# 1NC vs Marlborough ML

# OFF

## T — Nebel – Medicines

### 1NC

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

#### 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.

#### [b] Pragmatics are always subject to debate – empirically proven since there’s no consensus on whether NIBs are truly fair – but you can’t BS textual accuracy so semantics serves as an objective constraint on the aff.

#### 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

## 1 – Innov DA

#### 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.”

#### The aff reverses innovative potential

Cory 17 [Nigel Cory is a trade policy analyst at the Information Technology and Innovation Foundation.April 30, 2017, “How Intellectual Property Protection Incentivizes Innovation” <https://www.globaltrademag.com/intellectual-property-protection-incentivizes-innovation/> //gord0]

World Intellectual Property Day was marked last week, an important moment to consider the critical relationship between [intellectual property (IP) protection](https://www.globaltrademag.com/global-trade-daily/commentary/free-trade-and-the-threat-to-intellectual-property-protection-in-china) and innovation. Just as we have in years past, the [Information Technology and Innovation Foundation (ITIF)](https://www.globaltrademag.com/global-trade-daily/trump-right-china-poses-economic-threat) took a deeper look at the latest data on the strength of IP laws and the amount of innovative, creative output around the word, and found that overall, countries with stronger IP protection also have more creative output, even at varying levels of development. The results show why countries need to support efforts to ensure international rules address new and emerging IP issues in order to ensure that firms and countries are maximizing their innovative and creative potential. ITIF compared the strength of IP laws and the effectiveness of anti-counterfeiting laws based on data from the World Economic Forum’s Global Competitiveness Report 2016-17 with creative output scores from the Global Innovation Index 2016, a report from Cornell University, INSEAD, and the World Intellectual Property Organization (WIPO). The Global Innovation Index combines three measures of creativity. First, “intangible assets” combines measures of domestic and international trademark applications and rates of information and communication technology adoption. Second, “creative goods and services” measures trade in creative services and output by a nation’s media, printing and publishing, and entertainment industries. Finally, “online creativity” measures a nation’s top-level internet domains, as well as the number of YouTube videos uploaded and Wikipedia pages edited. The key finding is that there is a strong positive correlation (0.74) between the strength of IP protections and countries’ score on creative outputs, based on a sample of 119 countries (only those countries which had all the necessary data). ITIF assessments in 2016 and 2014 produced similar results of 0.70 (from a sample of 127 countries) and 0.72 (from a sample of 136). Some advocates that are opposed to IP protections claim IP only benefits high-income countries. To test whether the correlation was solely based on income, the data were divided between high-income (>$20,000 GDP per capita), middle-income ($5,000-$19,999 GDP per capita), and low-income nations (<$5,000 GDP per capita). The sample has 33 high-income countries, 37 middle-income countries, and 49 low-income countries. Similar to past years, the relationship between IP protection and creative output was strongest in high-income countries, with a correlation of 0.51, but it was still positive for both middle-income (0.19) and low-income countries (0.22). In other words, even for the poorest nations, stronger IP protection was associated with stronger creative outputs, which in turn lead to job creation and GDP growth. As in past reports, the Global Competitiveness Report 2016-17 shows that it’s difficult for countries to score well in creative outputs without ranking highly in intellectual property protections. The average level of IP protection for the top 20 most-creative countries (5.85 out of 7) is well above the average (4.37). Delving deeper, the analysis shows that the 50 countries with above average total creative outputs also have above average intellectual property protections (5.01). ***Setting New International Norms: Analyzing IP, Creative Output, and Trade Agreements*** At the multilateral level, the World Intellectual Property Organization’s Copyright Treaty sets a basic framework for its 95 member-countries to enact to prevent unauthorized access to and use of creative works on the Internet, such as for computer programs and databases. Along with the Performances and Phonogram Treaty, it comprises WIPO’s “Internet Treaties,” which aim to update and supplement core international IP agreements—the Berne Convention and Rome Convention—which were adopted or last revised over 50 years ago. This year’s analysis shows the value of the Copyright Treaty’s basic levels of digital IP protections. Our analysis included 88 of the 95 WIPO Copyright Treaty members. These nations had a level of IP protection and creative output above the average for the entire sample: 4.5 vs. 4.37, and 93.5 vs. 87.7, respectively. Meanwhile, non-members (the sample included 31) had an average level of protection and creative output well below the average: 4 vs. 4.37, and 71 vs. 87, respectively. These results show why bilateral, regional, and multilateral efforts to update the issues addressed by the Copyright Treaty and other digital IP issues should be supported. Given that this treaty was negotiated in the 1990s and came into force in 2002, there are obvious needs for further updates given changes in technology and the digital economy. Efforts to set higher common levels of IP protection and enforcement have mainly occurred at the regional level, especially in the Asia-Pacific, with the [Trans-Pacific Partnership (TPP)](https://www.globaltrademag.com/global-trade-daily/commentary/trans-pacific-partnership-questions-answers) leading the way and the Regional Comprehensive Economic Partnership (RCEP) addressing this as well. Unfortunately, the future of the TPP is in serious doubt given America’s withdrawal, but if the other 11 members were to decide to implement the agreement, it would hopefully include the TPP’s high-standard IP chapter. Still, the TPP’s developing-country members (Malaysia, Vietnam, and Peru) need to make significant progress to close the gap to developed-country-member levels of protection and creative output. In 2016, out 119 countries, Malaysia ranked 27th in IP protection and 42nd in output (both improvements from 109th and 34th in 2015, which had 127 countries), Vietnam ranked 92nd and 51st (up from 82nd and down from 54th), and Peru ranked 100th and 67th (slightly up from 96th and 61st). RCEP shows an even bigger gulf between leaders and laggards. The 16 members of RCEP include developed countries with high-standard free trade agreements and IP systems (such as Australia, Singapore, and Korea), but also a broader range of developing countries that do poorly with IP protection and creative output (such as Cambodia, China, India, the Philippines, and Thailand). Developing-country members of RCEP have a below-average level of IP protection (4.05) and total creative output (72.8). In reality, this underperformance is likely much worse given Laos and Myanmar are not included in the sample due to a lack of data. The membership complicates the potential for a high-standard IP chapter. While China has made efforts to improve its domestic IP and innovation systems, it has likewise sought to steal or coerce IP from foreign firms and has failed to push for strong IP as part of past trade agreements. Other RCEP members have also not prioritized IP in their past trade agreements, so the level of ambition in RCEP is going to be much lower than TPP if these members prevail over the countries with well-developed IP systems, such as Australia, Japan, Korea, and Singapore, especially if the RCEP succumbs to the same misguided scare campaign as the TPP’s IP chapter. However, IP is just one of many divisions that could prolong, or ultimately doom, RCEP’s future. ***Correlation Does Not Equal Causation, But IP is Key to Incentivizing Creativity and Innovation*** Of course, correlation does not equal causation, and enacting higher levels of intellectual property protections will not always automatically lead to greater creative output. IP does not function in a void without other policy support. An OECD literature review and empirical study found that efforts to strengthen IP protections over the last two decades had a positive economic impact but that variations were due to certain complementary factors, such as human capital, legal and institutional conditions, and fiscal incentives. This all leads back to a central point worth remembering this World Intellectual Property Day: Whether a country is trying to catch up to the technology frontier, or push it ahead, stronger intellectual property protections are crucial to incentivizing the creativity and innovation that helps make this happen. Given this, countries—at all levels of development—that want to spur innovation need to support efforts to ensure international norms reflect the modern challenges facing IP protection and enforcement and help set better, shared IP rules in order to ensure that firms and countries are maximizing their innovative and creative potential.

#### 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.~~**

## 2 – China Bioterror

### 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 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.

#### 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.

# CASE

## Circumvention

### Whole Res

#### States wouldn’t implement TRIPS – endless filibustering in the squo by Europe, the UK, Russia, etc. should be enough proof, but they also have no incentive to listen since countries are split on the issue, and its not unanimous

#### All aff ev is in the context of nations agreeing to the TRIPS waiver, which is distinct [explain contextual to the aff]

#### ~~Circumvention is a neg argument – core of the topic literature is whether countries would do it which is why there are huge debates on the EU, UK, China, etc agreeing to a waiver~~

### WTO

#### 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~~

~~Halaijan 13~~

~~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~~](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~~

### ~~Parallel Imports~~

#### ~~Restricting parallel imports is good—it reduces both inaccessibility and corruption~~

~~Halaijan 13~~

~~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~~](https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil)

~~3. Parallel Importation~~

~~In addition to the compulsory license, another significant TRIPS flexibility is the concept of parallel importation alluded to in Article 6.63 Parallel importation results from price discrimination, where a particular product is sold at different prices in different countries, and is based on the concept of exhaustion.64 Exhaustion, or the first sale doctrine, states that after a sale the prior possessor of a product relinquishes all rights to the product and the new possessor is able to distribute and import it at will.65 Opponents of exhaustion, including pharmaceutical companies, contend that it “decreases profitability and~~ **~~removes the incentive to sell drugs to poor countries at lower prices.~~**~~”66 Further, there is a concern that some~~ **~~corrupt governments~~** ~~of developing countries may resell the discounted drugs received at higher profits to other countries, rather than provide the discounted drugs to their citizens in need.67 TRIPS neither bans nor authorizes parallel importation.68~~

### ~~Data Exclusivity~~

#### ~~Data exclusivity is necessary to ensure effective clinical research~~

~~Bing 21~~

~~Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf~~

~~Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.~~

#### ~~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/~~](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.

#### Tech transfer is a huge alt cause—they don’t have reverse causal evidence that the plan will force or even incentivize companies to release IP

Kay et. al. 5/13 [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.