# 1nc vs KT

### 1NC Must Spec IPRs

#### Interp – The affirmative debater must specify which Intellectual property rights they reduce in a delineated text in the 1AC

#### Violation – They don’t

#### There are different entities within “intellectual property rights”

**Stallman 15** [Did you say "intellectual property"? It's a seductive mirage - gnu project - free software foundation. &nbsp;[A GNU head]&nbsp;. (n.d.). <https://www.gnu.org/philosophy/not-ipr.en.html>.] CB DM

**It has become fashionable to toss copyright, patents, and trademarks**—three separate and different entities involving three separate and different sets of laws—**plus a dozen other laws into one pot and call it “intellectual property”.** The distorting and confusing term did not become common by accident. Companies that gain from the confusion promoted it. The clearest way out of the confusion is to reject the term entirely.

#### Prefer-

#### 1. Shiftiness—Lacking of definition, the aff is vague. Leads to ability to shift advocacies. CX doesn't check because a. they can be sketchy and b. it kills pre-round prep

#### 2. Ground- Hurts my strategy since I’ll err on the side of caution, especially hurts CPs and DAs that may apply to one type of test but not others. Fairness-restricts the choices that the neg has.

#### 3. Clash—Not defining means I don’t know what to run in-round which kills high-quality engagement—absent clash debate becomes two ships passing in the night which is irresolvable—also means vote neg on presumption b/c the aff gets circumvented. Clash key to fairness- if aff gets circumvented, then the aff gets additional route to ballot. Education- allows for critical thinking skills and argument generation.

#### 4. Good Norms- the other side would justify an infinite number of affirmatives because the definition is vague. Fairness- leads to unpredictability which forces underplaying and shallower debates.

#### Voters

#### Fairness because its constitutive of debate

#### DTD – a) norms b) prevents abuse

#### CI- a) judge intervention b) arbitrary brightline

#### No RVI- a) time skew b) chilling effect

#### No 1AR theory- creates 7-6 time skew in the rebuttals which kills fairness

#### CX Doesn’t Check

#### [a] topic ed: asking a million questions about the advocacy means that we don’t get to discuss the central issues of the case or the warrants, that’s what makes the case true

#### [b] They can shift out in CX as I ask disad questions, which is the abuse of my shell.

#### [c] Infinitely regressive – this justifies the aff just saying “if you don’t understand the Plan – ask me about it in cross-x”

#### [d] Not verifiable. We can’t know if they would have actually specified. People are trained in CX to be shady as possible- no way I could get an actual concession.

#### [e] Prep skew –I don’t know what they will be willing to clarify until CX which means I could go 6 minutes planning to read a disad and then get screwed over in CX when they spec something else – means CX can’t check.

### 1NC - PIC

#### Counterplan text: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines except for cannabis, medical marijuana, and medicines containing chemicals from cannabis.

#### It competes – weed is a medicine and is used in medicine

WebMD 20 [WebMD Medical Reference, WebMD is an American corporation known primarily as an online publisher of news and information pertaining to human health and well-being. The site includes information pertaining to drugs. It is one of the top healthcare websites by unique visitors. It was founded in 1998 by internet entrepreneur Jeff Arnold., August 20, 2020, "Medical Marijuana FAQ,", WebMD LLC, https://www.webmd.com/a-to-z-guides/medical-marijuana-faq, 8-21-2021] //WHS MR

What is medical marijuana? Medical marijuana uses the marijuana plant or chemicals in it to treat diseases or conditions. It's basically the same product as recreational marijuana, but it's taken for medical purposes. The marijuana plant contains more than 100 different chemicals called cannabinoids. Each one has a different effect on the body. Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are the main chemicals used in medicine. THC also produces the "high" people feel when they smoke marijuana or eat foods containing it. What is medical marijuana used for? Researchers are studying whether medical marijuana can help treat a number of conditions including: Alzheimer's disease Appetite loss Cancer Crohn's disease Diseases effecting the immune system like HIV/AIDS or Multiple Sclerosis (MS) Eating disorders such as anorexia Epilepsy Glaucoma Mental health conditions like schizophrenia and posttraumatic stress disorder (PTSD) Multiple sclerosis Muscle spasms Nausea Pain Seizures Wasting syndrome (cachexia) But it’s not yet proven to help many of these conditions, with a few exceptions, Bonn-Miller says. "The greatest amount of evidence for the therapeutic effects of cannabis relate to its ability to reduce chronic pain, nausea and vomiting due to chemotherapy, and spasticity [tight or stiff muscles] from MS," Bonn-Miller says. How does it help? Cannabinoids -- the active chemicals in medical marijuana -- are similar to chemicals the body makes that are involved in appetite, memory, movement, and pain. Limited research suggests cannabinoids might: Reduce anxiety Reduce inflammation and relieve pain Control nausea and vomiting caused by cancer chemotherapy Kill cancer cells and slow tumor growth Relax tight muscles in people with MS Stimulate appetite and improve weight gain in people with cancer and AIDS Can medical marijuana help with seizure disorders? Medical marijuana received a lot of attention a few years ago when parents said that a special form of the drug helped control seizures in their children. The FDA recently approved Epidiolex, which is made from CBD, as a therapy for people with very severe or hard-to-treat seizures. In studies, some people had a dramatic drop in seizures after taking this drug. Has the FDA approved medical marijuana? The cannabidiol Epidiolex was approved in 2018 for treating seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. In addition, the FDA has approved two man-made cannabinoid medicines -- dronabinol (Marinol, Syndros) and nabilone (Cesamet) -- to treat nausea and vomiting from chemotherapy. The cannabidiol Epidiolex was approved in 2018 for treating seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. How do you take it? To take medical marijuana, you can: Smoke it Inhale it through a device called a vaporizer that turns it into a mist Eat it -- for example, in a brownie or lollipop Apply it to your skin in a lotion, spray, oil, or cream Place a few drops of a liquid under your tongue How you take it is up to you. Each method works differently in your body. "If you smoke or vaporize cannabis, you feel the effects very quickly," Bonn-Miller says. "If you eat it, it takes significantly longer. It can take 1 to 2 hours to experience the effects from edible products."

### 1NC - DA

#### The weed industry is growing, but needs investors to stay afloat – patents draw in investors and help companies expand

Roberts 20 [Chris Roberts, An award-winning investigative reporter and covered the legalization movement and the cannabis industry with a political economy lens for more than a decade. He launched northern California’s first cannabis-centric print vertical and founded San Francisco’s first dedicated drug-policy column. His work’s been featured in VICE, The Daily Beast, The Guardian, Deadspin, Observer, Curbed, Leafly News, High Times, SF Weekly, and many other places. He hold a master’s degree in politics from Columbia Journalism School, 5-28-2020, "Why Patent Cannabis? For Markets, Mostly.," Forbes, https://www.forbes.com/sites/chrisroberts/2020/05/28/why-patent-cannabis-for-markets-mostly/, 8-21-2021] //WHS MR

On May 20, Charlotte’s Web, the Colorado-based CBD giant and arguably one of the biggest names in legal cannabis, announced that the company was awarded its second federal patent on a cannabis plant. Unlike the company’s 2018 plant patent on a Farm Bill-compliant high-CBD hemp cultivar—which was the first hemp strain to receive federal intellectual property protection—US Patent No. 10,653,085 is a utility patent. This means, after satisfying a more rigorous process, including dropping off thousands of seeds at an official United States depository, Charlotte’s Web now claims as its intellectual property both the cultivar of hemp the company calls CW1AS1 as well as “methods” of plant production and cannabinoid extraction. Okay! But so what? Why patent a hemp strain—why patent two? What does it all mean? Does Charlotte’s Web now have legal claim to the entire CBD game?To the last question, no. And as for what this means, for normal people and cannabis consumers, very little. For patent attorneys or competitors of Charlotte’s Web in the CBD industry, it portends a little more, but just a little. At least for now, cannabis patents like this one aren’t really intended to defend intellectual property in court—which is where a patent has its most practical value. No, this patent is probably meant for the market. Patents like this exist mostly for companies to satisfy and woo investors, for whom a company’s ability to say “Look! I have a patent” might be the difference between signing a check, or not. And like all publicly traded cannabis companies, Charlotte’s Web has a lot of spooked and angry investors who need pleasing. Patents “generate interest in the company, and are something investors would look at,” said Jonathan Hyman, an attorney and partner at the Los Angeles office of Knobbe Martens. Whether Charlotte’s Web would enforce the patent, and how, “remains to be seen,” he added. Company officials were not available to discuss the matter. In a statement provided by Sylvia Tawse, the company’s director of communications, CEO Deanie Elsner said Charlotte’ Web “will continue to pursue patent protection for unique and novel hemp genetics developed by our horticulture division.” Whether that meant there are any pretenders the company plans to sue, she did not say. Though cannabis-related patent applications have been a thing since well before legalization and have tripled since 2015, as IP Watchdog noted, the mere phrase “cannabis patent” can still be triggering in cannabis circles. Patent talk can often lead to galaxy-brain thinking like the “Monsanto is supporting legalization in order to steal cannabis” or the “Philip Morris is buying up land in Humboldt County” conspiracy theories. In the case of Charlotte’s Web, the company’s already locked up what’s probably its most valuable asset: its name. Charlotte’s Web is named for Charlotte Figi, the sufferer of childhood epilepsy who enjoyed relief from her symptoms after taking an extract of high-CBD cannabis grown by the Stanley brothers (and who died earlier this month after contracting COVID-19). The world came to know Charlotte Figi and the Stanley brothers, seven photogenic Coloradans whose first names all begin with J, after they were prominently featured in a 2014 CNN special hosted by Sanjay Gupta. A very famous children’s book and a very famous and recognizable name, the company was sure lock down the name “Charlotte’s Web” with a trademark—one the company is currently defending in federal court, after a rival company dared market CBD products called Charlotte’s Web. That’s what patents are for in terms of the law. But markets are another matter—and it’s worth observing that the company went public after securing its first patent. Like almost all publicly traded companies in the cannabis sector, Charlotte’s Web is stuck in high-loss doldrums after hitting early peaks. For the past week, shares in Charlotte’s Web have been trading in the $7 to $9 range in the Toronto Stock Exchange. That’s a big gain from the $4.24 seen at the company’s mid-March nadir, but still far below last summer’s high-water mark of $28.21, set in August. Despite being sold in more than 11,000 stores, the company still lost $1.7 million in 2020—a hit smaller than other companies in the cannabis sector, but still in the red. Patenting hemp genetics and the processes to achieve them won’t be enough to rescue the rest of the company’s lost value. But if Charlotte’s Web wants to be a global CBD brand, with product in supermarkets and convenience stores all over the globe—and why wouldn’t it?—this means something. "Having this patent, that they can wave around and say, 'Hey, we've got coverage on it, and it's the best variety [of CBD rich hemp] that you're going to get,’ ” said Andrew Merickel, who holds a Phd in neuroscience and is also an attorney and partner at the San Francisco office of Knobbe Martens. “That’s pretty valuable.” How valuable? That’s all up to the logic of the market.

#### Cannabis is key to agricultural tech innovation – k2 long term sustainability and security

Yamazaki 17 Kevin Yamazaki (founder and CEO of [Sidebench](http://sidebench.com/), a leading digital product and venture studio that creates custom software and apps), 3-27-2017, "High Tech: How Marijuana Legalization Breeds Innovation," Observer, https://observer.com/2017/03/high-tech-how-marijuana-legalization-breeds-innovation/, SJBE

With the competition blazing and increased legalization on the horizon, we can expect to see the weed market become a hotbed for tech innovations. Forecasts indicate that revenue in the U.S. from medical marijuana alone will reach at least [$10.8 billion by 2018](http://fortune.com/2016/02/01/marijuana-sales-legal/). When states expand to allow recreational use, this number will surely increase. As investors become more comfortable deploying capital around cannabis, tech will revolutionize the marijuana ecosystem for producers, distributors, and consumers alike. The future of marijuana innovation Innovation has begun to outpace legalization as tech organizations make groundbreaking strides in researching and developing applications for marijuana. For example, [Kalytera](https://kalytera.co/) is exploring how cannabidiol — a non-psychoactive cannabinoid with a number of potential medical applications — can be used to target diseases such as obesity and osteoporosis. The findings of such research could transform how people cope with chronic illness and pain. Companies are also experimenting with improvements in [weed-growing processes](http://www.ibtimes.com/legal-marijuana-cultivation-driving-technology-revolution-industrial-agriculture-1925167). Cannabis is a finicky crop, so the ability to fine-tune growing processes could generate products far superior to today’s. Several organizations are devising smart, energy-efficient systems that automatically adjust growing environments according to changes in moisture, temperature, and sunlight. Meanwhile, data-capture technologies enable growers to identify optimal conditions for their plants, leading to larger and better-quality yields. The primary speed bump for the industry at this point is that marijuana is still classified as a Schedule I drug and is illegal at the federal level. Even if this factor doesn’t inhibit marijuana-centric technology innovation directly, it certainly has a strong indirect effect, as many potential financiers (and entrepreneurs) are scared away by either fear of prosecution or skepticism about the industry’s stability. That said, as more states allow for medical marijuana or legalize the drug entirely, the potential market size for marijuana-centric products expands as well. Perhaps more importantly, with some form of state legalization becoming the norm rather than the exception, there is a degree of safety in numbers. Assuming we see the trend of legalization for medical and recreational uses continue, production will inevitably become an even bigger business. Technology will play an increasing role in ensuring quality, consistency, and efficiency on the production side. We’re already seeing startups like [Cannafuse](http://cannafuse.com/) and [Teewinoit Life Sciences](https://tlscorp.com/) focusing on providing a tech-enabled scientific approach to the mass scientific production and distribution of cannabis. Advances in the irrigation systems, efficiency lamps, and data tracking processes used to grow marijuana may have far-reaching effects beyond the cannabis industry. Industrial farmers could adopt these techniques to increase their outputs and reduce energy expenses, while building managers can use them to lower energy loads from their properties. On the consumer side, the medical marijuana industry, in particular, will likely see an explosion of on-demand delivery services. Consumers are accustomed to using their smartphones to book cars, buy groceries, and mail packages. Why wouldn’t they receive their medical marijuana that way, too? Expect to see personalized services as well — think apps that recommend strains of marijuana on the basis of your preferences. Apps such as [MassRoots](https://massroots.com/) bring the social media aspect to what is, for many people, a social product by connecting weed enthusiasts to one another through news updates and other types of content. Even Microsoft is throwing its hat into the ring with [marijuana tracking software](http://www.businessinsider.com/microsoft-marijuana-tracking-software-2016-11) that ensures growers comply with their tax obligations and prevents legally grown pot from ending up on the black market. As the cannabis industry expands, the opportunities for growth are diverse and extensive. Tech-enabled companies will inevitably spur that growth, driving breakthroughs in medicine, crop development, and customer experiences. The momentum created by legalization will transform a once-taboo drug into a mainstream commodity, and the tech world stands to benefit enormously.

#### Extinction – food insecurity causes conflict and goes nuclear

FDI 12 FDI Team, 25 May 2012, “Food and Water Insecurity: International Conflict Triggers & Potential Conflict Points,” Future Directions International, <https://www.futuredirections.org.au/publication/international-conflict-triggers-and-potential-conflict-points-resulting-from-food-and-water-insecurity/>, SJBE

There is little dispute that conflict can lead to food and water crises. This paper will consider parts of the world, however, where food and water insecurity can be the cause of conflict and, at worst, result in war. While dealing predominately with food and water issues, the paper also recognises the nexus that exists between food and water and energy security. There is a growing appreciation that the conflicts in the next century will most likely be fought over a lack of resources. Yet, in a sense, this is not new. Researchers point to the French and Russian revolutions as conflicts induced by a lack of food. More recently, Germany’s World War Two efforts are said to have been inspired, at least in part, by its perceived need to gain access to more food. Yet the general sense among those that attended FDI’s recent workshops, was that the scale of the problem in the future could be significantly greater as a result of population pressures, changing weather, urbanisation, migration, loss of arable land and other farm inputs, and increased affluence in the developing world. In his book, Small Farmers Secure Food, Lindsay Falvey, a participant in FDI’s March 2012 workshop on the issue of food and conflict, clearly expresses the problem and why countries across the globe are starting to take note. . He writes (p.36), “…if people are hungry, especially in cities, the state is not stable – riots, violence, breakdown of law and order and migration result.” “Hunger feeds anarchy.” This view is also shared by Julian Cribb, who in his book, The Coming Famine, writes that if “large regions of the world run short of food, land or water in the decades that lie ahead, then wholesale, bloody wars are liable to follow.” He continues: “An increasingly credible scenario for World War 3 is not so much a confrontation of super powers and their allies, as a festering, self-perpetuating chain of resource conflicts.” He also says: “The wars of the 21st Century are less likely to be global conflicts with sharply defined sides and huge armies, than a scrappy mass of failed states, rebellions, civil strife, insurgencies, terrorism and genocides, sparked by bloody competition over dwindling resources.” As another workshop participant put it, people do not go to war to kill; they go to war over resources, either to protect or to gain the resources for themselves. Another observed that hunger results in passivity not conflict. Conflict is over resources, not because people are going hungry. A study by the International Peace Research Institute indicates that where food security is an issue, it is more likely to result in some form of conflict. Darfur, Rwanda, Eritrea and the Balkans experienced such wars. Governments, especially in developed countries, are increasingly aware of this phenomenon. The UK Ministry of Defence, the CIA, the US Center for Strategic and International Studies and the Oslo Peace Research Institute, all identify famine as a potential trigger for conflicts and possibly even nuclear war.

### 1NC – 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.”

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

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

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

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

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

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

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

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

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

But the Biden policy is bad for many other reasons.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Changing our environment

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

## 1NC-Case

#### Magnitude first—we must calculate future descendants

Matheny 7 (Jason, Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University, “Reducing the Risk of Human Extinction,” Risk Analysis, Vol 27, No 5)

**Even if extinction events are improbable, the expected values of countermeasures could be large, as they include the value of all future lives. This introduces a discontinuity between** the CEA of **extinction and nonextinction risks.** **Even though the risk to any existing individual of dying in a car crash is much greater than the risk of dying in an asteroid impact, asteroids pose a much greater risk to the existence of future generations** (we are not likely to crash all our cars at once) (Chapman, 2004). **The “death-toll” of an extinction-level asteroid impact is the population of Earth, plus all the descendents of that population who would otherwise have existed if not for the impact. There is thus a discontinuity between risks that threaten 99% of humanity and those that threaten 100%.**

### No Inherency: Plan already done

#### WTO already did the AFF – Doha Declaration nullifies medical patents for developing countries struggling with pricing

**World Trade Organization 17** (World Trade Organization – you should know who this is, “WTO IP rules amended to ease poor countries’ access to affordable medicines”, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm>, 23 January 2017, EmmieeM)

**An amendment to** the agreement on **intellectual property entered** into force today (23 January) **securing for developing countries a legal pathway to access affordable medicines under WTO rules**.

The amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement marks the first time since the organization opened its doors in 1995 that WTO accords have been amended.

The WTO Secretariat has received in recent days notifications from five members that they have ratified the protocol amending the WTO TRIPS Agreement. These notifications — from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam — brought to two-thirds the number of WTO members which have now ratified the amendment. The two-thirds threshold was needed to formally bring the amendment into the TRIPS Agreement.

Members took the decision to amend the TRIPS Agreement **specifically to adapt** the **rules** of the global trading system **to the public health needs of people in poor countries**. This action follows repeated calls from the multilateral system for acceptance of the amendment, most recently by the United Nations General Assembly High-Level Meeting on Ending AIDS in June 2016.

“This is an **extremely important amendment**. It **gives legal certainty that generic medicines can be exported at reasonable prices to satisfy the needs of countries with** no pharmaceutical production capacity, or those with **limited capacity**. By doing so, **it helps the most vulnerable** access the drugs that meet their needs, helping to deal with diseases such as HIV/AIDS, tuberculosis or malaria, as well as other epidemics. I am delighted that WTO members have now followed through on their commitment and brought this important measure into force,” said WTO Director-General Roberto Azevêdo. In video statements available here, some of the key players share their thoughts on the TRIPS amendment.

Unanimously adopted by WTO members in 2005, the protocol amending the TRIPS Agreement **makes permanent a mechanism to ease poorer WTO members’ access to affordable generic medicines produced in other countries**. The amendment **empowers** importing **developing and least-developed countries facing public health problems and lacking** the **capacity to produce drugs** generically to seek such medicines from third country producers under "compulsory licensing" arrangements. Normally, most medicines produced under compulsory licences can only be provided to the domestic market in the country where they are produced. This amendment allows exporting countries to grant compulsory licences to generic suppliers exclusively for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.

“As important as trade policy is, health and well-being must take precedence,” said Amina Mohamed, Kenya’s Foreign Minister who chaired the WTO General Council at the time when the amendment was approved in December 2005. “WTO members recognise this and have proven how seriously they take health issues by ratifying and putting into force an amendment to WTO rules which will facilitate access to essential medicines in low income countries.”

The amendment provides **a secure and sustained legal basis for** both potential exporters and importers to adopt legislation and establish the means needed to allow **countries** with limited or no production capacity **to import affordable generics from countries where pharmaceuticals are patented**. More and more WTO members are taking practical steps to implement the system in their laws. The bulk of global medicine exports is covered by laws enabling exports under this system, opening up new options for potential beneficiaries to access a wider range of potential suppliers and enabling new, innovative procurement strategies.

### AT Developing Countries

#### It doesn’t solve – there are tons of barriers to access to vaccines, especially in developing countries. Even if it’s legal to make generics, lack of raw materials, expertise, and production facilities mean the plan is a drop in the bucket for responding to global covid

Herper et al 21 [Matthew Herper Senior Writer, Medicine, Editorial Director of Events at STAT. "Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive." https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/]

Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said.

“My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.”

That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents.

Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines.

“We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.”

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### IPR harmonization undermines the ability to market counterfeit drugs.

**Ferrill**, Spring **2007** (Elizabeth – Law Clerk to the Honorable Liam O’Grady, Magistrate Judge, U.S. District Court for the Eastern District of Virginia, Clearing the Swamp for Intellectual Property Harmonization: Understanding and Appreciating the Barriers to Full TRIPS Compliance for Industrializing and Non-Industrializing Countries, University of Baltimore Intellectual Property Law Journal, p. Lexis-Nexis)

In 1994, the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was created. n2 TRIPS requires all 150 members n3 of the World Trade Organization (WTO) to provide minimal standards of protection for intellectual property (IP). n4 TRIPS is part of the larger WTO framework that promotes trade liberalization. n5 Through a series of [\*138] agreements designed to lower trade tariffs and eliminate other barriers to trade, the WTO strives to improve standards of living of all members, expand production of and trade in goods and services, and sustain development, especially in developing countries worldwide. n6 Most economists view trade liberalization as a means to wealth maximization. n7 If each country produces what it is best at producing, then output of efficiently produced products is higher worldwide. n8 Hence, countries that are the most efficient producer of a certain good would produce that good and trade with other countries for those goods it produces more efficiently, all without the cost of trade barriers. n9 Yet, countries are reluctant to unilaterally lower their trade barriers. n10 To avoid this problem, the WTO established rules for reciprocal [\*139] lowering of trade barriers. n11 In the realm of intellectual property, harmonization, defined as the standardization of intellectual property laws, is analogous to trade liberalization. If every country were to respect and protect the intellectual property rights of all other countries, inventors and creators would have the maximum incentive to create, mutually benefiting the world. More than a decade after its ratification, there remains tension and widespread noncompliance with TRIPS, as many countries continue to not enforce foreign IP rights, despite the potential benefits of harmonization. Counterfeiting, n12 which could be mitigated by such enforcement, costs the world economy about $ 600 billion annually and includes a multitude of products, such as pharmaceuticals, DVDs, software, toys, spare parts for cars and aircraft, and apparel. n13 This prompts the question of why complying with TRIPS and curbing counterfeiting and pirating has been so difficult over the past decade. There are a number of possible explanations.

#### Counterfeit drugs bolster antibiotic resistance.

**Washington Post**, 2/5/**2013** (How fake drugs cause the spread of untreatable TB in developing countries, p. <http://www.washingtonpost.com/blogs/worldviews/wp/2013/02/05/how-fake-drugs-cause-the-spread-of-untreatable-tb-in-developing-countries/>)

Tuberculosis, a disease that destroys lung tissue, is more commonly associated with the Victorian era than with the modern age. Today, TB can be cured with several heavy rounds of antibiotics, but the emergence of drug-resistant strains of the disease in India and other countries around the world have raised alarm among health workers. One culprit in the rise of untreatable TB is counterfeit drugs, which can undermine treatment efforts by packing insufficient active ingredients to fully kill off bacteria, breeding new, stronger super-strains of the disease. Though the scourge of counterfeit malaria drugs has shaken up the public health world in recent years, researchers are now turning their attention to fake TB drugs, as well, as cases of drug-resistant TB have emerged in both the developing world and in higher-income cities such as London and Moscow. A new study published in the International Journal of Tuberculosis and Lung Disease found that 16.6 percent of tuberculosis drugs in Africa, 10.1 percent in India and 3.9 percent in other middle-income countries were “failures,” meaning they had less than 80 percent of the active ingredient necessary to treat the disease. “The biggest determinant of drug quality is wealth [of the country],” said one of the study’s lead authors, Roger Bate, an economist who researches international health policy with the American Enterprise Institute. The study analyzed drugs in 17 countries — those that are home to about 60 percent of the world’s total cases of multidrug resistant TB. Over the past five years, teams of researchers have been purchasing antibiotics at random pharmacies in each of the countries and testing the medicines’ active ingredients. (To find the samples for middle-income countries, researchers visited Bangkok, Beijing, Istanbul, Moscow and Sao Paulo.) When patients take these fake drugs, they remain sick longer or die. In some patients, germs multiply and morph into new strains, making them harder and more expensive to treat.