key

Caleb **Watney 6/15** [Caleb Watney is Director of Innovation Policy at PPI. "A Marshall Plan to Solve the Global Vaccine Shortfall" A16Z, June 15, 2021 https://future.a16z.com/marshall-plan-to-solve-global-vaccine-shortfall/]

Fourth, we should view this as an opportunity to build goodwill around the developing world. The total U.S. foreign aid budget was around $40 billion in 2019, right in the range of what we are proposing here. I’m inclined to believe sharing new, highly effective technology around the world during this unique crisis would generate a significantly higher return diplomatically than the projects we usually get with this scale of funds. Already we’ve seen China and Russia attempt to leverage their vaccine exports for diplomatic purposes. Much like the Belt and Road initiative that has helped China make inroads across Africa, the U.S. would be helping with technological infrastructure investment.

1. Soft power turns disease and WMD conflict. Joseph Nye[[1]](#endnote-1) 04

Joseph Nye [professor of International Relations at the Kennedy School]. “US military primacy is fact - so, now, work on 'soft power' of persuasion.” Christian Science Monitor, 4/29/2004. <http://www.csmonitor.com/2004/0429/p09s02-coop.html>.

**Soft power co-opts people rather than coerces them. It rests on the ability to set the agenda or shape the preferences of others.** It is a mistake to discount soft power as just a question of image, public relations, and ephemeral popularity. It is a form of power - a means of pursuing national interests. When America discounts the importance of its attractiveness to other countries, it pays a price. **When US policies lose their** **legitimacy and credibility in the eyes of others, attitudes of distrust tend to fester and further reduce its** **leverage.** The manner with which the US went into Iraq undercut American soft power. That did not prevent the success of the four-week military campaign, but it made others less willing to help in the reconstruction of Iraq and made the American occupation more costly in the hard-power resources of blood and treasure. Because of its leading edge in the information revolution and its past investment in military power, the US probably will remain the world's single most powerful country well into the 21st century. But not all the important types of power come from the barrel of a gun. Hard power is relevant to getting desired outcomes, but **transnational issues such as climate change, infectious diseases, international crime, and terrorism cannot be resolved by military force alone. Soft power is particularly important in dealing with these issues, where military power alone simply cannot produce success, and can even be counterproductive. America's success in coping with the new transnational threats of terrorism and weapons of mass destruction will depend on a deeper understanding of the role of soft power** and developing a better balance of hard and soft power in foreign policy.

### DA - Innovation

#### Economy’s recovering now – Delta and inflation are challenges but surmountable

**Sully 8/19** - Evan Sully, 8/19/21, Reuters, U.S. leading indicator points to further economic recovery in July, https://www.reuters.com/world/us/us-leading-indicator-points-further-economic-recovery-july-2021-08-19/ WJ

(Reuters) -**A gauge of future U.S. economic activity increased in July, suggesting the economy continued to expand from the recession caused by the coronavirus pandemic even in the face of a resurgence in cases fueled by the Delta variant**.

**The Conference Board on Thursday said its index of leading economic indicators (LEI) rose 0.9% last month to 116.0. Economists polled by Reuters had expected an increase of 0.8**%.

Even though the U.S. economy is forecast to grow this year at its fastest pace since the 1980s, **there are signs the recovery could be cooling off.** **Supply-chain bottlenecks continue to slow manufacturing growth, and consumer sentiment plummeted in early August to a decade-low** as **Americans gave faltering outlooks on everything from personal finances to inflation and employment**.

Meanwhile, consumer price increases slowed in July, the Labor Department said last week, but **inflation overall remained at a historically high level amid supply-chain disruptions as well as stronger demand for travel-related services**.

"The U.S. LEI registered another large gain in July, with all components contributing positively," said Ataman Ozyildirim, the Conference Board's senior director of economic research. "**While the Delta variant and/or rising inflation fears could create headwinds for the U.S. economy in the near term, we expect real GDP** (gross domestic product) growth for 2021 **to reach 6.0% year-over-year, before easing** to a still robust 4.0% growth rate for 2022."

The LEI's coincident index, a measure of current economic conditions, rose 0.6% in July after increasing 0.4% in June.

But the lagging index increased 0.6% last month after being unchanged in June and increasing 0.8% in May.

"**Even with more moderate growth in the second half of the year, the economy’s momentum remains encouraging with constraints on labor supply easing, a trove of excess savings still waiting to be drawn down, and strong vaccine numbers that will insulate the economy from the worsening health situation more so than prior waves**," said Mahir Rasheed, U.S. economist at Oxford Economics.

#### Strong IP protections are key to innovation; a waiver would chill future R&D.

Caleb **Watney 6/15** [Caleb Watney is Director of Innovation Policy at PPI. "A Marshall Plan to Solve the Global Vaccine Shortfall" A16Z, June 15, 2021 https://future.a16z.com/marshall-plan-to-solve-global-vaccine-shortfall/]

On the anti-suspension side, one argument is that these new vaccines (especially the new mRNA vaccines) required billions of dollars and decades of uncertain private investment to reach the technical breakthroughs that have given us a chance to end this pandemic. Basic science work funded by the government helped a lot and certainly established a strong foundation for much of this work. But enterprising individuals with a profit motive played just as large a role. Katalin Karikó, the Hungarian scientist who helped pioneer mRNA vaccines spent most of the 1990s receiving rejection letters for government grants, and ultimately turned to the private sector where she co-founded her own company in 2006.  But even if all the basic research for vaccines were federally funded, the argument for suspension would still create incentive issues. Operationalization and commercialization of scientific breakthroughs are essential, and cost a lot of money. There is a whole series of difficult engineering, logistics, and optimization problems that have to be solved when taking a complex biological product like a vaccine from research to reality. They do not pop out into the world fully formed from a peer-reviewed publication in a scientific journal. It’s also not an accident that the countries with the most well-developed biotechnology and pharmaceutical clusters are the ones that produced these wonders. Where most public health interventions failed miserably, the pharmaceutical companies worked around the clock to develop, test, and roll out a whole new genre of vaccine in record-breaking time and at high private cost. Intellectual property helps protect the whole investment pipeline (including the time and cost of failures), making it worth it in the first place; expropriating IP places future R&D investments under a great shadow.  And this is not going to be the last global pandemic we face. We got lucky that COVID-19 has a low fatality rate, relatively speaking, and that we were able to so easily target its spike protein (which is where most of the vaccines concentrated their approaches). On an unlucky Earth Two, these companies spent billions of dollars on a vaccine that flopped and cost them billions of dollars in wasted vaccine development and early preparation.

#### Empirics confirm that profits are key to pharmaceutical R&D.

**Goldman and Lakdawalla 18** [Dana Goldman (Nonresident Senior Fellow - Economic Studies, USC-Brookings Schaeffer Initiative for Health Policy) Darius Lakdawalla (Director of Research - USC Schaeffer Center for Health Policy & Economics Quintiles Chair in Pharmaceutical Development and Regulatory Innovation - USC School of Pharmacy Professor - USC Price School of Public Policy) "The global burden of medical innovation" This report was originally published at the Schaeffer Center for Health Policy & Economics at the University of Southern California. This analysis is part of the USC-Brookings Schaeffer Initiative for Health Policy, which is a partnership between the Center for Health Policy at Brookings and the University of Southern California Schaeffer Center for Health Policy & Economics. January 30, 2018 https://www.brookings.edu/research/the-global-burden-of-medical-innovation/]

What we pay for medicines today affects the number and kinds of drugs discovered tomorrow. Empirical research has established that drug development activity is sensitive to expected future revenues in the market for those drugs. The most recent evidence suggests that it takes $2.5 billion in additional drug revenue to spur one new drug approval, based on data from 1997 to 2007.[3 ]Another study assesses the Orphan Drug Act, passed in 1982 to stimulate development of treatments for rare diseases. Its key feature was the granting of market exclusivity that would restrict entry by competitors — in other words, allow for higher prices. The result was a dramatic increase in the number of compounds brought into development to treat rare diseases (figure 3).[4 ] This linkage may not help patients with tuberculosis today in Nigeria and Indonesia — two poor countries hardest hit by tuberculosis — but it is currently benefiting patients in the same countries who have HIV. Decades ago, demand for HIV treatment in wealthy countries spurred medical breakthroughs that have since found their way — albeit more slowly than we would like — into the poorest corners of the globe. As of July 2017, 20.9 million people living with HIV were accessing antiretroviral therapy globally; 60 percent of them live in eastern and southern Africa.[5]

#### Biotech is resilient and fundamentals are strong – but this trend relies on innovation and investment

**Cancherini et al 21** -- Laura Cancherini is a consultant in McKinsey’s Brussels office; Joseph Lydon is an associate partner in the Zurich office, where Jorge Santos da Silva is a senior partner and Alexandra Zemp is a partner, McKinsey, What’s ahead for biotech: Another wave or low tide?, April 30, 2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide WJ

**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**, 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 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**.

#### Bipoharma collapse causes economic meltdown – it’s far worse than previous recessions

**Howrigon 17** -- Ron Howrigon “(President and Founder of Fulcrum Strategies. He earned a Bachelor's degree in Business Administration from Western Michigan University and a Master's in Economics from North Carolina State University, focusing in the area of Health Economics) http://www.kevinmd.com/blog/2017/01/health-care-crash-u-s-economy.html, January 19 2017, WJ

In recent history, **the U.S. economy has experienced the near catastrophic failure of two major market segments**. The first was the auto industry and the second was the housing industry. While each of these reached their breaking point for different reasons, they **both required a significant government bailout to keep them from completely melting down**. What is also true about both of those market failures is that, looking back, it’s easy to see the warning signs. What happens **if health care is the next industry to suffer a major failure and collapse?** It’s safe to say that **a health care meltdown would make both** **the automotive and housing industries’ experiences seem minor** in comparison. While that may be hard to believe, it becomes clear if you look at the numbers. The auto industry contributes around 3.5 percent of this country’s GDP and employs 1.7 million people. This industry was deemed “too big to fail” which is the rationale the U.S. government used to finance its bail out. From 2009 through 2014, the federal government invested around $80 billion in the U.S. auto industry to keep it from collapsing. **Health care is five times larger than the auto industry in terms of its percentage of GDP, and is ten times larger than the auto industry in terms of the number of people it employs**. The construction industry (which includes all construction, not just housing) contributes about 6 percent of our country’s GDP and employs 6.1 million people. Again, the health care market dwarfs this industry. It’s three times larger in terms of GDP production and, with 18 million people employed in the health care sector, it’s three times larger than construction in this area, too. **These comparisons give you an idea of just how significant a portion health care comprises of the U.S. economy**. **It also begins to help us understand the impact it would have on the economy if health care melted down like the auto and housing industries did**. So, let’s continue the comparison and use our experience with the auto and housing industries to suggest to what order of magnitude the impact a failure in the health care market would cause our economy. The bailout in the auto industry cost the federal government $80 billion over five years. Imagine **a similar failure in health care that prompted the federal government to propose a similar bailout program**. Let’s imagine the government felt the need to inject cash into hospital systems and doctors’ offices to keep them afloat like they did with General Motors. Since health care is five times the size of the auto industry**, a similar bailout could easily cost in excess of $400 billion**. That’s about the same amount of money the federal government spends on welfare programs. To pay for a bailout of the health care industry, **we’d have to eliminate all welfare programs in this country**. Can you imagine the impact it would have on the economy if there were suddenly none of the assistance programs so many have come to rely upon? **When the housing market crashed, it caused the loss of about 3 million jobs** from its peak employment level of 7.4 million in 1996. Again, if we transfer that experience to the health care market, we come up with a truly frightening scenario. **If health care lost 40 percent of its jobs** like housing did, **it would mean** **7.2 million jobs lost.** That’s more than four times the number of people who are employed by the entire auto industry — an industry that was considered too big to be allowed to fail. The loss of 7.2 million jobs would increase the unemployment rate by 5 percent. That means **we could easily top the all-time high unemployment rate for our country**. OK, now it’s time to take a deep breath. I’m not convinced that health care is fated to unavoidable failure and economic catastrophe. That’s a worst-case scenario. The problem is that at **even a fraction the severity of the auto or housing industry crises we’ve already faced, a health care collapse would still be devastating**. Health care can’t be allowed to continue its current inflationary trending. I believe we are on the verge of some major changes in health care, and that how they’re implemented will determine their impact on the overall economic picture in this country and around the world. **Continued failure to recognize the truth about health care will only cause the resulting market corrections to be worse than they need to be**. I don’t want to diminish the pain and anguish that many people caught up in the housing crash experienced. I think an argument can be made, though, that if **the health care market crashes and millions of people end up with no health care**, **the** resulting **fallout could be could be much worse than even the housing crisis**.

#### Extinction

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

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

### Sinopharm PIC

#### CP Text: The member nations of the World Trade Organization ought to waive intellectual property for medicines in public health emergencies except for the Sinopharm vaccine.

#### The best study shows that Sinopharm is the least effective vaccine -- leads to more infection, death, and hospitalization especially with the Delta variant -- turns case.

Stephen **Kalin 8/28** [Stephen Kalin is a Middle East correspondent covering Saudi Arabia and the Gulf from Riyadh and Dubai. "Sinopharm Covid Vaccine Seen as Less Effective in Bahrain Study" The Wall Street Journal, Aug. 28, 2021 https://www.wsj.com/articles/sinopharm-covid-vaccine-seen-as-less-effective-in-bahrain-study-11630150885]

The Covid-19 vaccine made by China’s Sinopharm was less effective than others at preventing infection, hospitalization and death, especially among people over 50, according to a study by the kingdom of Bahrain and Columbia University researchers. Chinese vaccines have become a key tool of Beijing’s international diplomacy, especially in developing nations unable to secure sufficient doses of U.S. and European-made shots. Despite high levels of inoculation with the Sinopharm vaccine, Bahrain in May started giving booster shots to vulnerable citizens using a different shot made by Pfizer Inc. and BioNTech SE. BNTX -0.63% It now also offers booster shots for other vaccines. The study, posted online this week ahead of peer review, shows that all the vaccines administered since December in the Persian Gulf island nation—which also include Covishield, an Indian-made version of AstraZeneca’s vaccine, and the Russian-made Sputnik V—were effective in reducing severe illness compared to the unvaccinated population. But the percentage of deaths among all PCR positive post-vaccination Covid-19 cases was 0.46% for Sinopharm recipients compared to 0.15% for Pfizer-BioNTech and 0.03% for AstraZeneca, the study showed. That trend was consistent for infection and hospitalization, even with the advent of the Delta variant. Sputnik V results were intermediate. “They found that there is significant difference between hospitalization, ICU admission and death in favor of Pfizer compared to Sinopharm, especially in older populations and in the context of the emergence of the Delta variant,” said co-author Dr. Jaleela Al-Sayed Jawad. “This gives a preliminary indication, but it needs further in-depth analysis to say that this is really superior,” said Dr. Jawad, who is chief executive of Bahrain’s primary healthcare centers and helped roll out its vaccination campaign. The paper is under consideration at a Nature Portfolio journal. Sinopharm couldn’t immediately be reached for comment. Julian Tang, a clinical virologist and professor of respiratory medicine at the University of Leicester, said that while there are notable differences between vaccines’ effectiveness against different variants, it could be misleading to compare outcomes in sequential or overlapping rollouts without more data on comorbidities and pre-vaccination infections. “Vaccines earlier in the rollout may have had less natural infection than vaccines later in the vaccine rollout,” said Dr. Tang, who is unaffiliated with the Bahrain study. Sinopharm, along with another shot manufactured by China’s Sinovac Biotech Ltd., has already received emergency approval from the World Health Organization, though published clinical data on its efficiency among the population groups most vulnerable to severe disease remains scant. The two vaccines are manufactured with inactivated virus, a long-used technique for making vaccines. The Pfizer-BioNTech shot relies on a new technology employing messenger RNA. Bahrain, one of the world’s early vaccination leaders, has fully vaccinated 66% of its population, more than the 52% vaccination rate in the U.S. It has reported some 272,000 infections and 1,388 deaths in a population of around 1.5 million. The Sinopharm vaccine was deployed there earlier than other vaccines and at a rate three times higher than the Pfizer-BioNTech shot. The study acknowledges that the vaccines’ staggered rollouts and an oversampling of individuals who received the Chinese-made shot could have impacted the results, but researchers concluded that such factors were unlikely to explain the highly significant differences in outcomes. Dr. Sayed said the direct comparison between Sinopharm and Pfizer was possible because of similar age and sex characteristics among recipients, calling the study “a unique resource on the impact of various vaccines in one population.” Peter English, a retired consultant in communicable disease control, said the quantity of variables in the study created potential for misinterpretation but that its conclusions appeared to be sound. “It’s particularly valuable because **they have done as close as anyone has to head-to-head comparisons**. The world will want to know which vaccines work best,” he said.

#### Use sufficiency framing: no reason Sinopharm is key out of all the available vaccines. Only a risk that its waiver prevents countries from developing more effective vaccines.

## Case

#### **Yeisley is really bad – its from 2011 which doesn’t assume climate change, and African political changes – theres – the card is talking generally, it should’ve already happened if china and the us wanted to**

#### **There is zero internal link to us china war – literally it makes no sense;**

#### **No US-China war.**

Lei 20, PhD and MA in International Politics, associate research fellow with the China Institute of International Studies. (Cui, 7-24-2020, "Despite heated talk, risk of a US-China hot war is small", *South China Morning Post*, https://www.scmp.com/comment/opinion/article/3094121/why-risk-us-china-hot-war-small-despite-heated-talk)

Many observers are pessimistic about deteriorating US-China relations and believe the two countries are heading towards a cold war. Even worse, some argue that the situation might be more dangerous than the US-Soviet Union Cold War, and that a hot war might break out between the two. This argument is unconvincing. First of all, deterrents to a flare-up are much stronger in US-China relations than in US-Soviet relations. Although economic and people-to-people ties between China and the US are declining, they are still close compared to US-Soviet ties. It is hard to decouple two closely intertwined economies and societies. Take two examples. China is expected to become the world's largest consumer market, a temptation hard to resist for exporters, including those from the US. And in education, more than 300,000 Chinese students study in the US, bringing in huge revenues for the US education industry. Many universities go to great lengths to woo international students. Recently Harvard and the Massachusetts Institute of Technology even sued the government over its new visa restrictions, now aborted, on international students. Second, even if there is decoupling, the pain would not be too great and can be kept out of the national security sphere if properly handled. In fact, for national security reasons, a modest degree of isolation will make both sides more secure and comfortable. For instance, if China’s information technology equipment cannot capture Western markets, the US will be more relaxed. If China cannot get advanced technologies from the US and its technological progress slows down, the US will be less anxious. In the same vein, China feels assured knowing that if the Trump administration does impose a travel ban on Communist Party members, it would be abandoning one of the tools available to the US to promote “peaceful evolution” in China. Economic decoupling is undeniably more painful for China than for the US. But unlike Japan during WWII, which was hit hard by the US oil embargo because of its lack of natural resources, China has no such problems. Given its large domestic market, losing the US as a major customer is not a disaster for China, and can be compensated through more dynamic economic activities at home. China can also make up for being freezed out of technological exchanges by turning to indigenous innovation. As for the US, it can import goods from other developing countries, albeit less cheaply. The relative loss is acceptable when weighed against the heightened perception of economic independence and security. Third, the ideological confrontation between China and the US is less intense than that during the Cold War. Unlike the obsession with ideology in those days, the line between capitalism and socialism is blurred today. The market economy has become universally recognised as the best way to promote economic growth and, politically, many countries have embraced democracy. Even North Korea calls itself the Democratic People’s Republic of Korea. Although ideological hawks in the US still long for the day when the beacon of freedom will light up the world, after many years of fighting bloody wars overseas, most American people are not interested in promoting democracy abroad. Meanwhile, China just wants to preserve its political system and has no interest in exporting it to other countries, as the Soviet Union did. Thus, ideological antagonism in China-US relations can easily be eased by calculations of realistic interests, which create conditions for compromise and cooperation. Fourth, both China and the US have many options other than war to achieve their policy goals. While they have no allies to serve as a buffer, given the nature of the potential conflict in the South China Sea or Taiwan Strait, both countries are adept at operating in grey zones and fighting psychological, public opinion or diplomatic warfare below the threshold of war. The forced closure of the Chinese consulate in Houston by the US government is just the latest act of brinkmanship. In addition, given China’s huge economic and financial interests in the US, the latter can wield the stick of sanctions when use of force is highly risky or not worth it. When both sides have many tools and options, why would they rush to war to achieve their goals? Last but not least, the imbalance of power will act as a deterrent. Some say the US and Soviet Union did not fight a hot war because they were evenly matched. It was not the case, actually. At the beginning of the Cold War, the Soviet Union was at a relative military disadvantage. Moreover, a country needs the will to fight before going to war, even if it is stronger militarily than its adversary. Having fought years of meaningless wars, the US is weary of war. China, too, abhors war. Having a clear understanding of US strength, especially when its own economy is slowing down and it is facing various domestic challenges, China would not wish to recklessly start a war with the US. In summary, the possibility of a hot war between China and the US is very small. The greatest danger for China is not a cold or hot confrontation with the US, but policymakers’ interpretation of the momentary hostility towards Beijing of a portion of the American population and the larger world. An erroneous interpretation could end China’s march to further opening up, and see it turn instead towards self-isolation.

#### Won’t go nuclear---both sides will contain conventional disputes.

---AT Talmadge

---conventional capabilities are physically separate from nuclear forces and are distinguishable to both sides

---we wouldn’t try to destroy China’s nuclear arsenal

---even if we did accidentally destroy an intermingled asset, China would adhere to NFU and wait to see if it was part of a broader counter-forcing campaign

Blair 19, MA, Chair of the Board, Sasakawa Peace Foundation USA; U.S. Director of National Intelligence, 2009-10; Commander of U.S. Pacific Command, 1999-2002 . (Dennis C., January/February, "Would China Go Nuclear?", *Foreign Affairs*, https://www.foreignaffairs.com/articles/2018-12-11/would-china-go-nuclear)

I read with interest Caitlin Talmadge’s article “Beijing’s Nuclear Option” (November/December 2018), in which she quotes me estimating in 2015 that the odds of a U.S.-Chinese nuclear exchange were “somewhere between nil and zero.” She then goes on to make a case against remaining complacent in the face of the risk of escalation, with no discussion of what is in fact a very high nuclear threshold in a U.S.-Chinese confrontation or conflict. I continue to believe that the chances of nuclear use are very small.

Talmadge’s basic argument is that in any conflict with China, the United States will immediately launch a full-scale air and missile assault against military targets in mainland China and against Chinese attack submarines at sea. In so doing, she argues, the United States will inadvertently hit either China’s ballistic missile submarines or its mobile nuclear missiles. That, in turn, will present Chinese leaders with a “use it or lose it” dilemma concerning their nuclear arsenal, and they may well decide to launch a nuclear attack against the United States.

Such a scenario is extremely unlikely; indeed, I would say the odds are somewhere between nil and zero. A U.S.-Chinese conflict would be a maritime campaign in which the two sides tried to conquer or defend islands. Attacks on land targets beyond the contested islands and the waters around them, whether carried out by the United States against Chinese territory or by China against U.S. overseas bases, would be aimed at military installations and systems that supported the maritime campaign

—ports, air bases, and command-and-control centers. The intercontinental nuclear deterrent forces of both countries are physically separate from these facilities.

In addition, U.S. planners are very mindful of the danger of attacking any state’s nuclear arsenal and take extraordinary precautions to avoid doing so. Although there is always a chance for an isolated mistake, it is in fact possible to distinguish nuclear-armed submarines from conventional ones. Likewise, it is possible to distinguish the shorter-range, dual-use missiles that threaten Taiwan, China’s neighbors, and U.S. bases in the Pacific from the intercontinental missiles that threaten the United States.

If by mistake a U.S. strike destroyed a land-based medium-range nuclear missile or sank a ballistic missile submarine, China would be greatly concerned, but it is highly unlikely that Beijing would respond by reflexively launching a nuclear attack against the United States. Rather, before even considering violating their long-held “no first use” doctrine, Chinese leaders would wait to see if a concerted, sustained U.S. campaign against their nuclear arsenal was under way. The United States has no incentive to attempt such a campaign and in fact would take every precaution to avoid it.

#### Interdependence, institutions, geography check war

Shifrinson 19, assistant professor of international relations at Boston University. Joshua. (2/8/19, “The ‘new Cold War’ with China is way overblown. Here’s why.”, *Washington Post*, https://www.washingtonpost.com/news/monkey-cage/wp/2019/02/08/there-isnt-a-new-cold-war-with-china-for-these-4-reasons/?noredirect=on)

Is a new Cold War looming — or already present — between the United States and China? Many analysts argue that a combination of geopolitics, ideology and competing visions of “global order” are driving the two countries toward emulating the Soviet-U.S. rivalry that dominated world politics from 1947 through 1990.

But such concerns are overblown. Here are four big reasons why.

1. The historical backdrops of the two relationships are very different

When the Cold War began, the U.S.-Soviet relationship was fragile and tenuous. Bilateral diplomatic relations were barely a decade old, U.S. intervention in the Russian Revolution was a recent memory, and the Soviet Union had called for the overthrow of capitalist governments into the 1940s. Despite their Grand Alliance against Nazi Germany, the two countries shared few meaningful diplomatic, economic or institutional links.

In 2019, the situation between the United States and China is very different. Since the 1970s, diplomatic interactions, institutional ties and economic flows have all exploded. Although each side has criticized the other for domestic interference (such as U.S. demands for journalist access to Tibet and China’s espionage against U.S. corporations), these issues did not prevent cooperation on a host of other issues. Yes, there were tensions over the past decade, but these occurred against a generally cooperative backdrop.

2. Geography and powers’ nuclear postures suggest East Asia is more stable than Cold War-era Europe

The Cold War was shaped by an intense arms race, nuclear posturing and crises, especially in continental Europe. Given Europe’s political geography, the United States feared a “bolt from the blue” attack would allow the Soviet Union to conquer the continent. Accordingly, the United States prepared to defend Europe with conventional forces, and to deter Soviet aggrandizement using nuclear weapons.

Unsurprisingly, the Soviet Union also feared that the United States might attack and wanted to deter U.S. adventurism. Concerns that the other superpower might use force and that crises could quickly escalate colored Cold War politics.

Today, the United States and China spend proportionally far less on their militaries than the United States and the Soviet Union did. Though an arms race may be emerging, U.S. and Chinese nuclear postures are not nearly as large or threatening: Arsenals remain far below the size and scope witnessed in the Cold War, and are kept at a lower state of alert.

As for geography, East Asia is not primed for tensions akin to those in Cold War Europe. China can threaten to coerce its neighbors, but the water barriers separating China from most of Asia’s strategically important states make outright conquest significantly harder. Of course, as scholars such as Caitlin Talmadge and Avery Goldstein note, crises may still erupt, and each side may face pressures to escalate. Unlike the Cold War, however, U.S.-Chinese confrontations occur at sea with relatively limited forces and without clear territorial boundaries. This suggests there are countervailing factors that may give the two sides room to negotiate — and limit the speed with which a crisis unfolds.

#### Manufacturing is at capacity -- vaccine makers are already incentivized to maximize output -- the barriers are supply and logistics not IP -- plus supply-chain nationalism is an alt cause to the aff.

Alex **Tabarrok 5/6** [professor of economics at George Mason University "Patents are Not the Problem!" Marginal Revolution, May 6, 2021 https://marginalrevolution.com/marginalrevolution/2021/05/ip-is-not-the-constraint.html]

Patents are not the problem. All of the vaccine manufacturers are trying to increase supply as quickly as possible. Billions of doses are being produced–more than ever before in the history of the world. Licenses are widely available. AstraZeneca have licensed their vaccine for production with manufactures around the world, including in India, Brazil, Mexico, Argentina, China and South Africa. J&J’s vaccine has been licensed for production by multiple firms in the United States as well as with firms in Spain, South Africa and France. Sputnik has been licensed for production by firms in India, China, South Korea, Brazil and pending EMA approval with firms in Germany and France. Sinopharm has been licensed in the UAE, Egypt and Bangladesh. Novavax has licensed its vaccine for production in South Korea, India, and Japan and it is desperate to find other licensees but technology transfer isn’t easy and there are limited supplies of raw materials: Virtually overnight, [Novavax] set up a network of outside manufacturers more ambitious than one outside executive said he’s ever seen, but they struggled at times to transfer their technology there amid pandemic travel restrictions. They were kicked out of one factory by the same government that’s bankrolled their effort. Competing with larger competitors, they’ve found themselves short on raw materials as diverse as Chilean tree bark and bioreactor bags. They signed a deal with India’s Serum Institute to produce many of their COVAX doses but now face the realistic chance that even when Serum gets to full capacity — and they are behind — India’s government, dealing with the world’s worst active outbreak, won’t let the shots leave the country. Plastic bags are a bigger bottleneck than patents. The US embargo on vaccine supplies to India was precisely that the Biden administration used the DPA to prioritize things like bioreactor bags and filters to US suppliers and that meant that India’s Serum Institute was having trouble getting its production lines ready for Novavax. CureVac, another potential mRNA vaccine, is also finding it difficult to find supplies due to US restrictions (which means supplies are short everywhere). As Derek Lowe said: Abolishing patents will not provide more shaker bags or more Chilean tree bark, nor provide more of the key filtration materials needed for production. These processes have a lot of potential choke points and rate-limiting steps in them, and there is no wand that will wave that complexity away. Technology transfer has been difficult for AstraZeneca–which is one reason they have had production difficulties–and their vaccine uses relatively well understood technology. The mRNA technology is new and has never before been used to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Moderna or Pfizer would be happy to license since they are producing in their own factories 24 hours a day, seven days a week (monopolies restrict supply, remember?). Why do you think China hasn’t yet produced an mRNA vaccine? Hint: it isn’t fear about violating IP. Moreover, even Moderna and Pfizer don’t yet fully understand their production technology, they are learning by doing every single day. Moderna has said that they won’t enforce their patents during the pandemic but no one has stepped up to produce because no one else can.

#### Global vaccine rollout is strong now -- aff flips this through supply chain disruptions

Michelle **McMurry-Heath 8/18** [physician-scientist and president and CEO of the Biotechnology Innovation Organization. "Waiving intellectual property rights would compromise global vaccination efforts" Statnews, Aug. 18, 2021 https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/]

Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive.

Here’s why. Before Covid-19 emerged, the world produced at most 5.5 billion doses of various vaccines every year. Now the world needs an additional 11 billion doses — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease.

Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production.

As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months.

The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit.

Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.

Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another four to six months to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available.

That’s slower than our current production rate. According to a report from Duke University’s Global Health Innovation Center, companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity.

Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid $23.50 per dose for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during just two days of shutdowns in the country.

Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose.

Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. COVAX, the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year.

President Biden vowed to make America the world’s “arsenal of vaccines.” The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate 500 million more by the end of summer. Other countries are following the administration’s leadership and ramping up their donations.

To be sure, the United States and other wealthy nations still need to give considerably more. But the fact remains that ramping up production in bona fide facilities and donating doses are the most straightforward steps to producing the vaccine doses needed to end the pandemic. The effort to strip intellectual property rights, by contrast, would put success against the global scourge of Covid-19 even further out of reach.

#### IP is not the bottleneck- raw materials and skills, which means no solvency and CP outweighs since mRNA exacerbates raw material and worker problems

Garde et al 5-6 [Damian Garde , Helen Branswell , and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] // WW LD

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic. For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.” Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave. Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

1. Joseph Nye [professor of International Relations at the Kennedy School]. “US military primacy is fact - so, now, work on 'soft power' of persuasion.” Christian Science Monitor, 4/29/2004. <http://www.csmonitor.com/2004/0429/p09s02-coop.html>. [↑](#endnote-ref-1)