## 1NC

### 1NC – T

#### Interpretation: The aff must defend that member nations reduce intellectual property protections for all medicines

#### Violation: They specify medicines for novel pandemics

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

#### Vote negative:

#### 1] Precision – they justify arbitrarily mooting words in the resolution at their own whim in order to justify some potentially good interp.

#### Semantics outweighs:

#### [a] Lexical priority – it doesn’t matter if their interp if the debate is not pertinent i.e. it might me more educational for me to study for AP physics, outweighs since the topic constrains what pragmatics are relevant.

#### 2] Limits and ground – their model allows affs to defend any medicine which explodes neg prep bc theres an infinite amount I can’t prepare for, like covid-19 vaccines, influenza, common colds, Marijuana, etc. and they all bracket out different DA’s

#### 3] TVA: Read a whole res aff with the same advantage

### 1NC – CP

#### CP Text: Vaccine developers should enter into binding contractual agreements with generic producers to ensure the quality of generic products and establish royalty rates on generic sales. The member nations of the WTO should publicly declare their support of legitimate compulsory licensees in the cases where voluntary requests have been ignored.

Silverman 3/15 [Rachel Silverman is a policy fellow at the Center for Global Development where she leads policy-oriented research on global health financing and incentive structures. Silverman’s current research focuses on the practical application of results-based financing; global health transitions; efficient global health procurement; innovation models for global health; priority-setting for UHC; alignment and impact in international funding for family planning; and strategies to strengthen evidence and accountability. BA with distinction in international relations and economics from Stanford University.) “Waiving vaccine patents won’t help inoculate poorer nations” Washington Post, PostEverything Perspective, <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/>] RM

There are better options than broadly waiving IP rules — notably, encouraging (and pressuring) vaccine manufacturers to cooperate and share knowledge with partners across the globe. Voluntary licensing is one route: It’s a common arrangement in which developers enter into binding contractual agreements with generic producers. Generic manufacturers get permission, know-how and assistance from the patent-holder to produce the vaccine for sales in specified markets; in exchange, the patent-holder can ensure quality of the generic product and may receive royalties on its sales, usually representing less than 10 percent of sales value.

These royalties may be lower than the profit margin on direct sales; for example, Pfizer expects a 25 to 30 percent profit on its vaccine sales, or roughly $5 for every $19.50 dose. (The U.S. government has agreed to buy 300 million doses at that price.) But voluntary licensing deals offer a new revenue stream that would otherwise be captured by competitors — not to mention good publicity. Already, **voluntary licensing deals from AstraZeneca and Novavax are facilitating large-scale production in India, Japan and South Korea**; many of the resulting vaccines are destined for lower-income countries through Covax.

The best route to vaccine equity involves creating the conditions to facilitate more of these voluntary deals.

How can governments and activists help push things in the right direction? By lifting the export curbs on materials such as filters and bioreactor bags intended to protect domestic supply, countries can help lubricate supply chains, creating a better environment for cross-national collaboration. Governments and development-finance institutions can invest to build up the capabilities of potential vaccine manufacturing plants, making it easier for originators to say yes. Domestically, the Biden administration did something like this when it [invested](https://www.merck.com/news/merck-to-help-produce-johnson-barda-to-provide-merck-with-funding-to-expand-mercks-manufacturing-capacity-for-covid-19-vaccines-and-medicines/) $269 million under the Defense Production Act to prepare Merck’s manufacturing facilities to produce the Johnson & Johnson vaccine — a crucial plank of the [joint production deal](https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html) announced this month. Similar efforts are underway abroad. On March 12, for example, the “Quad” — the United States, India, Japan and Australia — [announced](https://www.reuters.com/article/us-usa-asia/u-s-india-japan-and-australia-counter-china-with-billion-dose-vaccine-pact-idUSKBN2B40IP) a joint pledge to produce and disseminate 1 billion vaccine doses; as part of this effort, the Biden administration [announced](https://in.usembassy.gov/dfc-announces-support-for-manufacturing-of-vaccines-during-quad-summit/) that it would help finance an Indian generic manufacturer to make coronavirus vaccines, including the Johnson & Johnson product. The contractual language of licensing deals can explicitly protect IP from broader dissemination, helping originators feel more comfortable sharing commercially valuable information.

Sticks as well as carrots can facilitate partnerships. Under [existing World Trade Organization rules](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm), countries already have the right to issue “compulsory licenses” in certain cases pertaining to public health, allowing them to produce or import generic health products without permission from the patent-holder. Advocates correctly point out that countries face potential retaliation from industry and wealthy governments when they try to use these tools — a strong disincentive. (In 2006-2007, Thailand’s use of compulsory licenses to access more affordable AIDS drugs led the United States to revoke preferential trade status for some Thai exports.) This should change. The Biden administration and other global leaders should make clear that they will support legitimate compulsory licensees of coronavirus vaccines in cases where a valid voluntary license request has been rejected or ignored.

**But compulsory licensing is vastly inferior to voluntary deals in the case of vaccines, because with the former the generic producer would still need to figure out how to make the vaccines without the originator’s assistance — again, an extraordinarily difficult task.** It is useful mainly as a threat held in reserve, paired with the “carrots” of subsidies to local plants and so on. **Firms may choose to play ball on voluntary licensing deals rather than face a mess of legal challenges and bad publicity.** This month, for example, Canadian biotech firm Biolyse Pharma publicly requested a voluntary license to manufacture the Johnson & Johnson vaccine for global distribution. If Johnson & Johnson is unwilling, Biolyse made clear in its announcement, the company will appeal to the Canadian government for a compulsory license. The ball is now in Johnson & Johnson’s court — but this seems like the type of offer it should choose to accept, **both for the global good and its self-interest**.

Scaling up vaccine production is an imperative for equitable global access and an end to the pandemic**. But it is smart incentives for sharing knowledge, not the wholesale elimination of intellectual-property rights, that will get us to the finish line.**

### 1NC – DA

#### 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.

#### 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.

#### China biotech heg causes a laundry list of impacts

Moore 19 Scott Moore - Director of the Penn Global China Program at the University of Pennsylvania, Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S. Department of State, Giorgio Ruffolo Post-Doctoral Research Fellow with the Belfer Center for Science and International Affairs at Harvard University, Truman, Fulbright, and Rhodes Scholar., Foreign Policy, "China's Genetic Experiments Are Pushing Ethical Limits", NOVEMBER 8, 2019, 2:53 PM, https://foreignpolicy.com/2019/11/08/cloning-crispr-he-jiankui-china-biotech-boom-could-transform-lives-destroy-them/ - BD

When James Clapper, the U.S. director of national intelligence at the time, appeared before Congress in early January 2016 for an annual briefing of threats to the United States, he didn’t lack for material. Just a few weeks earlier, North Korea had tested a nuclear device, and Russia had begun deploying cruise missiles that appeared to violate a crucial arms-control agreement. But to the surprise of many experts, Clapper devoted a good chunk of his time to describing a much more exotic threat: biomedical research. Specifically, Clapper warned, “Research in genome editing conducted by countries with different regulatory or ethical standards than those of Western countries probably increases the risk of the creation of potentially harmful biological agents or products.”

Clapper’s statement didn’t explicitly mention China—but it didn’t need to. As his testimony went on to make clear, while in the 20th century the United States and Soviet Union held the keys to preventing planetary catastrophe, in the 21st the principal players are the United States and China. And while in a previous age keeping Pandora’s box closed meant preventing nuclear war, today it’s about preventing biotech dangers.

In just the past few years, the development of inexpensive gene-editing techniques has democratized biomedical research, producing a biotech bonanza in places such as China and creating a whole new category of security threats in the process, from the use of genetic information to persecute dissidents and minority groups to the development of sophisticated bioweapons.

When it comes to the United States, China, and technology, artificial intelligence tends to grab most of the attention. But policymakers need to come to grips with the even bigger threat of biotechnology—and soon. Fortunately, though, shared concerns about China’s role in biotechnology also provide a rare chance for meaningful and productive engagement in shaping the rules of a new world.

China’s starring role in preventing the 21st century’s biotech perils stems from its skyrocketing investment in biomedical research. Historically, Western countries, and especially the United States, have been the epicenter of research in the life sciences. The United States alone accounted for some 45 percent of biotech and medical patents filed in the 14-year period ending in 2013. But now, thanks to heavy state-backed investment, China is catching up. Economic plans instituted in 2015 call for the biotechnology sector to account for more than 4 percent of China’s total GDP by 2020, and estimates suggest that as of 2018, central, provincial, and local governments had already invested over $100 billion in the life sciences. Chinese venture capital and private equity investment in the life sciences, meanwhile, totaled some $45 billion just from 2015 to 2017.

China has also invested considerable effort in competing with countries like the United States for biotech talent. Of some 7,000 researchers recruited under the Thousand Talents Plan since 2008, more than 1,400 specialized in the life sciences. A leading American geneticist, Harris Lewin, has warned that the United States is “starting to fall behind … the Chinese, who have always been good collaborators, [are] now taking the lead.”

For the United States and other Western countries, China’s growing role in biomedical research is raising plenty of concern. Several Chinese researchers have shown a willingness to ignore ethical and regulatory constraints on genetic research. In 2018, He Jiankui became a poster child for scientific irresponsibility when he announced he had edited the genes of two twins in utero without following basic safety protocols. He reportedly dismissed them as guidelines, not laws.

Yet the reaction at home was not what He had hoped for. His research had been made possible by the relatively lax standards of Chinese universities, even as he had kept the true nature of it secret from many involved – while discussing it with a small group of Western bioethicists and scientists, who stressed their disapproval. It’s not uncommon in China to break the rules and be lauded for the results anyway, whatever the field. For He, though, the vast international attention that came after the story broke cost him his career and possibly his freedom. Chinese media rushed to stress official disapproval of the experiments. Even the overt purpose of the editing – to ensure that the babies, born to HIV+ mothers, enjoyed protection against the virus – turned out to be scientifically weak.

As China’s biotech sector grows, so too do fears that Chinese researchers like He will be more willing to push the limits of both science and ethics than those in the United States. Earlier this year, Chinese researchers recorded another mind-bending milestone when they implanted human genes linked to intelligence into monkey embryos—and then said that the monkeys performed better on memory tests.

The dominance of the party-state in China raises serious concerns around biotechnology, especially because it carries increasingly ethnonationalist tone. When in 2018 Chinese researchers created the world’s first primate clones, for example, they dubbed them Zhong Zhong and Hua Hua, from the term zhonghua meaning “The Chinese Nation”—an oddly jingoistic moniker for a pair of monkeys. Chinese government policies often blur the line between eugenics and education, lumped together as improving the “quality” (suzhi) of the population, which received another stamp of official endorsement following the recent Fourth Plenum. These programs are carried out through the country’s huge so-called family planning bureaucracy—originally established to enforce the one-child policy.

Moreover, Beijing is increasingly extending its formidable social control apparatus into the realm of genetics. While there are considerable restrictions on private firms sharing biomedical data, largely because of an ugly history of popular discrimination against hepatitis carriers, the government has no such restrictions. A New York Times report earlier this year suggested, for example, that Chinese authorities had assembled a vast trove of genetic data on Chinese citizens without their consent, with the Uighur minority group having been specifically targeted.

Beijing’s brand of bio-nationalism also directly threatens the United States. U.S. officials have been warning universities and research institutions that the biotech sector is a focal point for Chinese industrial espionage activities in the United States. And this past August, a senior Defense Department official warned Congress that China’s growing role in pharmaceutical manufacturing could allow it to disrupt deliveries of critical battlefield medicines, or potentially even alter them to harm U.S. forces

Yet the biggest risks posed by biotech, for China, the United States, and other countries, pertain to nonstate actors. A critical feature of modern biotech, in contrast to technology like nuclear weapons, is that it’s cheap and easy to develop. A technique known as CRISPR, which the Chinese researcher He used in his illicit gene-editing work, makes it practical for just about anyone to manipulate the genomes of just about any organism they can lay their hands on. CRISPR makes it much simpler to skirt ethical restrictions and terrifyingly straightforward for terrorist groups to develop fearsome biological weapons.

Researchers have already shown it’s possible to reconstruct the smallpox virus, which was eradicated in the real world in the 1970s, for as little as $200,000 using DNA fragments you can order online. If a terrorist or rogue state were to successfully do so, virtually no one alive would have any resistance to the virus—and most stockpiles of the vaccine were destroyed long ago. There is an organization, the International Gene Synthesis Consortium, that tries to screen suspicious orders for DNA fragments that might be used to build such bioweapons. And while most of the world’s major DNA synthesis firms belong to the consortium, membership is completely voluntary, and there’s also a thriving and entirely unregulated black market—much of it based in China.

All of this means that biosecurity standards in places like China matter more than ever. After all, if a major bioweapon were to be unleashed, it’s unlikely that any major, globally integrated country could escape unharmed. Fortunately, there are growing signs China is open to better regulation of its biotech sector. In February, the Chinese government announced that “high risk” biomedical research would be overseen by the State Council, China’s equivalent of the cabinet—a sign of the concern with which Beijing views incidents like the He Jiankui CRISPR scandal. In a further sign of this concern, in August, the Chinese Communist Party announced the creation of a new committee to advise top leaders on research ethics.

Government worry is matched by growing public concern within China. Opposition to genetically modified organisms is arguably stronger in China than in the West, and health concerns top the list of public issues. Rumors and panics largely center around health issues, especially after a series of vaccination scandals. That means that the government has to walk unusually carefully and offers plenty of scope to build ethical concerns into both law and practice.

There are plenty of issues for U.S.-China cooperation on biotechnology and biosecurity to address. Given China’s role in the He Jiankui scandal, meanwhile, it would make sense to partner with the United States and other countries as part of a new World Health Organization effort to set international guidelines for the use of CRISPR. Another promising area of U.S.-China cooperation, especially in the research community, relates to so-called gene drives, the process of editing genomes and then spreading them through an entire population in just a few generations. Using gene drives to prevent select mosquito species from reproducing, for example, might finally banish the world of debilitating, widespread diseases such as malaria and Zika, while endangered species might be engineered to survive climate change.

Microsoft founder Bill Gates once observed that “The world hasn’t had that many technologies that are both promising and dangerous. … We had nuclear weapons and nuclear energy.” But thanks in large part to the efforts of biomedical researchers in the United States and China, biotechnology is opening a similar Pandora’s box. And while the world has so far avoided nuclear war or conflict, it’s done so largely though efforts by governments, aided by the fact that nuclear technology is extremely difficult and expensive to master.

The new wave of synthetic biology is exactly the opposite: It’s cheap to use and employ. For that very reason, while the U.S., Chinese, and other governments will be critical to dealing with the threat of new technologies, the discussions can’t be limited to nation-states. They’ll also have to gather together individual researchers, institutions, companies, and organizations like the International Gene Synthesis Consortium. When it comes to the risks posed by emerging technologies, Beijing, like Washington, will have to face the limits of its ability to solve the problem on its own.

#### 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.

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#### Biotech R&D is set for high growth and investment now

NASDAQ 8/9 [NASDAQ is a stock market index that includes almost all stocks listed on the Nasdaq stock exchange. Along with the Dow Jones Industrial Average and S&P 500, it is one of the three most-followed stock market indices in the United States. This article was written by NASDAQ contributors and published on CNBC. The editorial staff of CNBC did not contribute to the creation of this study.) “Why the Nasdaq Biotechnology Index is poised for a run of sustainable growth” CNBC, NASDAQ, 8/9/2021, <https://www.cnbc.com/advertorial/2021/08/09/why-the-nasdaq-biotechnology-index-is-poised-for-a-run-of-sustainable-growth-.html>] RM

Between the recent bio innovation success stories in the battle against Covid-19 and the technology-driven advances ushering in new efficiencies for research and development (R&D), **the biotech industry has never been more relevant**.

As home to more than 265 companies, the pioneering Nasdaq Biotechnology Index (NBI) has long been committed to providing healthcare’s innovators with access to the capital they need to keep moving forward. Now, investors have access to the Index’s companies through a new ETF, the Invesco Nasdaq Biotechnology ETF (IBBQ).

Launched in 1993, in the wake of the original “biotech revolution” led by the discovery of recombinant DNA, NBI® remains the most representative index in the space. In fact, 98% of all U.S. listed biotech companies are listed on Nasdaq. When considering the massive growth taking place in the sector, it’s no surprise that NBI has outperformed both the S&P 500 (SPX) and Health Care Select Sector Index (IXVTR) in certain market environments.

According to Mark Marex, Index R&D Senior Specialist for Nasdaq who recently compiled an in-depth report on the NBI, global events and digital acceleration have contributed to the Index’s recent strong performance; and Nasdaq’s dedication to maintaining a true benchmark for technology-driven healthcare innovation has provided a framework for growth.

Building the ideal benchmark

Given the existence of pureplay biotech firms, hybrid biopharmaceutical companies, and less R&D-intensive pharmaceutical manufacturers, creating a single benchmark that truly captures the biotech sector and the symbiotic relationships among its players is no easy task.

One of the unique aspects of NBI, versus biotech-focused indexes created by other index providers, is its subsector classifications split between Biotechnology and Pharmaceuticals. As of June 30, 2021, ICB (FTSE Russell’s Industry Classification Benchmark) classified 222 NBI companies as Biotechnology and 47 as Pharmaceuticals. The resulting split by index weight is approximately 65% and 35%, respectively, which illustrates the major difference between the two groups: Pharmaceutical companies tend to be much larger than Biotechnology firms.

This split within a single index provides advantages for investors: While offering some exposure to more established pharmaceutical companies, it also includes R&D-heavy biotech firms that over time may transition into biotech-driven pharma companies. That’s exactly what happened this year when NBI’s largest company, Amgen (AMGN / $144Bn), was reclassified by ICB from Biotechnology to Pharmaceuticals. By retaining firms as they straddle the two classifications over the course of their lifecycle, NBI presents potential growth advantages when compared with index providers that focus rigidly on one classification versus the other.

Home to world-changing breakthroughs

Nasdaq’s vision for the Index has served it well, **both in terms of its longevity and its current role as a champion of the companies paving the way for a post-pandemic world through their technological advances and life-saving treatments**. The broad reach of NBI constituents across multiple fronts in the fight against Covid-19, for example — from diagnosis to vaccines and treatment —demonstrates the strength of its core approach.

NBI companies including Gilead and Regeneron made headlines for their successes during the pandemic with antiviral therapeutics and antibody-based therapeutics for high-risk patients. But it’s the stunning success of m-RNA vaccine technology from Moderna and BioNTech, two NBI companies, that most clearly showcase the home run potential among the biotech entrepreneurs in the space.

And while NBI is currently up 8.2% YTD on a price-return basis (as of June 30) **versus a broader market gain of 14.4% by SPX**, the S&P Biotechnology Select Industry Index (SPSIBI) is down 3.7%.

It’s worth noting that in 2020, NBI outperformed SPX with a price gain of 25.7% versus 16.3%, respectively. This shows the resilience of the NBI and the inherent strength of its current mix of companies.

The possibilities of accelerated R&D

As a whole, the life-changing work being done by NBI constituents requires enormous amounts of R&D. In 2020, R&D expenses for the entire group totaled $68.5Bn, nearly 31% of these companies’ revenue totals. Two-thirds of NBI’s firms reported R&D expenses that exceeded their revenues

For several NBI companies, however, these massive investments provided tangible benefits in the fight against Covid-19. Undoubtedly, years of back-end work and minimal profits ultimately helped deliver the very products that are now driving historic returns. Psychologically, their breakthroughs demonstrated the enormous potential of science and technology to serve humankind.

Looking ahead, **revolutions in Mapping and Engineering processes, boosted by rapid advancements in Machine Learning and Artificial Intelligence, are fostering a true fusion of Biology and Technology that could transform the traditionally costly and labor-intensive R&D function**. Some research estimates these advances could reduce the failure rate of drugs by up to 45% and shorten drug trials by up to 50%. The result could be even more breakthroughs, performed much more efficiently, greatly increasing the returns on biopharmaceutical R&D.

Even a conservative interpretation of the above numbers would significantly reduce R&D costs and boost the market capitalization of therapeutics companies from the current $2Tn up to $9Tn as soon as 2024, according to estimates from ARK Financial.

Meanwhile, increasingly cost-effective human genomics could revolutionize several other industries, from agriculture to biofuels.

By any measure, there is much to be excited about across the spectrum of biotech — especially coming out of a global pandemic. And while no person, nor index, can truly predict what the future holds, chances are strong that companies sitting within NBI will have a hand in leading the way.

“**For investors**, the Index already serves as a fascinating lens through which to view human society’s scientific and technological advancements,” says Mark Marex. “To me, it’s very exciting to ponder what the researchers, scientists, and business leaders in this space will accomplish next.”

#### IPR protections are key to sustain healthcare investments and manufacturing. Independently, it’s key to broader vaccine production.

Roberts 6/25/21 [James M. Roberts is a Research Fellow for Economic Freedom and Growth at the Heritage Foundation. Roberts' primary responsibility as one of The Heritage Foundation's lead experts in economic freedom and growth is to edit the Rule of Law and Monetary Freedom sections of [Index of Economic Freedom](https://www.heritage.org/index/). An influential annual analysis of the economic climate of countries throughout the world, the Index is co-published by Heritage and The Wall Street Journal.) “Biden’s OK of Global Theft of America’s Intellectual Property is Wrong, Dangerous.” 6/25/2021, The Heritage Foundation, Commentary—Public Health] RM

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.

**Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes**.

The best way to prevent and treat new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

Three U.S. companies—Pfizer, Moderna, and Johnson & Johnson—created and manufactured the world’s most effective mRNA COVID vaccines in record time. An increasing majority of Americans have now been inoculated, but much of the developing world remains in desperate need of vaccines. Americans naturally want to help. The question is how.

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines. This, he said, would help make the vaccines more plentiful and available in needy countries. **It’s a short-sighted approach and doomed to fail.**

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them.

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. **It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.**

Signaling that the United States will not fight to defend their intellectual property rights **actively undermines innovation and manufacturing** in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the **future development of vaccines** needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, **compulsory licensing legalizes the theft of intellectual property**. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding.  **It is and has been a bulwark of American prosperity**, but the strength of that protection has been weakening in the past few decades. **Compulsory licensing contributes to the erosion** of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

**The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production**.

That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### COVID was a precursor to deadlier pandemics—vaccine production will determine everything.

Lander 8/4/21 [Eric Lander, President Biden’s Science Advisory and Director of the White House Office of Science and Technology Policy) “Opinion: As bad as Covid-19 has been, a future pandemic could be even worse—unless we act now” 8/4/21, The Washington Post] RM

[Coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_3) vaccines can end the current pandemic if enough people choose to protect themselves and their loved ones by getting vaccinated. But in the years to come, we will still need to defend against a pandemic side effect: collective amnesia.

As public health emergencies recede, societies often quickly forget their experiences — and **fail to prepare for future challenges**. For pandemics, such a course would be disastrous.

**New infectious diseases have been emerging at an accelerating pace,** and they are spreading faster.

Our federal government is responsible for defending the United States against future threats. That’s why President Biden has asked Congress to fund his plan to build on current scientific progress to keep new infectious-disease threats from turning into pandemics like covid-19.

As the president’s science adviser, I know what’s becoming possible. For the first time in our history, we have an opportunity not just to refill our stockpiles but also to transform our capabilities. However, **if we don’t start preparing now for future pandemics, the window for action will close.**

Covid-19 has been a catastrophe: The toll in the United States alone is [more than 614,000 lives](https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/?itid=lk_inline_manual_11) and has been estimated to exceed [$16 trillion](https://jamanetwork.com/journals/jama/fullarticle/2771764), with disproportionate impact on vulnerable and marginalized communities.

But a future pandemic could be even worse — unless we take steps now.

It’s important to remember that the virus behind covid-19 is far less deadly than the 1918 influenza. The virus also belongs to a well-understood family, coronaviruses. It was possible to design vaccines within days of knowing the virus’s genetic code because 20 years of [basic scientific research](https://science.sciencemag.org/content/372/6538/109.full) had revealed which protein to target and how to stabilize it. And while the current virus spins off variants, its mutation rate is slower than that of most viruses.

**Unfortunately, most of the 26 families of viruses that infect humans are less well understood or harder to control**. We have a great deal of work still ahead.

The development of [mRNA vaccine technology](https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/?itid=lk_inline_manual_17) — thanks to more than a decade of foresighted basic research — was a game-changer. It shortened the time needed to design and test vaccines to less than a year — far faster than for any previous vaccine. And it’s been surprisingly effective against covid-19.

Still, there’s much more to do. We don’t yet know how mRNA vaccines will perform against other viruses down the road. And **when the next pandemic breaks out, we’ll want to be able to respond even faster.**

Fortunately, the scientific community has been developing a bold plan to keep future viruses from becoming pandemics.

Here are a few of the goals we should shoot for:

The capability to design, test and approve safe and effective vaccines within 100 days of detecting a pandemic threat (for covid-19, that would have meant May 2020); manufacture enough doses to supply the world within 200 days; and speed vaccination campaigns by replacing sterile injections with skin patches.

Diagnostics simple and cheap enough for daily home testing to limit spread and target medical care.

Early-warning systems to spot new biological threats anywhere in the world soon after they emerge and monitor them thereafter.

We desperately need to strengthen our public health system — from expanding the workforce to modernizing labs and data systems — including to ensure that vulnerable populations are protected.

And we need to coordinate actions with our international partners, because pandemics know no borders.

These goals are ambitious, but they’re feasible — provided the work is managed with the seriousness, focus and accountability of NASA’s Apollo Program, which sent humans to the moon.

Importantly, these capabilities won’t just prepare us for future pandemics; they’ll also improve public health and medical care for infectious diseases today.

Preparing for threats is a core national responsibility. That’s why our government invests heavily in missile defense and counterterrorism. We need to similarly protect the nation against biological threats, which range from the ongoing risk of pandemics to the possibility of deliberate use of bioweapons.

Pandemics cause massive death and disruption. From a financial standpoint, they’re also astronomically expensive. If, as might be expected from [history](https://www.cfr.org/timeline/major-epidemics-modern-era) and current trends, we suffered a pandemic of the current scale every two decades, the annualized cost would exceed $500 billion per year. Investing a much smaller amount to avert this toll is an economic and moral imperative.

The White House will put forward a detailed plan this month to ensure that the United States can fully prepare before the next outbreak. It’s hard to imagine a higher economic or human return on national investment.

#### Ecosystem sensitivity from climate change means future pandemics will cause extinction—assumes COVID

Supriya 4/19 [Lakshmi Supriya got her BSc in Industrial Chemistry from IIT Kharagpur (India) and a Ph.D. in Polymer Science and Engineering from Virginia Tech (USA). She has more than a decade of global industry experience working in the USA, Europe, and India. After her Ph.D., she worked as part of the R&D group in diverse industries starting with semiconductor packaging at Intel, Arizona, where she developed a new elastomeric thermal solution, which has now been commercialized and is used in the core i3 and i5 processors. From there she went on to work at two startups, one managing the microfluidics chip manufacturing lab at a biotechnology company and the other developing polymer formulations for oil extraction from oil sands. She also worked at Saint Gobain North America, developing various material solutions for photovoltaics and processing techniques and new applications for fluoropolymers. Most recently, she managed the Indian R&D team of Enthone (now part of MacDermid) developing electroplating technologies for precious metals.) “Humans versus viruses - Can we avoid extinction in near future?” News Medical Life Sciences, 4/19/21, https://www.news-medical.net/news/20210419/Humans-versus-viruses-Can-we-avoid-extinction-in-near-future.aspx] RM

Expert argues that human-caused changes to the environment can lead to the emergence of pathogens, not only from outside but also from our own microbiome, which can pave the way for large-scale destruction of humans and **even our extinction**.

Whenever there is a change in any system, it will cause other changes to reach a balance or equilibrium, generally at a point different from the original balance. Although this principle was originally posited by the French chemist Henry Le Chatelier for chemical reactions, this theory can be applied to almost anything else.

In an essay published on the online server Preprints\*, Eleftherios P. Diamandis of the University of Toronto and the Mount Sinai Hospital, Toronto, argues that changes caused by humans, to the climate, and everything around us will lead to changes that may have a dramatic impact on human life. Because our ecosystems are so complex, we don’t know how our actions will affect us in the long run, so humans generally disregard them.

Changing our environment

Everything around us is changing, from living organisms to the climate, water, and soil. Some estimates say about half the organisms that existed 50 years ago have already become extinct, and about 80% of the species may become extinct in the future.

As the debate on global warming continues, according to data, the last six years have been the warmest on record. Global warming is melting ice, and sea levels have been increasing. The changing climate is causing more and more wildfires, which are leading to other related damage. At the same time, increased flooding is causing large-scale devastation.

One question that arises is how much environmental damage have humans already done? A recent study compared the natural biomass on Earth to the mass produced by humans and found humans produce a mass equal to their weight every week. This human-made mass is mainly for buildings, roads, and plastic products.

In the early 1900s, human-made mass was about 3% of the global biomass. Today both are about equal. Projections say by 2040, the human-made mass will be triple that of Earth’s biomass. But, slowing down human activity that causes such production may be difficult, given it is considered part of our growth as a civilization.

Emerging pathogens

Although we are made up of human cells, we have almost ten times that of bacteria just in our guts and more on our skin. These microbes not only affect locally but also affect the entire body. There is a balance between the good and bad bacteria, and any change in the environment may cause this balance to shift, especially on the skin, the consequences of which are unknown.

Although most bacteria on and inside of us are harmless, gut bacteria can also have viruses. If viruses don’t kill the bacteria immediately, they can incorporate into the bacterial genome and stay latent for a long time until reactivation by environmental factors, when they can become pathogenic. They can also escape from the gut and enter other organs or the bloodstream. Bacteria can then use these viruses to kill other bacteria or help them evolve to more virulent strains.

An example of the evolution of pathogens is the cause of the current pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several mutations are now known that make the virus more infectious and resistant to immune responses, and strengthening its to enter cells via surface receptors.

The brain

There is evidence that the SARS-CoV-2 can also affect the brain. The virus may enter the brain via the olfactory tract or through the angiotensin-converting enzyme 2 (ACE2) pathway. Viruses can also affect our senses, such as a loss of smell and taste, and there could be other so far unkown neurological effects. The loss of smell seen in COVID-19 could be a new viral syndrome specific to this disease.

Many books and movies have described pandemics caused by pathogens that wipe out large populations and cause severe diseases. In the essay, the author provides a hypothetical scenario where a gut bacteria suddenly starts producing viral proteins. Some virions spread through the body and get transmitted through the human population. After a few months, the virus started causing blindness, and within a year, large populations lost their vision.

Pandemics can cause other diseases that can threaten humanity’s entire existence. **The COVID-19 pandemic brought this possibility to the forefront**. If we continue disturbing the equilibrium between us and the environment, we don’t know what the consequences may be and **the next pandemic could lead us to extinction.**

### 1NC – K

#### Apocalyptic pandemic reps lock in a neoliberal risk society of anxiety and health inequality that spreads disease. Independently, the aff masks health neoliberalism by spreading vaccine arms races horizontally instead of vertically.

Mannathukkaren 14

(Nissim Mannathukkaren, Dept. Chair and Associate Prof. of International Development Studies @ Dalhousie University, “Pandemics in the age of panic,” November 22, 2014, <http://www.thehindu.com/features/magazine/social-media-should-be-a-positive-force-and-public-health-systems-should-focus-on-prevention-of-epidemics/article6624674.ece>)

\*Evidence is edited to correct gendered language\*

If natural disasters induce panic, so do pandemics. In recent years, we have seen a series of pandemics: AIDS, avian influenza, SARS and H1N1. Now, we are in the midst of an epidemic, Ebola, which — according to experts — can acquire pandemic proportions. Natural disasters and pandemics have existed in the pre-modern era as well but what is remarkable is that, in the modern era, the attitudes towards hazards — both natural and man-made — have drastically changed. Panic is the order of the day, especially in sanitised spaces of the developed West. Medical scholars, Luc Bonneux and Wim Van Damme, term panic itself as a pandemic.

As they point out, in 1999, Belgium slaughtered seven million chicken and 60,000 pigs when dioxin, a cancer-causing chemical, entered animal feed. Not one person died from dioxin poisoning. In 2005, the chief avian flu coordinator of the UN predicted that 150 million people could be killed by the flu. However, in 10 years, it has killed less than 400 people. The same apocalyptic predictions were made about BSE/CJD, SARS, and H1N1 as well.

Media coverage and the responses of governments and people to Ebola and recent pandemics tell us an important and paradoxical truth: we might be living in an era that is the apogee of human scientific advancements but this has not necessarily mitigated our fears and panic about potential dangers. This has led theorists to argue that we live in a ‘risk society’, a society that generates a lot of risks precisely because it is obsessed with, as the sociologist Anthony Giddens puts it, “the aspiration to control and particularly with the idea of controlling the future.” Traditional cultures did not have a notion of risk as diseases and natural disasters were taken for granted and were attributed to God or fate.

Interestingly, many of the risks in the modern era, as Giddens elaborates, are manufactured by the “very progression in human development, especially by the progression of science and technology.” Diseases caused by industrial pollution, natural disasters caused by environmental destruction, man-made disasters like Bhopal gas tragedy, Chernobyl and Fukushima nuclear accidents, and latrogenesis — adverse effects caused by medical intervention and modern medicines — are examples of these manufactured risks. In the U.S., scholars estimate that 2,25,000 deaths annually are due to latrogenic causes, and is the third leading cause of death after heart disease and cancer! Thus, science and technology itself generates new uncertainties as it banishes old ones and fear of the unknown cannot be eliminated by further scientific progress.

We have to read the coverage of, and response to, Ebola in this wider context of a risk society. Politics of fear, panic, and scaremongering are inevitable outcomes of such a society. Look at the panic around Ebola in the U.S., where so far not one citizen has died of the disease. A nurse returning after treating Ebola patients in Sierra Leone has won a court order against a mandatory quarantine order imposed by the state. Australia and Canada have imposed visa ban on citizens travelling from the affected countries, violating WHO’s International Health Regulations.

Renowned journalist Simon Jenkins argues that “we have lost control of the language of proportion” in responding to Ebola and other pandemics. Similarly, other journalists have severely criticised the media’s coverage of Ebola. The scaremongering is seen in absurd and irresponsible statements like Ebola is ‘the ISIS of biological agents!’ One major responsibility of the mainstream media, other than providing detailed and proper information about the disease itself, is to enlighten the public about the socio-economic and political conditions that govern health and healthcare systems in various societies, which in turn impact the origin and spread of pandemics. Without educating the public about the root causes that condemn the poorer parts of the world to bear the brunt of global pandemics, the media becomes a handmaiden of the powers — developed countries and pharmaceutical corporations — that control global health.

This lack of knowledge about larger forces also adds to risks and the resultant panic. Thus, in the 2009 H1N1 pandemic, the media’s role in the investigation of allegations of whether it was a false pandemic was nothing to be proud of. The head of health at the Council of Europe had raised questions about the role of pharmaceutical corporations in the declaration of H1N1 as a pandemic. Later, an investigation by the British Medical Journal found that medical experts advising WHO on H1N1 had financial ties with pharmaceutical companies producing the vaccine for the pandemic. As all the developed countries stocked up on the vaccines, reportedly, the pharmaceutical companies made profits ranging from $ 7-10 billion.

In this context, the media’s role in the coverage of pandemics raises questions. Where are the stories in the media about the lack of vaccines for Ebola, 40 years after the disease emerged? Or about the drug firms now in the race to produce a vaccine (the share prices of one of the companies ahead in the race have shot up exponentially)?

While certain prominent Western media houses have definitely pushed the panic button with regard to Ebola, the hard data about the overall coverage as studied by the Foreign Policy magazine indicates that it is not the case. But this study is merely restricted to the English language coverage. Further, the mainstream media has failed miserably in countering the serious issue of the racialisation of Ebola (as with AIDS before) as an African disease caused and spread merely by its cultural practices.

In a risk society, we have to confront new unknowns too, like social media and its impact. One media source called Ebola ‘the first major outbreak in the era of social media’. But, in the coverage of the outbreak, social media has reportedly been a negative force spreading misinformation and rumours that, in some cases, even led to deaths due to dangerous treatments administered.

#### The alternative is to adopt a social medicine approach to health.

Mohan J. DUTTA 15, Professor and Head of the Department of Communications and New Media at the National University of Singapore, Adjunct Professor of Communication at the Brian Lamb School of Communication at Purdue University [*Neoliberal Health Organizing*, 2015, p. 231-234]

Latin American social medicine depicts a distinct and long strand of theorizing of health systems that challenges the liberal capitalist organizing of health, grounded in the organizing principles of social medicine and noting [END PAGE 231] that changing the overarching structures is central to transforming the conditions of poor health (Waitzkin, 1991, 2011; Waitzkin & Modell, 1974). That health is constituted within broader social conditions is the basis for research, teaching, clinical practice, and activism in socialist medicine, with early roots in Latin America. Social medicine thus connects health, healing, and health care delivery to the politics of social change and structural transformation, clearly voicing an activist agenda directed at transforming the unequal social conditions.

One of the earliest influences of social medicine was evident in the work of the medical student activist Salvador Allende, who would later become the president of Chile. In his book The Chilean Medico-Social Reality, Allende (1939) outlined the social conditions in Chile that resulted in poor health outcomes, emphasizing the broader conditions of foreign debt dependence, underdevelopment, international dependence, and resource consolidation in the hands of the local elite. Proposing social rather than medical solutions to health, Allende emphasized “income redistribution, state regulation of food and clothing supplies, a national housing program, and industrial reforms to address occupational health problems” (Waitzkin, 2011, p. 160). In his political life, Allende sought reforms in the Chilean national health service, complemented by reforms in the housing and nutrition areas, efforts at national income redistribution, and minimizing the role of multinational corporations.

The individualized model of public health that sees health and illness as a dichotomy is interrogated by the framework of social medicine that suggests that health and illness exist in a dialectical relationship that is dynamic and is continually shifting on the basis of social conditions, structures, cultural practices, economic production, reproduction, marginalizing practices, and processes of political participation. Thus, interventions in social medicine point toward the necessity for transforming the underlying relationships of production and resource distribution, resisting the public health narrative of interventions as mechanisms for improving economic productivity. Taking a social-class-driven approach to health inequities, Latin American social medicine sees the problems with health being situated within means of economic production, patterns of ownership of means of production, and control over productive processes. Therefore, health is approached from the framework of transforming the processes of economic production and labor processes.

The dominant framework of health as integral to growth and economic productivity is questioned by the framework of social medicine that situates the relationship between health and illness amid the very processes of economic organization, distribution of economic resources, and the pervasive effects of social class on health services and health outcomes. [END PAGE 232] The innovations in organizing of health structures in Chile, Cuba, Mexico, Bolivia, and Venezuela offer invaluable insights about the possibilities of alternative organizing that seek to redo the entire structure of social organizing that constitute health. The strong health indicators in Cuba demonstrate the effectiveness of a health system that is committed to addressing the structural determinants of health, creating equitable contexts for the realization and delivery of health (Campion & Morrissey, 2013). Social medicine research has looked at the relations among work, reproduction, the environment, and health, describing in-depth the material conditions that constitute health. For instance, researchers studying health in Mexico within the context of unions and local communities have documented health problems that relate to work processes and the environment. Similarly, researchers in Chile have documented the relations between gender, work, and environmental conditions. A key strand of social medicine examines the relationship between violence and health, connecting violence to poverty, the structures of organizing, and the inequities in ownership of processes of economic production. Investigations of violence attached to the U.S.-supported dictatorship in Chile, the violence connected to narcotics traffic and paramilitary operations, and the violence within the broader structures of the state-imperial networks draw linkages to the broader political economic configurations of neoliberalism.

Emerging from the broader framework of social medicine, the Barrio Adentro movement in Venezuela, started by former president Hugo Chavez, offers insights into structures and processes of alternative organizing of health, connecting local community structures, community ownership, and community solutions with state infrastructures and state-driven public health resources and solutions (Briggs & Mantini-Briggs, 2009; Muntaner et al., 2006; Waitzkin, 2011). The state-driven referendum by the Chavez government to create public health infrastructures and structures of delivery of integrated family medicine, build preventive infrastructures, and develop community health resources in extremely marginalized communities is supported by massive mass-based participation in popular politics and widespread community participation in developing local community infrastructures, community-based resources of problem solving, and community decision-making capacities. The community health centers built within the barrios serve approximately 250 families and are staffed with one integrated family care doctor, one community health worker, and one health promoter. The community health centers are stocked with medical supplies. The health team not only provides health care but also conducts health surveys in the communities and makes home visits for patients that are too ill to travel to the health centers. The Barrio Adentro is integrated with other missiones addressing education, food insecurity, housing, and [END PAGE 233] unemployment, addressing health within a broader structural context (Muntaner et al., 2006). Local community participatory processes are connected with state-driven processes of building community health infrastructures at the local level.

The narrative of Barrio Adentro offers an alternative to the neoliberal narrative of the community in mainstream health communication and yet is marked by its absence from disciplinary discourses. Similarly, social medicine and its tradition of addressing the structural contexts of health is marked by its absence from the dominant discourses of health communication. A review of the two major collections of health communication scholarship, The Routledge Handbook of Health Communication and The Handbook of Global Health Communication, depicts the marked absence of the Latin American innovations of social medicine from the discursive space. Opportunities for resistance to neoliberal organizing of health structures and the invitation to imagine alternative possibilities is grounded in materially grounded concrete politics of popular participation in supporting state policies for building public health and health care infrastructures, complemented by local processes of participation in the creation of health solutions.

### Case

Vote neg on presumption – the compulsory licensing clause and exception in TRIPS is the same as the aff—proves no solvency b/c generic vaccines havent been made

#### Waiving IP enforcement results in rampant increase in counterfeit vaccines – turns case.

Mercurio 21 (Bryan Mercurio is a Professor and Vice-Chancellor's Outstanding Fellow of the Faculty of Law at the Chinese University of Hong Kong, February 21, 2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820&download=yes>) CS

6. IP enforcement is of vital importance to maintaining safety standards.

The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation **of fraudulent and dangerous goods**. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licences, as this is the most responsible way to bring their technologies to the world and safeguard global health.

In addition, as the COVID-19 pandemic continues there has been a **noticeable increase in the circulation of fake medicines** around the world. According to the International Criminal Police Organization (Interpol), **organized crime groups** have been producing fake drugs and medical products and selling them for **lucrative profits in developing countries**.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to **disastrous consequences**, including **worsened illness and** **death** for the individual and the retardation of herd immunity for the population at large. Effective and proactive **IP** procurement is **essential** and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, **putting millions of human lives at risk** and reducing trust in vaccines.

#### Vaccine IP is insufficient for imitation; originators will challenge with intense litigation, and nations don’t have necessary ingredients and materials. Independently, the plan will cause companies to disengage from global efforts.

Silverman 3/15 [Rachel Silverman is a policy fellow at the Center for Global Development where she leads policy-oriented research on global health financing and incentive structures. Silverman’s current research focuses on the practical application of results-based financing; global health transitions; efficient global health procurement; innovation models for global health; priority-setting for UHC; alignment and impact in international funding for family planning; and strategies to strengthen evidence and accountability. BA with distinction in international relations and economics from Stanford University.) “Waiving vaccine patents won’t help inoculate poorer nations” Washington Post, PostEverything Perspective, <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/>] RM

According to some activists, the solution to this inequity is relatively simple: By suspending protections on covid-19 vaccine patents, the international community “could help break Big Pharma monopolies and increase supplies so there are enough doses for everyone, everywhere,” [claims](https://peoplesvaccine.org/take-action/)the People’s Vaccine Alliance. Indeed, 58 low- and middle-income countries have mobilized in support of a proposed World Trade Organization [waiver](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True) that would temporarily exempt [coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_4)-related intellectual property from normal international rules and protections. And while the effort to waive IP protections has been a global health hot topic for months, it gained a high-profile endorsement in the United States recently from Sen. Bernie Sanders (I-Vt.). In a March 10 video statement, Sanders [called upon President Biden](https://twitter.com/GlobalJusticeUK/status/1369734275818549252?s=20) to support the IP suspension while slamming “huge, multibillion-dollar pharmaceutical companies [that] continue to prioritize profits by protecting their monopolies.”

The logic of the argument seems clear and intuitive — at first. Without patents, which serve narrow commercial interests, companies all over the world could freely produce the vaccine. Sure, Big Pharma would lose money — but this is a pandemic, and human life comes before private profit, especially when vaccines receive substantial public financing to support research and development. As with HIV drugs in years past, widespread generic production would dramatically increase supply and drive down prices to levels affordable even in the developing world.

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have little effect**.** **It could even backfire, with companies using the move as an excuse to disengage from global access efforts**. **There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents.**

The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna [announced in October](https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19) that it would not enforce IP rights on its coronavirus vaccine — and yet it has taken no steps to share information about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the company’s direct control within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine [not yet participating in Covax](https://www.washingtonpost.com/world/coronavirus-vaccine-access-poor-countries-moderna/2021/02/12/0586e532-6712-11eb-bf81-c618c88ed605_story.html?itid=lk_inline_manual_9), a global-aid-funded effort (including a [pledged $4 billion from the United States](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort)) to purchase vaccines for use in low- and middle-income countries.

It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own.

One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, [lowering prices dramatically](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices).

Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. **Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth**. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

#### Underinvestment and regulation drive vaccine inefficiency---licenses are already available

Tabarrok 5/6/21 [Alex Tabarrok is Bartley J. Madden Chair in Economics at the Mercatus Center and a professor of economics at George Mason University. Along with Tyler Cowen, he is the co-author of the popular economics blog Marginal Revolution and co-founder of Marginal Revolution University. He is the author of numerous academic papers in the fields of law and economics, criminology, regulatory policy, voting theory and other areas in political economy. He is co-author with Tyler of Modern Principles of Economics, a widely used introductory textbook. He gave a TED talk in 2009. His articles have appeared in the New York Times, the Washington Post, the Wall Street Journal, and many other publications.) “Patents are not the problem!” Marginal Revolution University, 5/6/21, Current Affairs, Economics, Law, Medicine, <https://marginalrevolution.com/marginalrevolution/2021/05/ip-is-not-the-constraint.html>] RM

For the last year and a half I have been shouting from the rooftops, “invest in capacity, build more factories, shore up the supply lines, spend billions to save trillions.” Fortunately, some boffins in the Biden administration have found a better way, “the US supports the waiver of IP protections on COVID-19 vaccines to help end the pandemic.”

Waive IP protections. So simple. Why didn’t I think of that???

**Patents are not the problem**. All of the vaccine manufacturers are trying to increase supply as quickly as possible. Billions of doses are being produced–more than ever before in the history of the world. Licenses are widely available. **AstraZeneca have licensed their vaccine for production with manufactures around the world, including in India, Brazil, Mexico, Argentina, China and South Africa**. J&J’s vaccine has been licensed for production by multiple firms in the United States as well as with firms in Spain, South Africa and France. Sputnik has been licensed for production by firms in India, China, South Korea, Brazil and pending EMA approval with firms in Germany and France. Sinopharm has been licensed in the UAE, Egypt and Bangladesh. Novavax has licensed its vaccine for production in South Korea, India, and Japan and it is desperate to find other licensees but t**echnology transfer isn’t easy and there are limited supplies of raw materials:**

Virtually overnight, [Novavax] set up a network of outside manufacturers more ambitious than one outside executive said he’s ever seen, but they struggled at times to transfer their technology there amid pandemic travel restrictions. They were kicked out of one factory by the same government that’s bankrolled their effort. Competing with larger competitors, they’ve found themselves short on raw materials as diverse as Chilean tree bark and bioreactor bags. They signed a deal with India’s Serum Institute to produce many of their COVAX doses but now face the realistic chance that even when Serum gets to full capacity — and they are behind — India’s government, dealing with the world’s worst active outbreak, won’t let the shots leave the country.

Plastic bags are a bigger bottleneck than patents. The US embargo on vaccine supplies to India was precisely that the Biden administration used the DPA to prioritize things like bioreactor bags and filters to US suppliers and that meant that India’s Serum Institute was having trouble getting its production lines ready for Novavax. CureVac, another potential mRNA vaccine, is also finding it difficult to find supplies due to US restrictions (which means supplies are short everywhere). As Derek Lowe said:

Abolishing patents will not provide more shaker bags or more Chilean tree bark, nor provide more of the key filtration materials needed for production. These processes have a lot of potential choke points and rate-limiting steps in them, and there is no wand that will wave that complexity away.

Technology transfer has been difficult for AstraZeneca–which is one reason they have had production difficulties–and their vaccine uses relatively well understood technology. The mRNA technology is new and has never before been used to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Moderna or Pfizer would be happy to license since they are producing in their own factories 24 hours a day, seven days a week (monopolies restrict supply, remember?). **Why do you think China hasn’t yet produced an mRNA vaccine? Hint: it isn’t fear about violating IP**. Moreover, even Moderna and Pfizer don’t yet fully understand their production technology, they are learning by doing every single day. **Moderna has said that they won’t enforce their patents during the pandemic but no one has stepped up to produce because no one else can.**

The US trade representative’s announcement is virtue signaling to the anti-market left and will do little to nothing to increase supply.

What can we do to increase supply? Sorry, there is no quick and cheap solution. We must spend. Trump’s Operation Warp Speed spent on the order of $15 billion. If we want more, we need to spend more and on similar scale. The Biden administration paid $269 million to Merck to retool its factories to make the J&J vaccine. That was a good start. We could also offer Pfizer and Moderna say $100 a dose to produce in excess of their current production and maybe with those resources there is more they could do. South Africa and India and every other country in the world should offer the same (India hasn’t even approved the Pfizer vaccine and they are complaining about IP!??) We should ease up on the DPA and invest more in the supply chain–let’s get CureVac and the Serum Institute what they need. We should work like hell to find a substitute for Chilean tree bark. See my piece in Science co-authored with Michael Kremer et. al. for more ideas. (Note also that these ideas are better at dealing with current supply constraints and they also increase the incentive to produce future vaccines, unlike shortsighted patent abrogation.)

Bottom line is that producing more takes real resources not waving magic patent wands.

You may have gathered that I am angry. I am indeed angry that the people in power think they can solve real problems on the cheap and at someone else’s expense. This is not serious. I am also angry that they are sending the wrong message about business, profits and capitalism. So let me end on positive note. Like the Apollo program and Dunkirk, the creation of the mRNA vaccines by Pfizer and Moderna should be lauded with Nobel prizes and major movies. Churchill called the rescue at Dunkirk a “miracle of deliverance,” well the miracle of Moderna will rescue many more. Not only was a vaccine designed in under a year, an entirely new production process was set up to produce billions of doses to rescue the world. The creation of the mRNA vaccines was a triumph of science, logistics, and management and it was done at a speed that I had thought possible only for past generations.

c [Tamara Kay is a sociologist studying trade, global health and globalization at the Keough School of Global Affairs, University of Notre Dame. Adnan Naseemullah is an international relations scholar at King's College London. Susan Ostermann is a political scientist at the Keough School of Global Affairs, Notre Dame and a former attorney at O'Melveny & Myers LLP, specializing in intellectual property law.) “Waiving patents isn't enough — we need technology transfer to defeat COVID” The Hil, Opinion Contributors: Healthcare, 5/13/21, 2:01 PM EDT, <https://thehill.com/opinion/healthcare/553368-waiving-patents-isnt-enough-we-need-technology-transfer-to-defeat-covid?rl=1>] RM

On May 5, U.S. Trade Representative Katherine Tai announced that the Biden administration would support a waiver of intellectual property (IP) restrictions for coronavirus vaccines to enable low-income countries to vaccinate their populations. While such a waiver is necessary to stem the global COVID-19 pandemic, it is not sufficient. What is missing from discussions of intellectual property is that **few of the countries with the potential to produce sophisticated pharmaceutical products currently have the technological capacity to manufacture mRNA and adenovirus vaccines to global standards.** This is because of the highly concentrated nature of the global pharmaceutical industry, which has impeded the transfer of production technology beyond a handful of countries.

Even after U.S. support of the IP waiver, significant obstacles to increased vaccine production and distribution remain. Primary among them is continuing resistance by profit-concerned pharmaceutical companies to sharing their technological expertise more broadly with capable partners, and the governments in high-income countries that support these strategies.

Corporations argue that, particularly for the mRNA vaccines, **wider distribution and production are prohibitively difficult due to the complex and relatively new technology involved.**

There is some truth in this. The genetic sequence of the virus is already publicly available. The safe transfer of this sequence to human bodies, via mRNA or an inactivated adenovirus, by contrast, is a complicated and sophisticated operation. Pharmaceutical companies argue this process needs to be kept in capable hands. They argue that they are the only ones with this capacity, and have received and continue to receive tremendous public funding as a result. None are offering up their expertise and, in particular, technology that they deem trade secrets, for wider public use, which would dramatically widen production and distribution capability beyond wealthy countries.

However, in light of the significant public funding already invested, the windfall profits already achieved and the significant public interest at stake, we can and should do more than support an intellectual property waiver to enable capacity building for pharmaceutical manufacturing and distribution in low-income countries. Vaccine producers are essentially realizing their profits as government contractors, and it is in the interest of the U.S. government for the pandemic to end globally, not just in the U.S. This will occur only if low-income countries can make and distribute vaccines.

We already see some examples of production beyond the West. The Serum Institute of India already produces a large proportion of the AstraZeneca vaccine bound for Europe. There is no reason why it and other Indian manufacturers, and those in other countries with emerging scientific and technological capacity, could not produce much more for the developing world over the next year. This was envisioned by the WHO’s C-TAP program. But Pfizer and Moderna, with the backing of the Trump administration, opposed this program.

Yet given the global threat — a threat which will not truly diminish locally until it diminishes globally — we should create incentives for them to lend their expertise and support to manufacturing partners of their own choosing in low-income countries to radically expand production capacity.

#### Circumvention and they don’t solve – even if they say “durable fiat”, they have not defined the scope of the plan in the 1AC so you don’t know what the plan would materially look like

Mercurio 6/24 [Simon F.S. Li Professor of Law, The Chinese University of Hong Kong, Shatin, Hong Kong. June 24, 2021. “The IP Waiver for COVID-19: Bad Policy, Bad Precedent” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/> Accessed 8/25 //gord0]

The role of intellectual property rights (IPRs) and access to medicines is contentious. On the one hand, IPRs encourage investment, innovation and the advancement of health science. On the other hand, the limited-term monopoly rights can result in artificially high prices and become a barrier to access to medicines. While the wisdom of the IPRs system has at times been tested, it has proven its value in the current COVID-19 pandemic as IPRs played a large role in the rapid (and unprecedented) development and availability of multiple vaccines. Despite the success, India and South Africa proposed that the World Trade Organization (WTO) waive IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to increase access to vaccines and other COVID-19-related technologies.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn1) The proposal, tabled at a meeting of the TRIPS Council in October 2020, calls on Members to waive IPRs relating to and having an impact on the “prevention, containment or treatment of COVID-19”.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn2) The proposal attracted support from the majority of developing country Members,[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn3) but was opposed by a handful of Members including the United States (US).[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn4) Given that consensus could not be reached within the deadline of 90 days as set out in Art. IX:3 of the Agreement Establishing the WTO, Members agreed to keep the waiver proposal on the agenda of the TRIPS Council in 2021.[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn5) On 5 May 2021, the US reversed its position and announced that it would support a waiver for COVID-19 vaccines.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn6) To be clear, this does not mean that the US supported the waiver as proposed by India and South Africa. Instead, the US has simply agreed to negotiate the perimeters of a waiver. Others, including the European Union (EU), Canada, Australia, Norway, Switzerland, the United Kingdom (UK) and even leading developing countries such as Brazil, Chile and Mexico remain opposed or lukewarm on the waiver.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn7) The US dropping opposition does not mean the concerns of other Members will simply disappear – one would hope that these nations opposed the waiver for valid reasons and did not simply blindly follow the US. Indeed, many of the above-listed Members remain unconvinced that even such a draconian step as a waiver of IPRs would accomplish the goal of increased vaccine production.[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn8) For its part, the EU continues to favour an approach which makes better use of existing flexibilities available in the TRIPS Agreement.[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn9) Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the WTO are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn10) Issues of negotiation will include the scope of the waiver. Whereas the original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn11) industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn12) (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn13) The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn14) – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn15) These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations. With so many initial divergences and as yet undiscussed issues, the negotiations at best could be completed by the time of the next WTO Ministerial Conference, scheduled to begin on 20 November 2021. There is precedent in this regard, as previous TRIPS negotiations involving IP and pharmaceuticals were not fully resolved until the days before the Ministerial Conferences (in 2003 and 2005).[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn16) There is also a chance that the negotiations will continue past the calendar year 2021. The chance for a swift negotiation diminished with the release of a revised proposal by India and South Africa on 22 May 2021. As mentioned above, the proposal contains no limit as to product coverage, scope, notification requirements or safeguards and proposes that the waiver will remain in effect for what could be an indefinite period. This was not a proposal designed to engender quick negotiations and a solution. Instead, the proposal perhaps reveals India’s and South Africa’s true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world. It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn17) The US announcement remains meaningful, however, for two reasons. First, it signals a departure from the longstanding and bipartisan support for the pharmaceutical industry, which for decades has been instrumental in setting the IP and trade agenda.[18](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn18) Second, it sends a strong signal that the US does not oppose others from waiving patent protection for vaccines. This shift may also be part of a broader and alternative strategy to increase vaccine production and distribution, whereby the US is not viewing or supporting waiver negotiations as a legal tool but more so as a threat to encourage vaccine innovators to increase production. In essence, the desired reaction would be that the IP holders increase efforts to license, transfer technology and expand manufacturing – exactly what the world needs at this time. Alan Beattie, writing in the Financial Times, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[19](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[20](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the leading vaccines using mRNA are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production. Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. The know-how and trade secrets are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up. When asked if a waiver would improve vaccine availability and equity, Watal responded: “No. It won’t. That’s clear.”[21](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn21) I share Watal’s view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that “what the proposal … will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South”[22](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn22) I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn23) IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn24) Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor. Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.

#### TRIPS alone is too ambiguous to serve as a sufficient legal standard

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Dina Halaijan (JD, Brooklyn Law School). “Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem.” Brooklyn Journal of International Law. Volume 38, Issue 3, Article 7 (2013). JDN. <https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil>

3. Definitional Ambiguities & Ambiguities in Scope

Ambiguities in the interpretation of TRIPS due to the lack of substantive guidelines or definitions also hinder its effective use by **increasing the risk of litigation.**111 The Doha Declaration merely stated that individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency” in deciding to grant a compulsory license, and thus did little to ameliorate the different interpretive approaches of developed and developing countries.112 **The flexible scope** of compulsory licenses **lends to abuse which further instills resistance and suspicion** from pharmaceutical companies.113 For example, Egypt’s compulsory license for Pfizer’s Viagra tarnishes the reputation of compulsory licensing because erectile dysfunction is clearly a less dire situation and one likely not intended to be covered by the public health exception of TRIPS.114 Such excessive abuse and over-use of compulsory licensing likely encourages pharmaceutical companies to aggressively resist valid uses of compulsory licenses to prevent **over-expansion of scope.**

115 In addition to ambiguity in the scope of intended diseases, conflicting interpretations exist in the type of pharmaceutical products intended for compulsory licensing.116 The scope of countries that should benefit from compulsory licensing remains another area of contention.117 Not limiting the scope of applicable nations may create a **chilling effect** on the types of drugs pharmaceutical companies choose to invest in and develop to avoid the potential for a compulsory license, **which hurts developing nations most in need of help.**118 Interpreting the morality exclusion in Article 27(2) also proves difficult, as **there is no universally accepted definition.**119 In addition to causing differing interpretations between countries, the lack of concrete definitions allows countries to alter their position to fit their self-interest and creates potential for abuse.120 For example, despite the United States’ narrow interpretation of TRIPS flexibilities, the United States contradicted itself during the 2001 anthrax scare by suggesting use of a compulsory license for Cipro, a drug that combats the effects of anthrax.121 On a related note, as India’s government and pharmaceutical industry’s capabilities grow, the future of India’s willingness to grant compulsory licenses and produce cheap generic drugs for export to other developing countries is questionable.122 Indian companies may opt to serve their selfinterest and become “innovator companies” to compete globally with other large pharmaceutical companies.123 The vagueness of Article 30, which allowed a narrow interpretation to be given by the WTO dispute resolution panel, is a further impediment to increasing access to medicines.124 Calculating adequate remuneration for payment to the patent holder when a compulsory license is issued is another obstacle to successful use of TRIPS flexibilities and is further complicated by the requirement to take the economic value of the authorization into account, as TRIPS does not provide guidance to determine what is ‘adequate’ and what is the authorization’s ‘value.’125 The WTO members’ inability to reach a decision regarding parallel importation created a “fundamental flaw” of ambiguity.126 In regard to compulsory licensing under the Paragraph 6 Decision, drugs made for export must be distinguishable by special labels, colors, or shapes to prevent trade diversion.127 However, lack of monitoring guidelines and repercussions makes the re-exportation issue troubling.128