## OFF

#### Interpretation: Topical Affirmatives must defend the reduction of intellectual property protections for all medicines

#### Violation:

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It’s applicable to “Medicines” – adding “generally” to the res doesn’t substantially change its meaning because the res never specified further

#### Vote negative

#### 1] limits & ground– the aff can specify any medicine and explode the link scenario – cancer, marijuana, COVID, influenza, common cold - it’s uniquely bad because there’s no term of art like “substantial” in the res which explodes limits. Different affs bracket out different DAs and specific frontlines beat neg generics every time – that sidelines clash and pushes to the margins of the topic

#### 2] TVA – read whole res or specify states without medicines - everyone has generic impact defense on various regions and there are only so many legitimate scenarios but medicine prep is constrained by topic duration

#### Competing interps – you can’t be reasonably topical – it’s a binary question

#### No RVIs – T’s a stock issue, not a reason you should win

#### Reject the team – anything else servers out of plan text which is a voter because it moots the NC

## Off

#### Counterplan: The member states of the World Trade Organization ought to

* **offer generous payment per immunization in LMICs and subsidies to oversee distribution of COVID-19 related medicines to local pharmaceutical companies**
* **make rewards conditional upon speed and inoculation efficacy**
* **create IPTK banks to bypass trade secrets and encourage public-private collaboration**

#### Subsidized reward mechanisms harness market demand

**Karan et al 4/2**, Abraar Karan is an internal medicine physician at the Brigham and Women’s Hospital/Harvard Medical School and a columnist at The BMJ. He previously worked on the covid-19 response in Massachusetts state. The views expressed here are his own and do not represent those of his employers, Thomas Pogge is a professor and director of the Global Justice Program at Yale University. He co-founded Incentives for Global Health, a team effort toward creating the Health Impact Fund , 4-2-2021, "Solving global vaccine inequity requires new incentives for pharmaceutical companies,", The British Medical Journal <https://blogs.bmj.com/bmj/2021/04/02/solving-global-vaccine-inequity-requires-new-incentives-for-pharmaceutical-companies/> ]AAli

Scientists have been successful in bringing several highly effective covid-19 vaccines to market in record time. But manufacturing scale-up is slow—with a few companies holding the “know-how,” but unenthusiastic about licensing this to others. Current trends predict that 90% of people in 67 low income countries will not be vaccinated this year and that most poorer populations will not gain herd immunity even in 2022. This delay will facilitate the emergence of new disease strains that may endanger even those already vaccinated. More importantly, millions of people in poor countries will needlessly die, particularly those who are at higher risk of mortality, such as those who are older and immunocompromised. To speed up manufacturing, some 119 developing countries have called for a temporary suspension of intellectual property rights related to covid-19 to allow manufacturers worldwide to produce and sell approved vaccines without the patentee’s permission. Patentees and the affluent countries representing them have opposed such a waiver: it would undermine incentives to innovate against future pandemics, they say, and it would not help much because patentees would not share crucial technologies and know-how with manufacturers who had not paid them for a license to produce and sell (as was the case with Moderna, which liberalized its intellectual property, but little else). And there is a further problem: even with generic manufacturers in the driver’s seat, the world’s poorest populations are still very poor, and thus would still be served last, if ever. Ultimately, waiving global policy agreements like TRIPS is a stopgap measure; the system needs more fundamental change. The urgent needs of the world’s poorest people must be subsidized into effective market demand. This might be done through a massive increase in funding for the existing COVAX facility, which is currently projected to provide two billion doses per year, at best only around 20% of global vaccine needs. COVAX could then offer a generous payment per immunization to pharma companies, featuring a declining premium for early delivery and payment adjustment with regard to quality (for example, how much protection an immunization affords, for how long, against which variants). Such a pay for performance scheme would give firms with approved vaccines a financial incentive to ramp up production for fast delivery. To this end, they would, competing with one another, seek to engage and expand available manufacturing capacity while fully supporting contracted manufacturers. Supplies produced would be directed to where they can be most effective in suppressing the pandemic, without consideration for the poverty or affluence of the various populations. Even if such an initiative were to raise cost by a factor of 10—from the $6 billion COVAX currently has to $60 billion— this would still be a tiny fraction of the economic harm this pandemic has caused and might yet cause in the future. The US alone has just allocated $1.9 trillion to avert some of the economic damage it has sustained from covid-19. An extra $54 billion, spread over many countries, is a small price to pay for bringing this pandemic under control at least two years sooner. A key lesson of covid-19 is that the great benefits the pharmaceutical sector has to offer must fully include the world’s poorest people. This is a firm command of justice and, at least with communicable diseases, an imperative of prudence as well. We must place advanced pharmaceuticals within reach of poor communities and must ensure that the diseases concentrated among them are lucrative targets of pharmaceutical research and development. To achieve global pharmaceutical equity in a sustainable way, we should create a complementary reward mechanism, additional to patent monopolies, that is designed to pay for better health outcomes. This mechanism can be but is not limited to the Health Impact Fund (a system one of us, TP, co-founded), which gives innovators the option to have any of their new pharmaceuticals rewarded according to the health gains achieved with it, on condition that it is sold at the variable cost of supplying it. Here “health gains” would be understood to cover not merely the therapeutic improvements that users experience, but also wider societal benefits, such as reduced infections among non-users. Moreover, pharmaceutical companies would be incentivized to effectively oversee and coordinate the delivery of therapeutics to end users, whether that be through national health systems or public-private partnerships. As an immediate example, such a system could effectively benefit latecomers to vaccine rollouts, given that there is an immense market potential remaining in low and middle income countries, which is largely uninteresting to early comers like Moderna and Pfizer whose supply has already been sold to high income countries. With the Health Impact Fund in place, the global pharmaceutical sector would be much better prepared to respond effectively to future pandemics, and would have been for past ones too (we wrote about this in the context of the Ebola and Zika viruses previously). Furthermore, it would be able to profitably unleash its skills upon the enormously harmful diseases associated with poverty, including the 20 WHO listed neglected tropical diseases, which affect over a billion people, as well as tuberculosis, malaria, hepatitis, and pneumonia, which together kill millions of people each year. We can and must tackle these diseases. The investment for doing so would pay for itself many times over.

#### IPTK banks are key to DCVMs

**Crager 18** [Dr. Sara Crager, MD is a board certified emergency medicine physician in Los Angeles, California. She is affiliated with Ronald Reagan UCLA Medical Center, 2018 December, "Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6291766/> ]//AAli

\*developing country vaccine manufacturers

I propose a strategy that would integrate key aspects of both these models, creating a structure capable of facilitating access to new vaccines by establishing an entity that pools all relevant intellectual property, technology, and know-how: an IPTK bank. An IPTK bank would bring together the necessary intellectual property rights, manufacturing process information, know-how, and regulatory expertise into a single platform that could be licensed as a package with associated training modules; it could also offer assistance in navigating vaccine registration with national regulatory authorities. A licensing approach similar to that used by the MPP would be employed to address intellectual property barriers by creating a structure whereby the patented technology could be disseminated to multiple DCVMs, each paying royalties to the patent holder. The manufacturing process information, know-how, and regulatory expertise would be brought together through the organization hosting the IPTK bank, which would closely mirror the organizational model of the WHO technology transfer hub. Barriers to Creation of the Proposed Banks Funding, inevitably, will be a major barrier to the creation of IPTK banks. IPTK banks would require an initial period of funding in order to acquire and then disseminate the vaccine technology. Once a critical mass of DVCMs began producing the vaccine, however, provision of affordable vaccines would be self-sustaining, with reliance on market forces to ensure appropriate price declines. IPTK banks thus would not be as subject to the vagaries of sustained donor funding as organizations like GAVI, but would rather need to raise enough money to support the initial acquisition and dispersal period for each new vaccine technology. Given that projected spending on new vaccines necessary to achieve the GVAP goals is estimated at nearly US $30 billion, it may ultimately be more cost-effective to invest in upstream mechanisms to rapidly achieve sustained price reductions for new vaccines. The greatest barrier to the creation of IPTK banks is the need for close cooperation with innovator companies. Fundamentally, engaging with an IPTK bank would be similar to the technology transfer arrangements that multinational pharmaceutical companies frequently enter into with individual DCVMs to expand their regional vaccine production and distribution. The major departures from a traditional technology transfer agreement would include licensing terms that allow the IPTK bank to grant nonexclusive licenses to multiple DCVMs and the transfer of technology to a hub organization at a publicly funded institution rather than directly to a DCVM. Because an IPTK bank strategy depends on significant involvement from innovator companies, creating appropriate conditions that incentivize their participation is key to the success of this model. Engagement With Innovator Companies Multinational pharmaceutical companies frequently engage in successful technology transfer with DCVMs, and this trend appears to be growing. According to an International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) spokesperson, Technology transfer in medicines and vaccines were growing rapidly in the past decade, benefiting both pharmaceutical companies and the health of recipient countries’ population alike.51 In fact, so much interest has developed around this topic that the IFPMA recently issued a research paper titled “Technology Transfer: a Collaborative Approach to Improve Global Health—the R&D Pharmaceutical Industry Experience.” In addition to providing numerous case studies of technology transfer partnerships, the paper identified 8 conditions that the pharmaceutical industry considers necessary for successful technology transfer relationships: a viable and accessible local market, political stability and good economic governance, clear economic development priorities, adherence to high regulatory standards, availability of skilled workers, adequate capital markets, strong intellectual property rights and effective enforcement, and a high-quality relationship between industry and government, and their ability to work together effectively for long periods of time. An IPTK bank as a technology partner would fulfill most of these criteria. The fact that an IPTK bank would almost certainly be based in a high-income country would also address a number of these issues. In this context, there should be relatively little concern over issues such as political stability and good economic governance, and most industrialized-country governments are generally considered to have relatively good relationships with industry and a long history of working together effectively. These conditions may not be guaranteed to the same degree in all countries that receive technology from an IPTK bank, but that risk would not be directly borne by the company and would be distributed over multiple potential technology partners. In addition, high-income countries generally have well-established systems of strong intellectual property rights with effective enforcement. Again, this may or may not be true to the same extent in all countries that are recipients of IPTK bank technology; however, industry has already shown itself willing to discuss licensing arrangements with the MPP that would involve licensing intellectual property rights to a central organization, which would then provide nonexclusive licenses to multiple other entities in countries that may not have similarly strong enforcement of intellectual property rights. Regarding access to viable local markets, although the IPTK bank itself would not directly have such access, licenses would be granted only to partners with demonstrable access to local markets large enough to achieve economies of scale such that significant price reductions could be generated (as occurs with the MPP). Finally, if the IPTK bank is based at an institution such as the Netherlands Vaccine Institute or the International Vaccine Institute, availability of skilled workers should be more than adequate. Basing the IPTK bank within such organizations would provide a strong base of experience in adherence to high regulatory standards that would be passed on to IPTK bank technology recipients. Overall, IPTK banks would fulfill the criteria that the IFPMA has identified as being critical to the decision of multinational pharmaceutical companies to engage with a technology transfer partner. The major departure from the technology transfer arrangements described in the IFPMA report would be use of a licensing covering all necessary intellectual property modeled on the MPP licenses rather than the traditional sublicense negotiated between pharmaceutical companies and their technology partners. Companies have demonstrated their willingness to enter into negotiations involving such licenses with the MPP, providing a precedent that this may not present an insurmountable barrier to companies engaging in technology transfer agreements with an IPTK bank. Although an IPTK bank would require a high degree of commitment and cooperation from innovator companies, it seems possible that industry might be willing to consider engaging in discussion regarding this approach to expanding vaccine access.

## Off

### TRIPs Waiver

#### Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) “As Washington Ties Pharma’s Hands, China Is Leaping Ahead” Barron’s Magazine: Commentary, China., 6/11/2021] RM

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, [47% of all new medicines](https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf) were invented by U.S. biopharma companies, with [homegrown startups](https://www.cbo.gov/publication/57126) driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market.

An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from [$1 billion to over $200 billion](https://www.bloomberg.com/news/articles/2021-03-01/xi-mobilizes-china-for-tech-revolution-to-cut-dependence-on-west). China saw over [$28 billion](https://www.bioworld.com/articles/506978-china-sees-five-year-highs-in-life-sciences-investments-and-partnering) invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast.

In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies.

The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in [contravention](https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail) of international standards, and the U.S. national security community believes China is [pushing ahead](https://www.nbcnews.com/politics/national-security/china-has-done-human-testing-create-biologically-enhanced-super-soldiers-n1249914) with experimental concepts for biological and cognitive enhancement of soldiers and civilians. American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.

#### TRIPs waiver undermines the innovation ecosystem

**Pitts 5/21** [Peter J. Pitts, a former associate commissioner of the FDA, is president of the Center for Medicine in the Public Interest. Robert Popovian is the chief science policy officer of the Global Healthy Living Foundation and a senior health policy fellow at the Progressive Policy Institute. Wayne Winegarden, Ph.D., directs the Center for Medical Economics and Innovation at the Pacific Research Institute. 5-5-2021, PRI Center for Medical Economics And Innovation “Waiving Covid-19 Vaccine Patents Is a Bad Idea and Sets a Dangerous Precedent”, 5-21-2021, <https://medecon.org/waiving-covid-19-vaccine-patents-is-a-bad-idea-and-sets-a-dangerous-precedent/> ]//AAli

Nor is such a process going to produce faster results. Historically, under compulsory rather than voluntary licensing arrangements, it has taken even legitimate generic manufacturers years to receive the formulas, work out logistical challenges, and scale up production. In one case of compulsory licensing, it took over four years to bring a generic AIDS drug to Rwanda. The World Health Organization regularly publishes a list of “essential” medications, the vast majority of which patent protections have long expired. Any generic manufacturer can therefore set itself up producing them. Yet the WHO reports that availability of these medicines in many parts of the developing world remains spotty, at best. The quality of many of these essential medicines is also questionable. Yet none of the drugs on the WHO list are in the same universe of complexity as the Covid-19 vaccines. The patent system is not the problem here. But, some ask, why should private companies enjoy the property rights to innovation driven by government funding? This question likewise misses the mark. In a study of 478 drugs less than 10 percent had a public-sector patent associated with it. While providing no gain, compulsory licensing promises lots of pain. Shunting aside patent and intellectual property rights sends a dangerous signal to innovative biopharmaceutical companies and their investors. Biopharmaceutical research is risky. It costs almost $3 billion, on average, to bring a single medicine to pharmacy shelves. Biotech investors take these risks because of strong patent protection like those in the United States. Scientists in America now develop over half of all new drugs worldwide. It’s important to understand the current advocacy for a “temporary” IP waiver. A small but vocal and influential public health policy cohort believes that IP protections are the most significant cause of global healthcare disparities. Their philosophies repeat and reinforce many misconceptions about the problem of improving global access to medicines. The reality is that, in order to save the world, we must all work together as partners. A free-market healthcare paradigm for drug development, although far from perfect, works. A well-appointed armamentarium of Covid-19 diagnostic tools, therapeutics, and vaccines – all invented in under one year, speaks to the power of today’s innovation ecosystem. That ecosystem is built on IP protections. Right now, under voluntary licensing, global production capacity for Covid vaccines and treatments is expanding and accelerating. A move to nullify IP will not result in a single resident of the developing world getting vaccinated one minute sooner.

#### The plan recapitulates IP to China, destroying competitive advantages

WSJ 5/6 [Wall Street Journal Editorial Board, WSJ Opinion Philosophy: “We speak for free markets and free people, the principles, if you will, marked in the watershed year of 1776 by Thomas Jefferson's Declaration of Independence and Adam Smith's “Wealth of Nations.” So over the past century and into the next, the Journal stands for free trade and sound money; against confiscatory taxation and the ukases of kings and other collectivists; and for individual autonomy against dictators, bullies and even the tempers of momentary majorities.” Edited by Paul A. Gigot and Daniel Henninger, “Biden’s Vaccine IP Debacle: His patent heist is a blow to the Covid fight and U.S. biotech.” The WSJ Opinion: Review and Outlook, May 6, 2021] RM

We’ve already criticized President Biden’s bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon’s wage-and-price controls.

In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, set a destructive precedent that will reduce pharmaceutical investment, and surrendered America’s advantage in biotech, a key growth industry of the future. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away.

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India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested.

Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S.

But suspending IP isn’t necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world.

Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer’s 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year.

AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But India has restricted vaccine exports to supply its own population. IP simply isn’t restraining vaccine production.

Busting patents also won’t speed up production, since it would take months for these countries to set up new facilities. Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines.

There’s also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that’s in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back?

The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America’s crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals.

Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches.

Thanks to Mr. Biden, all this could become the property of foreign governments. Licensing agreements allow developers to share their IP while maintaining quality control. Breaking patents and forcing tech transfers will enable China and low-income countries to manufacture U.S. biotech products on their own.

China’s current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. The U.S. has spent years deploring China’s theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation.

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Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck.

Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism.

Mr. Biden ought to listen to Angela Merkel. Pfizer’s partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: “The protection of intellectual property is a source of innovation and it must remain so in the future.”

At least IP is safe in Germany. Mr. Biden has sent a signal around the world that nobody’s intellectual property is safe in America.

### Impact – China Rise

#### China will leapfrog the US through biotech primacy

Cumbers 20 [John Cumbers, “I am the founder and CEO of SynBioBeta, the leading community of innovators, investors, engineers, and thinkers who share a passion for using synthetic biology to build a better, more sustainable universe. I publish the weekly SynBioBeta Digest, host the SynBioBeta Podcast, and wrote “What’s Your Biostrategy?”, the first book to anticipate how synthetic biology is going to disrupt virtually every industry in the world. I also founded BetaSpace, a space settlement innovation network and community of visionaries, technologists, and investors accelerating the industries needed to sustain human life here and off-planet. I’ve been involved with multiple startups, I am an operating partner and investor at the hard tech investment fund Data Collective, and I'm a former bioengineer at NASA. I earned my PhD in Molecular Biology, Cell Biology, and Biochemistry from Brown University and am originally from the UK.”) “China’s Plan To Beat The U.S. In The Trillion-Dollar Global Bioeconomy” Forbes, 2/3/2020] RM

The report, entitled “Safeguarding the Bioeconomy,” looks at how research and innovation in the life sciences is driving rapid growth in agriculture, biomedical science, information science and computing, energy, and other sectors of the U.S. economy. This economic activity—collectively referred to as the bioeconomy—presents many opportunities to create jobs, improve the quality of life, and continue to drive the U.S. economy as a whole. The report says that while the U.S. has been a leader in advancements in the biological sciences, other countries are actively investing in and expanding their capabilities in this area—and the U.S.’s lead is beginning to slip. Four reasons everyone should care about the U.S. bioeconomy It might be easy for some to dismiss the report out of hand as a bunch of alarmist professors lobbying for more research money. But when you consider all the ways that biotechnology powers the economy and impacts our daily lives, it becomes clear that this is about something more: The economy: at $1 trillion in value, the U.S. bioeconomy represents hundreds of thousands of quality, high-paying jobs for Americans. Health & medicine: innovators in the bioeconomy are making next-generation therapies for cancer and diabetes, tackling emerging diseases like Coronavirus, and even increasing human longevity. Food & farming: biotechnology is not only making agriculture more sustainable, it’s also bringing to market new and improved crops that are more nutritious, more affordable, and more delicious. The environment: humanity’s health and well-being depend on our ability to stop and reverse climate change, and we can’t do it without biological solutions that treat carbon not as a waste product, but as the starting point for chemicals and materials that today use petroleum. Considering all this, it doesn’t seem like an overstatement when the report authors say that U.S. competitiveness in the bioeconomy is key to maintaining the economic health and security of the country. The very real risks to the U.S. bioeconomy There are many things that can go wrong, causing the U.S. to lose its current edge in the global bioeconomy. Some of these are economic risks, and others present serious national security risks. All of them are related to a failure of our government to act now. Here’s a sampling of the risks to U.S. leadership at the frontiers of tech and bio: Insufficient government R&D investment. Money for basic research and development builds the foundations of the bioeconomy. We learn, achieve new results, and create new applications. Investments that help develop enabling tools, technologies, and standards have the potential to maintain the U.S. bioeconomy competitive in a global bioeconomy. Ineffective or inefficient regulations. Regulatory uncertainty stifles creative new approaches that may have unknown paths, long delays, or that might be prohibited by later changes. Inadequate workforce. The U.S.’s K-12 education system may not prepare students to study STEM subjects at the university and postgraduate level, hindering the quality of workers. A skilled workforce gives U.S. companies the best talent to choose from, and it also encourages international firms to establish research and production facilities here. Ineffective or inefficient intellectual property protections. Uncertainty over what is patentable could discourage innovators who are considering whether and how to bring their innovations to market. Patent eligibility is also important to venture capitalists and private equity investors when considering whether to invest in biotechnology companies. Cybersecurity. As biological engineering depends more and more on massive datasets, the emerging bioeconomy now exists at the intersection of information science and biotechnological science. The bioeconomy’s growing reliance on software, networking, and computer hardware tools yields the same cyber vulnerabilities present in any other sector, including hacking, sabotage, breached privacy, or theft of intellectual property. Biosafety and biosecurity risks. The tools of today’s bioeconomy are enabling new capabilities that can generate concerns regarding traditional biothreats. These can include the accidental or intentional creation or release of dangerous or lethal pathogens. Such biothreats can harm humans, animals, plants, agriculture, the environment, and materials. Risks from climate change. Food and feed crops, biofuels crops, and crops used with bio-based fermentation products are susceptible to temperature and water stresses, as well as insects and pathogens that migrate with changing weather patterns. China: the biotech elephant in the room I’ve written previously written how the Chinese government is already making substantial investments in its bioeconomy. Here are three scary statistics, courtesy of Greg B. Scott of the ChinaBio Group: China is out-investing the U.S. China’s private investors poured $14.4 billion into its bioeconomy in 2019. That compares to the United States’ more meager investment of $10.4 billion. China is building a bigger bioeconomy workforce. China graduates about 8-10 million students each year. In the U.S., that number is closer to 400,000. Many Chinese students graduating from U.S. institutions stay here, but they are increasingly returning home to start highly innovative companies. China is investing in itself. Historically, China has invested heavily in foreign companies, tech, and debt. Now we’re seeing an uptick in China-to-China investments—the country no longer needs to look abroad to find plenty of good biotech opportunities. Chinese investments have led to centers of excellence in the regional technology hub of Shenzhen, including the Institute of Synthetic Biology at the Shenzhen Institute of Advanced Sciences (SIAT) and BGI Genomics. Shenzhen will compete for technological and economic leadership with U.S. regional biotech powerhouses such as San Francisco/Silicon Valley and Boston/Cambridge in the years to come. Many of China’s long-standing challenges—environment, food, water, waste management, and rapid innovation to retain its global manufacturing competitiveness—are areas where synthetic biology is seen as a key technology for the future. In other words, synthetic biology is not just an academic pursuit for China. Rather, its leaders are thinking proactively about how biological engineering can be used to address the country’s strategic national interests—while U.S. leadership stands idly by. What do we do? So what can U.S. policymakers do to protect the U.S. bioeconomy and ensure continued technological and economic leadership in biology for the next twenty years? Straight from the top. China has made clear its ambition to become a global tech superpower, with President Xi Jinping calling science and technology one of the main battlefronts of the economy. The U.S. administration needs to step up its game, too. President Trump recently declared January 2020 to be National Biotechnology Month, citing “boundless possibilities for economic growth, national security, healthcare, manufacturing, and agriculture.” That’s the right sentiment—now we need real action. New legislation. Late last year, the U.S. House of Representatives passed the Engineering Biology Research and Development Act of 2019, which would direct the Office of Science and Technology Policy (OSTP) to implement a national research strategy for engineering biology. The explicit goal: maintain U.S. science, technology, and economic leadership in synthetic biology. The bill now resides in the Senate and awaits committee action. Legislative leadership is now needed to give this bill the appropriations necessary to give it real teeth, and then put it squarely on the President’s desk. Investing for returns. The Human Genome Project is said to have returned $141 for every dollar invested by taxpayers. While “Big Science” yields tremendous benefits for everyone, it doesn’t happen without federal funding. In 2019, politically courageous Republicans and Democrats came together to produce a 2020 final spending bill that is kind to science, in essence ignoring President Trump’s proposed cuts and instead giving increases to each of the NIH, NSF, NASA, and DOE’s Office of Science. But the U.S. isn’t even in the top ten for R&D spending as a percentage of GDP, while China continues to close in on the U.S., meaning that the U.S. is no longer the uncontested global leader in science. Leading the global bioeconomy: Have some courage There are many things the U.S. could do to protect the American bioeconomy. But above all else, policymakers need to come together and demonstrate the kind of courage and vision needed to be a world leader. Science and technology know no partisan lines. Everybody wants healthy lives, clean water, and good jobs. Federal initiative and assistance are needed to bring these benefits to everyone living in the U.S.. Today, the American synthetic biology industry may be unprepared for the global competition it will face, lacking initiative and leadership at the highest levels of government. But this could change quickly. If a country like the U.S. makes engineering biology a national priority, anything is possible in the new bioeconomy.

#### Heg solves arms races, land grabs, rogue states, and great power war

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6

From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep.

This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance.

Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,” but it was not at all inaccurate.

American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap.

Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled.

THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors.

First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment.

## Off

### UQ - Recent

#### Infrastructure will pass now BUT it’ll be close – razor-thin majorities means there no room for defections – the aff derails negotiations

**Wong and Lillus 9/9** – Senior reporters at The Hill (Scott and Mike, “Democrats hit crunch time for passing Biden agenda,” *The Hill*, 9-9-21, [https://thehill.com/homenews/house/571418-democrats-hit-crunch-time-for-passing-biden-agenda](about:blank), Accessed 9-10-21, LASA-AH)

September is crunch time for Democrats racing to realize President Biden’s legacy-defining economic agenda. Over the next three weeks, House Democrats will be in a nonstop sprint to complete work on a sweeping $3.5 trillion reconciliation package that would dramatically expand America’s social safety net, revamp its tax and energy systems — and test the party’s unity one year before the high-stakes midterm elections. More than a dozen House committees are rushing to finish drafting and marking up key sections of the massive package so they can send them to the Budget Committee by the Sept. 15 deadline set by Speaker Nancy Pelosi (D-Calif.). She suggested Wednesday that the plan is on track. “Our committees are working feverishly and diligently,” Pelosi said in the Capitol. “And we will be ready to fulfill the president's vision.” They have their work cut out for them. Democrats are already facing fierce resistance from powerful business interests — particularly over proposed corporate tax hikes — as well as from Republicans who are unanimously opposed to wide-scale government expansion. Complicating their task, Democrats are operating with **razor-thin majorities in both chambers**, leaving virtually **no room for defections** even as the party’s ideological factions are sniping over the policy particulars, including whether to expand certain health care benefits through Medicare or ObamaCare. Pelosi said Wednesday that they’ll do both. “I think both will be present,” she said. House lawmakers return to Washington from their long summer recess on Sept. 20, and **leaders hope to bring the package to the floor by Sept. 27**, the date Pelosi promised moderates that she’d hold a vote on a separate, Senate-passed infrastructure bill. But that deadline could slip as key centrists and progressives begin to battle over the size and scope of the reconciliation proposal. Senate centrists — most vocally Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.) — have balked at both the $3.5 trillion price tag, vowing to demand cuts, and the speed with which the Democrats want to move the enormous package. Manchin has asked leaders to “hit the pause button,” a request they’ve readily dismissed. "We're moving full-speed ahead,” Senate Majority Leader Charles Schumer (D-N.Y.) said Wednesday. Pelosi allowed that the price tag might come down in talks with the Senate — "We will have our negotiations,” she said — but also stressed that the **House will stick with Biden’s $3.5 trillion figure initially.** “I don't know what the [final] number will be,” she said. “We are marking at $3.5 trillion, we're not going above that.” The timing could be crucial to the success of Biden’s agenda. Last month, Pelosi and her leadership team struck a deal with House moderates **guaranteeing a floor vote on the Senate’s $1.2 trillion infrastructure bill by Sept. 27**, while liberals are warning they’ll sink that bipartisan proposal without assurances that the larger reconciliation package will pass the Senate.

### Link – Backlash

#### Pharma backlashes to the Plan and will circumvent – they’re aggressive lobbyists and will do anything to preserve patent rights.

* Turns Case – Waters down the Plan due to lobbying
* Optional Card – still thinking on if its necessary [note from Elmer]

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### Democrat Senators in Big Pharma’s pocket derails the Plan.

Sirota 8-23 David Sirota 8-23-2021 "Dem Obstructionists Are Bankrolled By Pharma And Oil" <https://www.dailyposter.com/dem-obstructionists-are-bankrolled-by-pharma-and-oil/> (an American journalist, columnist at The Guardian, and editor for Jacobin. He is also a political commentator and radio host based in Denver. He is a nationally syndicated newspaper columnist, political spokesperson, and blogger)//Elmer

The **small group of conservative Democratic lawmakers** that has been **threatening to** help Republicans **halt** **Democrats’ budget package** have **raked in more than $3 million from donors in the pharmaceutical** and fossil fuel **industries** that could see reduced profits if the plan passes. As the House reconvenes today to tackle the budget reconciliation process, nine Democrats legislators have been promising to kill their party’s $3.5 trillion budget bill until Congress first passes a separate, smaller infrastructure spending measure, which has garnered some Republican support and which some environmental advocates say would exacerbate the climate crisis. Indeed, an ExxonMobil lobbyist was recently caught on tape saying the company had worked to strip climate measures out of the infrastructure bill. “**We will vote against a budget resolution** if the infrastructure package isn’t brought up first,” Democratic **Rep**. Josh **Gottheimer** **told** the Washington Post this weekend, **though** the American Prospect reported on Sunday that “**several**” of the **legislators** now **indicated they could back down**. **In the narrowly divided House**, **obstructionism from these** conservative Democrats **could decouple the infrastructure** and budget **measures** from one another. Many believe that would kill the latter by letting conservative Democrats in the Senate such as Kyrsten Sinema (D-Ariz.) and Joe Manchin (D-W.Va.) get the infrastructure bill they want without having to provide the votes necessary to enact the much larger and more progressive budget measure. “If we were to pass the bipartisan [infrastructure] bill first, then we lose leverage,” Democratic Rep. Ritchie Torres (NY) told the Wall Street Journal. Along with Gottheimer, the eight other Democrats who have threatened to obstruct the budget bill are Carolyn Bordeaux (Ga.), Ed Case (Hawaii), Jim Costa (Calif.), Henry Cuellar (Texas), Jared Golden (Maine), Vicente Gonzalez (Texas), Kurt Schrader (Ore.), and Filemon Vela (TX). The U.S. Chamber of Commerce — Washington’s most powerful corporate lobby group — has been airing digital ads thanking the nine Democrats for their maneuvers. Eight of the nine Democrats represent congressional districts won by President Joe Biden, who supports the reconciliation package. Big Pharma’s Big Allies The reconciliation bill is still being negotiated, and many Democratic lawmakers — including those in key swing districts — are pushing for it to include long-promised legislation to allow Medicare to use its enormous purchasing power to negotiate lower prices for prescription drugs. The **pharmaceutical industry** has **aggressively lobbied against the initiative**, which the Congressional Budget Office has estimated would save Medicare $345 billion in medicine costs. The nine House Democrats threatening to derail the reconciliation bill have raked in nearly $1.2 million from donors in the pharmaceutical and health products industries, according to data compiled by OpenSecrets. Among them are two of the Democratic Party’s **top recipients of health care industry money**: **Gottheimer** ($228,186) **and Schrader** ($614,830). Schrader’s third biggest career donor is Pfizer’s political action committee, and his former chief of staff is now a registered lobbyist for the Pharmaceutical Researchers and Manufacturers Association, the pharmaceutical industry’s main lobbying group. Both Gottheimer and Schrader signed a letter earlier this year slamming Democratic leaders’ legislation to lower prescription drug prices. Eight out of the nine Democrats threatening to kill the budget bill also declined to sponsor Democrats’ standalone legislation to let Medicare negotiate lower drug prices. In the Senate, Sinema’s renewed threat to vote down a final reconciliation bill came after she received $519,000 from donors in the pharmaceutical and health products industries.

### Impact – Warming

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much more is needed if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. The vehicle for these additional proposals would be a second infrastructure bill. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

## Case

#### Patent Waiver can’t solve trade secrets or infrastructure

**Rutschman et al 5/5** [Ana Santos Rutschman and Julia Barnes-Weise, Her legal scholarship has appeared or is forthcoming in UCLA Law Review, Emory Law Journal, Arizona Law Review, Yale Law Journal Forum, University of Chicago Legal Forum, Michigan Law Review Online, Annals of Health Law and Duke Law and Technology Review, among other, 5-5-2021, "The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal," Bill of Health, <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/> ]//AAli

As the toll of COVID-19 continues to increase in many countries in the Global South, there has been a renewed push to address the problem of vaccine scarcity through a waiver of patent rights. Calls for waivers have been recurring throughout the pandemic, from formal proposals introduced in 2020 by some of the larger developing economies (India and South Africa), to op-eds in mainstream media, and editorials in scientific publications, such as Nature. This push gained momentum in early May 2021, just before the meeting of the World Trade Organization’s General Council. Waiver proposals have attracted the support of prominent names in public health. Dr. Tedros Adhanom Ghebreyesus, the Director-General of the World Health Organization, endorsed patent waivers as a tool to address the current vaccine scarcity problem in an article titled Waive Covid Vaccine Patents to Put World on “War Footing.” Others — including, most recently, Dr. Anthony Fauci — have been critical of waiver proposals. In this piece, we explain the mechanics of patent waivers and argue that waivers alone are the wrong policy tool in the context of the COVID-19 pandemic. We agree with supporters of the waivers in their ultimate goal — that of scaling up the manufacturing of COVID-19 vaccines, and then distributing them according to more equitable models than the ones adopted thus far. However, we doubt that the particular types of goods at stake here can be easily replicated and produced in substantially larger quantities simply through a waiver of intellectual property rights. Vaccines and Intellectual Property: The Informational Function of Patents Intellectual property rights, and especially patent rights, are governmental grants embedded into national legal systems across the world for utilitarian reasons: longstanding intellectual property theory and policy rests on the idea that the prospect of obtaining a patent will incentivize players in research and development (R&D) to invest in areas that might be otherwise underfunded. While a vast body of research demonstrates that this utilitarian approach is not universally applicable to all types of goods (and especially to certain types of health goods), it remains the main driver of modern patent regimes. In exchange for getting this particular type of intellectual property rights, patentees disclose critical information about the invention covered by the patent. On the one hand, a patent gives the patentee lead time on the market for a relatively lengthy period of time (formally 20 years, in practice less than that, especially for products like vaccines that must undergo review and approval by drug regulators). On the other hand, by requiring that the patent applicant share information about the invention that is subsequently published by the patent office, the patent system promotes the flow of scientific and technical information that can be used by other innovators in the field. It is well known by now that existing COVID-19 vaccines — including the ones that represent the application of a new type of vaccine technology, mRNA vaccines — are covered by multiple layers of patent rights. Proponents of a patent waiver for COVID-19 vaccine emphasize the problems created by the exclusivity created by intellectual property rights, and they are correct in their diagnosis. Having adopted a legal regime that grants patent rights to any inventions meeting the substantive criteria set forth in international and national patent laws (a threshold that many of the current patent applications on COVID-19 will, in all likelihood, clear), we now face the logical consequences of such a regime: absent some kind of intervention, vaccine patent holders have the ability to refuse licensing their technology to others, even against a backdrop of vaccine scarcity. A waiver is thus portrayed as a mechanism to overcome this exclusionary ability that traditionally inheres to a patent: in light of the tragic proportions of our shared public health problem, let us do away with the exclusionary right for a certain period of time and other companies will be able to 1) replicate existing vaccines and 2) manufacture at scale so that considerably more doses of vaccine will start flowing towards populations in the Global South. These two propositions would be accurate if the information disclosed in patents were enough to increase the supply of COVID-19 vaccines. Unfortunately, it is not. A Mismatch Problem: The Informational Limitations of Patents Patents cover both processes and products. In the case of vaccines, the former category includes methods of vaccine production, while the latter covers a myriad of vaccine components, from antigens (substances used to elicit a reaction from the immune system), to inactive ingredients, such as adjuvants (substances that help enhance the immune response, like oil-in-water emulsions) and stabilizers (substances that help maintain the potency of the vaccine, like sugars), to the vaccine delivery mechanism. In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem. First, we are still left with a significant informational problem: as many commentators have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine. From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere. Second, even if all types of legal restrictions on the use of vaccine technology were lifted — or had never existed in the first place — there is simply not enough infrastructure (manufacturing facilities and equipment) nor raw materials (the components needed to manufacture and deliver vaccines) to produce and distribute COVID-19 vaccines as predicted under current waiver proposals. We have long faced a global vaccine manufacturing problem that will not be fully resolved during the current pandemic. In the case of vaccines that need to be kept at ultra-cold temperatures, these problems intensify. One of us (Barnes-Weise) has been involved in the contractual negotiations for the development, manufacturing and transfer of technology related to COVID-19 vaccines. In addition to the informational gaps described above, COVID-19 vaccine manufacturers are most concerned about how well the recipients of the technology transfer will understand and be able to implement such knowledge in making vaccines of the necessary quality. Shortages do not merely affect materials necessary to manufacture vaccines and facilities adequate to manufacture the vaccines; they also affect the availability of personnel qualified to instruct the licensee and recipient of this information. Sending an employee of this caliber out of the original manufacturing site to a partner site risks reducing the capacity of the first site. And remote instruction, necessitated by the pandemic, has its own shortcomings. In relation to the patents on the vaccines themselves, most of the concerns that the vaccine manufacturers express are around the protection of their vaccine platforms for the purposes of making future or non-COVID-19 vaccines. Moderna shared information about its patents in summer 2020. The manufacturers, as evidenced by the number of licenses to manufacture granted to date, are eager to find partners with the capabilities to expand production. It is not to their benefit to produce an inadequate supply of a highly sought-after vaccine. However, even willingness to transfer patented vaccine technology has faced numerous practical hurdles to date: 1) infrastructural limitations; 2) scarcity of raw materials; 3) concerns about licensees having the ability to actually manufacture effective vaccines in light of the infrastructural and product scarcity, even in situations in which there might be no informational gaps. A patent waiver would not address any of the practical concerns currently at the root of tech transfer negotiations involving COVID-19 vaccine technology. Compounding these problems is the fact that, should a waiver be issued, there is no legal mechanism that can compel the transfer of certain types of know-how or trade secrets should a company be unwilling to license its intellectual property — which, again, at this point in the pandemic, is not a problem we have observed. Finally, it is important to keep in mind that a waiver would be temporary: supporters of current waiver proposals should consider what will happen once demand for vaccines begins diminishing and fewer manufacturers remain on the market. Moreover, they should consider the legal and practical uncertainty that a waiver would introduce, as it is unclear how technology transfer between companies would cease (or continue) once the waiver expires

#### Waiving IPR does nothing; bottleneck is the real problem

Stephen **Ezell 3/9** https://itif.org/publications/2021/03/09/trips-waiver-covid-19-ip-rights-wouldnt-help-vaccine-access(Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.) [AB]

**In the face of a COVID-19 pandemic that has caused** [**2.6 million fatalities**](https://news.google.com/covid19/map?hl=en-US&mid=%2Fm%2F02j71&gl=US&ceid=US%3Aen) **worldwide, life-sciences companies have raced to bring forward a wide range of life-saving innovations,** including novel diagnostic tests like Lumira DX’s that can detect the virus within minutes; therapeutics such as Gilead’s remdesivir; and highly effective vaccines such as those from Moderna, Pfizer, and Johnson & Johnson. In fact, over 600 novel COVID-19 treatments are [under development](https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap), including 130 vaccines in global clinical trials and 176 in pre-clinical trials. **Yet, amidst this unprecedented pace of innovation, some 90 developing nations, led by India and South Africa, have petitioned the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council calling for a** [**waiver**](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True) **to suspend all intellectual property rights (IPR) associated with COVID-19 innovations, again asserting the false narrative that IP rights inhibit access to medicines.** The waiver petition itself suggests the various fallacies underlying the request. First, the waiver (initially submitted on October 2, 2020) acknowledges that, “To date, there is no vaccine or medicine to effectively prevent or treat COVID-19.” **This admission immediately confirms that intellectual property rights are not and have never been the challenge in the COVID-19 pandemic.** Rather, the challenge initially was the very lack of intellectual property; we had to, and did, discover and invent the scientific and technical knowledge necessary to understand the operation of the virus and how to defeat it with novel vaccines and therapeutics. Much of this involved new-to-the world technologies, such as novel mRNA-based vaccines. Far from being an inhibitor of this process, the robust intellectual property regimes in place in many nations contributed to a body of biomedical knowledge and technologies that provided a crucial platform for the innovation of COVID-19 solutions. Second, the [waiver](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True) petition vaguely references “several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients.” The [first](https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots) of two cited instances pertained to Labrador Diagnostic LLC, a patent-licensing firm which—although it did file a suit against a French firm, bioMerieux SA, developing coronavirus tests, in order to ensure that its IP was not infringed—has actually committed to offering its patents royalty-free to any company developing coronavirus tests. The second instance referenced Kentucky Governor Andy Beshear’s [call](https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/) for 3M to release a patent on N95 respirators. But that was it; on those two incredibly thin reeds, with nary any serious evidence whatsoever that IP rights were inhibiting access to COVID-19 treatments—let alone the fact that no COVID-19 vaccines existed at the time—the petitioners took the radical step to call for a suspension of all IPR rights pertinent to COVID-19 technologies throughout the duration of the pandemic. And while petitioners made this call on the alleged grounds of ensuring sufficient access to needed vaccines and therapeutics, their call for the suspension of every facet of IP rights on every conceivable COVID-19 related technology—even such as for copyrights and industrial designs—betrays the reality that the petitioners’ core goal isn’t really about access, but about undermining the global intellectual property rights system. To be sure, the developed world needs to be fully committed to ensuring that the world’s citizens receive the COVID-19 vaccines and therapeutics they need. But this can be accomplished through structures such as licensing and product development partnerships, without requiring an abrogation of intellectual property rights. For instance, in February 2021, the Biden administration announced it would [contribute](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort) up to $4 billion to COVAX, a vaccine alliance seeking to distribute COVID-19 vaccines to 92 low- and middle-income countries. COVAX aims to deliver at least 2 billion vaccine doses by the end of 2021, covering at least 20 percent of the most vulnerable citizens in poor- and middle-income countries. I**nnovative life-sciences companies have entered into a number of licensing agreements to facilitate dramatically expanded manufacturing of COVID-19 vaccines and therapeutics. For instance, Gilead Sciences has licensed its therapeutic remdesivir royalty-free to** [**nine generic drug manufacturers**](https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir)**, in Egypt, India, and Pakistan. AstraZeneca reached a licensing and technology transfer agreement enabling** [**India’s Serum Institute**](https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html) **to manufacture one billion vaccine doses for low- and middle-income countries. The Serum Institute has further** [**entered into manufacturing licenses**](https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/) **with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers.** Johnson and Johnson has announced plans to allocate up to [500 million vaccine doses](https://www.jnj.com/latest-news/johnson-johnson-signs-communique-on-expanded-global-access-for-covid-19-vaccines) to lower-income countries, with delivery starting by mid-2021. Companies like Johnson & Johnson are making the vast majority of these vaccine doses available on a not-for-profit basis. **Thus, the fundamental problem isn’t high prices due to IP rights; it’s dramatically scaling up manufacturing capacity. It takes** [**60 to 110 days**](https://www.cbsnews.com/news/covid-vaccine-johnson-and-johnson-factory/) **to produce one batch of COVID-19 vaccine.** When Serum Institute CEO Adam Poonawalla [was asked](https://www.theguardian.com/global-development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jabs-than-anyone) if vaccine rollout was slowed because vaccine patentholders were licensing too few manufacturers to make them, he responded, **“No. There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” Poonawalla actually cited the lack of global regulatory harmonization as a far greater cause of delays in the vaccine rollout. Even Médecins Sans Frontières’ Rose Scourze acknowledged (in a January 20, 2021 *BBC* interview) that suspending patent rights “wouldn’t produce millions of more vaccines.”** Instead of forcing the disclosure of IP, policymakers should encourage the use of voluntary licensing agreements to expand production of the needed COVID-19 vaccines and therapeutics. One reason this critically matters is to ensure consistency and safety in the production of these treatments. The mRNA-based vaccines developed by Moderna and Pfizer are [incredibly complex biologic products](https://itif.org/publications/2021/01/28/covid-19-vaccines-are-even-bigger-story-you-think) that require specialized experience, expertise, and equipment to manufacture. For example, mRNA vaccines require a complicated technique known as “bioprocess” that requires specialty bioreactors to first manufacture DNA that codes for the desired mRNA sequence, and then uses a second bioprocess to create billions of identical mRNA segments. These are then wrapped in a nanolipid wrapper using yet another very specialized fluidics and mixing process, and for which there are only three facilities in the world that can execute the step of creating the liquid capsule around the RNA. Instead of simply being forced to divulge their IP or see it be compulsorily licensed to other manufacturers, in light of the extreme complexity of manufacturing COVID-19 vaccines and therapeutics, companies should have the right to evaluate potential license partners and ensure that they can meet the production standards required to safely and reliably produce COVID-19 vaccines or treatments before entering into license arrangements with them. **Indeed, this is critical for it would be disastrous if defective vaccines or therapeutics were produced at facilities not properly equipped to produce such complex treatments. As Phil Stevens and Mark Schultz** [**have written**](https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/)**, there’s simply no evidence that invalidating IP rights would achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries such as India and Brazil.** Instead of rolling back intellectual property rights, policymakers in developed and developing nations alike should focus on mechanisms to scale up production of vaccines and make them affordably available to citizens in developing countries. But to achieve that, there is simply no compelling reason for a blanket suspension of the intellectual property rights associated with COVID-19 products and technologies. For this reason, the Biden administration should continue the previous administration’s stance of opposing the waiver at the WTO TRIPS council, where deliberations resume on March 10, and reject [calls from some in Congress](https://news.bloomberglaw.com/health-law-and-business/democratic-lawmaker-pushes-biden-to-back-vaccine-patent-waiver) to endorse the proposed TRIPS waiver.

#### Top Level Framing to all of their arguments – COVID thumps – if their impacts are true, then they should have already happened. The fact that they didn’t should make you highly skeptical – we’ll contextualize this

#### Our innovation da turns their war scenario, more covid won’t lead to war, Chinese heg will. Also no solvency on this because if covid is so bad to cause war itll happen regardless of the plan

#### No Bioterror impact

Marc-Michael **Blum 20**, 6-22-2020, Marc-Michael Blum is a former Head of Laboratory at the Organization for the Prohibition of Chemical Weapons. He holds a PhD in Biochemistry from the University of Frankfurt, "Corona and Bioterrorism: How Serious Is the Threat? ," War on the Rocks, <https://warontherocks.com/2020/06/corona-and-bioterrorism-how-serious-is-the-threat/> ]//AAli

* empirics: no one has ever died
* requires experience, prevent spread to terrorists, weather

The novel coronavirus pandemic has put the threat of bioterrorism back in the spotlight. White supremacist chat rooms are teeming with talk about “biological warfare.” ISIL even called the virus “one of Allah’s soldiers” because of its devastating effect on Western countries. According to a recent memo by the U.S. Department of Homeland Security, terrorists are “[making] bioterrorism a popular topic among themselves.” Both the United Nations and the Council of Europe have warned of bioterrorist attacks. How serious is the threat? There is a long history of terrorists being fascinated by biological weapons, but it is also one of failures. For the vast majority, the technical challenges associated with weaponizing biological agents have proven insurmountable. The only reason this could change is if terrorists were to receive support from a state. Rather than panic about terrorists engaging in biological warfare, governments should be vigilant, secure their own facilities, and focus on strengthening international diplomacy. A History of Failures Biological warfare, which uses organisms and pathogens to cause disease, is nearly as old as war itself. The first known use of biological agents as a weapon dates back to 600 B.C., when an ancient Greek leader poisoned his enemies’ water supply. Throughout the Middle Ages, especially during the time of the Black Death, it was common to hurl infected corpses into besieged cities. And during the two world wars, all major powers maintained biological weapons programs (although only Japan used them in combat). Among terrorists, however, the use of biological weapons has been rarer, although groups from nearly all ideological persuasions have contemplated it. Recent examples include a plot to contaminate Chicago’s water supply in the 1970s; food poisoning by a religious cult in Oregon in the 1980s; and the stockpiling of ricin by members of the Minnesota Patriot Council during the 1990s. No one died in any of these instances. The same is true for the biological warfare programs of al-Qaeda and the Islamic State group. Both groups have sought to buy, steal, or develop biological agents. For al-Qaeda, this seems to have been a priority in the 1990s, when its program was overseen by (then) deputy leader Ayman al-Zawahiri, a trained physician. With the Islamic State, evidence dates back to 2014, when Iraqi forces discovered thousands of files related to biological warfare on a detainee’s laptop. Yet none of these efforts succeeded. The only al-Qaeda plot in which bioterrorism featured prominently — the so-called “ricin plot” in England in 2002 — was interrupted at such an early stage that none of the toxin had actually been produced. The Islamic State’s most serious attempt, in 2017, involved a small amount of ricin, whose only fatality was the hamster on which it was tested. Of the tens of thousands of people that jihadists have murdered, not a single one has died from biological agents. It may be no accident that the most lethal bioterrorist attack in recent decades was perpetrated by a scientist and government employee. In late 2001, the offices of several U.S. senators and news organizations received so-called “anthrax letters,” which killed five people and injured 17. Following years of investigation, the FBI identified the sender as Bruce Ivins, a PhD microbiologist and senior researcher at the U.S. Army’s Medical Research Institute of Infectious Diseases. Unlike the others, he was no amateur or hoaxer, but a trained expert with years of experience and full access to the world’s largest repository of lethal biological agents. Technical Challenges Ivins’ case helps to explain why so many would-be bioterrorists have failed. At a technical level, launching a sophisticated, large-scale bioterrorist attack involves a toxin or a pathogen — generally a bacterium or a virus — which needs to be isolated and disseminated. But this is more difficult than it seems. As well as advanced training in biology or chemistry, isolating the agent requires significant experience. It also has to be done in a safe, contained environment, to stop it from spreading within the terrorist group. Contrary to what al-Qaeda said in one of its online magazines, you can’t just make a (biological) weapon “in the kitchen of your mom!” In addition, there is the challenge of dissemination. Unless the agent is super-contagious, a powerful biological attack relies on a large number of initial infections in perfect conditions. In the case of the bacterium anthrax, for example, only spores of a particular size are likely to be effective in certain kinds of weather. State-sponsored programs often needed years of testing and experimentation to understand how their weapons could be used. Though not impossible, it is unlikely that terrorist groups possess the resources, stable environment, and patience to do likewise. Doomsday Scenarios Even if terrorists somehow succeeded, it is nearly inconceivable that the resulting “weapon” would be as powerful as the recent coronavirus, SARS-CoV-2. One of its uniquely devastating features has been that people are infectious while experiencing no symptoms. As it spread across the globe, there was no treatment, no vaccine, an incomplete understanding of its pathological modes of action, and no easy, cheap and widely available testing. It was the viral equivalent of a “zero-day exploit” — a cyber-attack that happens before any patch is available. None of the viruses on the U.S. Centers for Disease Control and Prevention’s list of the most dangerous biological agents could be easily “weaponized” or would have the same, devastating effects as SARS-CoV-2. Pathogenic viruses such as smallpox, Ebola, Marburg, and Lassa are extremely hard to find, isolate, and spread. Botulinum and ricin are dangerous toxins, but not contagious, while Tularemia cannot be transmitted from human to human. The plague is, of course, capable of causing pandemics, but most countries are nowadays well prepared for this particular virus, and will be able to limit — and cope with — localized outbreaks. This leaves only anthrax, a soil bacterium which is relatively easy to obtain. Even so, isolating a highly pathogenic strain is difficult. More importantly, anthrax is not contagious, and while its spores are durable and affected areas can be hard to de-contaminate, it is unable to spread on its own. Regarding SARS-CoV-2, it is important to distinguish between the possibility that the virus occurred naturally and escaped from a laboratory, and the idea that it was engineered for maximum infectiousness and deliberately released. The first remains a possibility, although other explanations are equally — if not more — plausible, while the second has been debunked by a comprehensive examination in the journal Nature Medicine, which concluded that SARS-CoV-2 was “not a laboratory construct or a purposefully manipulated virus.” The chances that terrorists would be capable of engineering a virus such as SARS-CoV-2 without access to a state’s resources are virtually zero. If anything, the possibility of a lab escape — however remote — highlights the importance of biosafety. While governments have paid much attention to laboratories with the highest biosafety level (level 4), work on bat-born coronaviruses is regularly performed at lower levels (level 3, and even level 2), and should instead be subject to similar safety requirements. In sum, small-scale attacks using anthrax or other agents may be possible, but the risk of a highly advanced, weaponized pathogen that spreads among large populations — a terrorist-initiated biological doomsday — is very low. The only exception, of course, is if terrorists received support from a state, acted as its proxies, or were able to draw on its resources — as in Ivins’ case. A Preventable Catastrophe It seems clear, therefore, that governments’ priority should be to limit the potential for states and terrorist groups to cooperate, because it is only through states that terrorists are likely to obtain a significant bio-terrorist capability. In practical terms, this means developing intelligence capabilities, securing facilities, and making sure that government scientists — especially those working with high-risk pathogens — are regularly vetted. Biosecurity also requires well-funded and functioning public health systems, which limit the potential consequences of any attack. Not least, countering bioterrorism involves strengthening diplomacy. The Biological Weapons Convention, which has been in effect since 1975, is a powerful international norm, but continues to lack both an implementing organization and a verification mechanism. In their absence, governments should push for bi- and multilateral agreements, the full implementation of UN Security Council Resolution 1540 (which calls on all states to refrain from supporting any nonstate actor seeking nuclear, chemical, or biological weapons), capacity-building programs, and the creative use of existing tools. This includes the Chemical Weapons Convention, which already deals with ricin and saxitoxin, but could be used to regulate other high-risk toxins as well. If governments take it seriously — and act strategically — bioterrorism is a catastrophe that never needs to happen.

#### Empirically denied. The worst case scenario happened… four times.

Dove 12

<Alan Dove, PhD in Microbiology, science journalist and former Adjunct Professor at New York University, “Who’s Afraid of the Big, Bad Bioterrorist?” Jan 24 2012, http://alandove.com/content/2012/01/whos-afraid-of-the-big-bad-bioterrorist/>

The second problem is much more serious. Eliminating the toxins, we’re left with a list of infectious bacteria and viruses. With a single exception, these organisms are probably near-useless as weapons, and history proves it. There have been at least three well-documented military-style deployments of infectious agents from the list, plus one deployment of an agent that’s not on the list. I’m focusing entirely on the modern era, by the way. There are historical reports of armies catapulting plague-ridden corpses over city walls and conquistadors trying to inoculate blankets with Variola (smallpox), but it’s not clear those “attacks” were effective. Those diseases tended to spread like, well, plagues, so there’s no telling whether the targets really caught the diseases from the bodies and blankets, or simply picked them up through casual contact with their enemies. Of the four modern biowarfare incidents, two have been fatal. The first was the 1979 Sverdlovsk anthrax incident, which killed an estimated 100 people. In that case, a Soviet-built biological weapons lab accidentally released a large plume of weaponized Bacillus anthracis (anthrax) over a major city. Soviet authorities tried to blame the resulting fatalities on “bad meat,” but in the 1990s Western investigators were finally able to piece together the real story. The second fatal incident also involved anthrax from a government-run lab: the 2001 “Amerithrax” attacks. That time, a rogue employee (or perhaps employees) of the government’s main bioweapons lab sent weaponized, powdered anthrax through the US postal service. Five people died. That gives us a grand total of around 105 deaths, entirely from agents that were grown and weaponized in officially-sanctioned and funded bioweapons research labs. Remember that. Terrorist groups have also deployed biological weapons twice, and these cases are very instructive. The first was the 1984 Rajneeshee bioterror attack, in which members of a cult in Oregon inoculated restaurant salad bars with Salmonella bacteria (an agent that’s not on the “select” list). 751 people got sick, but nobody died. Public health authorities handled it as a conventional foodborne Salmonella outbreak, identified the sources and contained them. Nobody even would have known it was a deliberate attack if a member of the cult hadn’t come forward afterward with a confession. Lesson: our existing public health infrastructure was entirely adequate to respond to a major bioterrorist attack. The second genuine bioterrorist attack took place in 1993. Members of the Aum Shinrikyo cult successfully isolated and grew a large stock of anthrax bacteria, then sprayed it as an aerosol from the roof of a building in downtown Tokyo. The cult was well-financed, and had many highly educated members, so this release over the world’s largest city really represented a worst-case scenario. Nobody got sick or died. From the cult’s perspective, it was a complete and utter failure. Again, the only reason we even found out about it was a post-hoc confession. Aum members later demonstrated their lab skills by producing Sarin nerve gas, with far deadlier results. Lesson: one of the top “select agents” is extremely hard to grow and deploy even for relatively skilled non-state groups. It’s a really crappy bioterrorist weapon. Taken together, these events point to an uncomfortable but inevitable conclusion: our biodefense industry is a far greater threat to us than any actual bioterrorists.

#### No link on India, their first card is talking about the US not India, don’t let them conflate the two

#### We turn the India impact

#### India’s COVID crisis killed Modi’s appetite for international adventurism, but increasing vaccine production reverses the trend.

Singh ’21 (Sushant; senior fellow with the Centre for Policy Research in India; 5-3-2021; “The End of Modi’s Global Dreams”; Foreign Policy; https://foreignpolicy.com/2021/05/03/india-vishwaguru-modi-second-wave-soft-power-self-sufficiency/; Accessed: 8-27-2021)

India’s prime minister advanced a **muscular foreign policy**, but his mishandling of the pandemic is an **embarrassing step back**. In December 2004, when an earthquake and tsunami struck Asia, then-Indian Prime Minister Manmohan Singh decided it was high time for India to stop accepting aid from other countries to deal with disasters and rely on itself instead. “We feel that we can cope with the situation on our own,” he said, “and we will take their help if needed.” It was a pointed political statement about India’s growing economic heft, and it wasn’t the last. Singh’s government offered aid to the United States in the wake of Hurricane Katrina in 2005 and to China after the 2008 Sichuan earthquake. Seen as a matter of national pride, an indicator of self-sufficiency, and a snub to nosy aid givers, the practice continued under Indian Prime Minister Narendra Modi despite pressure to change course during floods in the southern state of Kerala in 2018. Modi, who has consistently campaigned on **virulent nationalism** captured by the slogan “Atmanirbhar Bharat” (or self-reliant India), has been forced to abruptly change policy. Last week, with images of people dying on roads without oxygen and crematoriums for pet dogs being used for humans’ last rites as the second wave of the COVID-19 pandemic overwhelmed the country, his government accepted offers of help from nearly 40 other nations. Its diplomats have lobbied with foreign governments for oxygen plants and tankers, the arrival of medicines, and other supplies hailed on social media. “We have given assistance; we are getting assistance,” said Harsh Vardhan Shringla, the country’s top diplomat, to justify the embarrassing U-turn. “It shows an interdependent world. It shows a world that is working with each other.” The world may be working with each other, but it is not working for Modi in the **realm of foreign policy**. Rather, this is a moment of reckoning, triggered by the rampaging coronavirus. After seven years as prime minister, Modi’s **hyper-nationalistic** domestic agenda—including his ambition of making the country a “Vishwaguru” (or **master to the world**)—now lies in tatters. India, which has been envisaged since former U.S. President Donald Trump’s administration became the Quadrilateral Security Dialogue’s lynchpin and focused other efforts in the Indo-Pacific strategy to counter China, will have to work harder to justify that role. Meanwhile, China has redoubled its efforts in India’s neighborhood since the second wave began, strengthening its existing ties with South Asian countries and contrasting its strength and reliability with India’s limitations. No doubt, New Delhi will be able to regain a certain sense of normalcy in a few months, but the **mishandling of the pandemic** has dealt it a weaker hand in **ongoing backchannel talks with Islamabad** and border negotiations with Beijing. But even **longer-lasting damage** has been done to India’s soft power, which was already dented under Modi’s authoritarian regime. This is a big problem for the government as it was soft power that allowed New Delhi to assert itself for a seat at the global high table to begin with. Front page images and video clips of constantly burning pyres and dying patients may recede from the foreground with time, but rebuilding India’s diplomatic heft and geopolitical prominence will need more than the passage of months and years. It will take a concerted effort, and S. Jaishankar, Modi’s chosen man to be India’s foreign minister, has so far appeared unequal to the task. In March, when the second wave of the pandemic started unfolding in India, Jaishankar’s ministry was busy issuing official statements and organizing social media storms against popstar Rihanna and climate change activist Greta Thunberg. On Thursday, at the peak of the health crisis, Jaishankar’s focus in a meeting with all the Indian ambassadors to various global capitals was on countering the so-called “one-sided” narrative in international media, which said Modi’s government had failed the country by its “incompetent” handling of the second pandemic wave. Until recently, Jaishankar was also the most enthusiastic promoter of the government’s Vaccine Maitri (or “Vaccine Friendship”) program, under which New Delhi supplied around 66.4 million doses of the India-made AstraZeneca vaccine to 95 countries in packing boxes marked prominently with large pictures of Modi. These vaccines were either commercially contracted, given as bilateral grants, or transferred under the World Health Organization’s COVID-19 Vaccines Global Access (COVAX) scheme for poorer countries. Meanwhile, India’s own vaccination rollout has been **dismal**. Around 2 percent of Indians have been fully vaccinated, despite the country being the world’s biggest vaccine manufacturer—a misstep that has emerged as one of the key culprits for India’s uncontrolled second wave. Having exported doses in a quest for personal glory, Modi is now awaiting 20 million doses of AstraZeneca vaccines from the United States after abruptly reversing 16 years of policy, as indicated in its disaster management documents, against **accepting bilateral aid**. It is bad enough that India is getting help from traditional partners like the United States and Russia, but it is also accepting supplies coming from China, with which India’s relationship has been increasingly strained under Modi. And it must have been particularly galling to the prime minister that **even Pakistan** made an offer to help with medical supplies and equipment. So woeful is India’s situation that it has started importing 88,000 pounds of medical oxygen daily from the tiny Himalayan kingdom of Bhutan. Most Indians acknowledge their country was in an economic recession last year, and accepting bilateral aid is more of a compulsion than a choice. But how will they reconcile that with the fact that work on a $2 billion project to reconstruct a government office complex in the national capital, including building a new residence for Modi, continues unabated as an “essential service” during the pandemic? Modi boasted of having made India a **Vishwaguru** and personally enhancing national prestige through his numerous global trips. His ultranationalist supporters had started assuming India was already a **global power** in the same league as the United States and China. This feeling tied in with his domestic political positioning. Hindutva, or homogenized Hindu nationalism, was offered as the ideology that had made this supremacy possible. But now Modi’s supporters find their dreams of a **global power shattered.** They must instead confront the harsh reality of being citizens of a so-called “third world country,” which is dependent once again on the largesse of others. As the Indian economy continues to be hammered by the pandemic, there is little Modi can offer economically to his base. The edifice of **nationalist** pride, prestige, and **global respect** built by Modi on his so-called foreign-policy prowess has been demolished by the pandemic. The pandemic has hurt India in other ways too. Australia, a member of the Quadrilateral Security Dialogue (or Quad), has imposed a ban on its citizens from returning home, threatening five-year prison sentences, if they have spent time in India. In its first leaders’ summit in March, the grouping decided to provide a billion doses of the COVID-19 vaccine to the Indo-Pacific region by 2022. The vaccines were to be produced in India, funded by the United States and Japan, and distributed by Australia, in what was seen as the showpiece initiative to move the Quad away from its security-centric approach and soften its reputation as an anti-China grouping. With India struggling to produce vaccines for its own citizens hit by the pandemic, it is unlikely the Quad will be able to keep its scheme on schedule. In the bargain, New Delhi’s position as the lynchpin of the Quad stands considerably diminished. If India stumbles, the American dream of the Quad can never become a reality. Beijing has already moved in to take advantage of India’s misfortune to strengthen its ties with other South Asian countries. Last Tuesday, the Chinese foreign minister held a meeting with his counterparts from Afghanistan, Bangladesh, Nepal, Pakistan, and Sri Lanka for cooperation against COVID-19. India was absent from the meeting. And although Afghanistan, Bangladesh, Nepal, and Sri Lanka have received some vaccine supplies from India and expect more, these countries are now looking toward Beijing for doses after New Delhi failed to keep up its commercial and COVAX commitments. In the race between the two Asian giants to be an attractive and reliable partner in South Asia, India seems to have finished behind China. China has also pressed its advantage along its restive border with India. After an initial disengagement in Ladakh, India, China refused to pull back any further from other Indian-held territories it had moved into last summer. It stonewalled Indian attempts to discuss these areas in the last round of talks between the two sides, and it has constructed permanent military infrastructure and deployed troops close to the disputed border. If there were ever a time for India to demonstrate its strength, it would be now. But the second wave of COVID-19 has forced **the opposite**. A similar impact will be felt during New Delhi’s ongoing backchannel talks with Islamabad, where Pakistan will likely try to take **full advantage** of any **chinks in India’s armor**. India cannot afford to walk away from those talks as it has already been forced to engage with Islamabad due to its own inability to handle a two-front threat from China and Pakistan. An economy and a country ravaged by the pandemic makes the dual threat an even more **challenging proposition** for India—and hands Pakistan an unexpected advantage in the talks.