# 1NC 5-off

### 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 - K

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

Mannathukkaren 14

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

\*Evidence is edited to correct gendered language\*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.**

# Case

### Case

**FW-Moral uncertainty means preventing extinction should be our highest priority.  
Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.

#### SV is good but Util is a lexical prereq:

#### if no one is alive we can’t do anything about anything:

#### We can’t formulate an ethical theory if no one is alive

#### If actors fear for bodily security, then an ethical theory can’t be legitimate

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

#### 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.

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

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

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

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

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

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

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

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

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

#### 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.

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

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

3. Definitional Ambiguities & Ambiguities in Scope

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

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