# 1nc vs Cabot

#### Framework:

#### I value Morality as the Resolution uses the word “ought” invoking a moral obligation in action

#### Evaluate Morality through the Value Criterion of Maximizing Expected Well-Being

#### I agree with the affirmative framing for this round, however urge a neg ballot

#### For me to win this round, my job is to explain how negating the resolution maximizes well being for more people. Furthermore, I also agree with my opponents point about preventing extinction.

## C1 - Investment and Innovation

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The aff crushes innovation in the pharma sector---incentivizes them to focus on non-important issues.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

## C2 – Counterfeit Drugs

#### Strong trademark protection under intellectual property rights is the best defense against counterfeit drugs.

**Powell**, February **2010** (Adam – Research Fellow for the Law & Bioscience Project, J.D. Candidate at the University of California, Hastings College of the Law, Benchmark Legislation: A Measured Approach in the Fight Against Counterfeit Pharmaceuticals, Hastings Law Journal, p. Lexis-Nexis)

Traditionally, the first line of defense for pharmaceutical companies is a portfolio of strong intellectual property rights. Much of the legislation and criminal sanctions discussed below depend on pharmaceutical companies adequately protecting their intellectual property. This provides the company with private redress as well as the ability to fully utilize government aid and criminal prosecution. Some forms of intellectual property are uniquely suited for preventing counterfeit drugs from entering the market. Antoinette Konski, an expert in global intellectual property protection, asserts that, while patents are considered the first line of defense, they are actually less practical at enforcing rights against counterfeiters than other types of intellectual property protection. n122 Patent protection rewards innovation and generally grants the patent holder a right to exclude others from manufacturing, using, importing, selling, or offering for sale an exact or close copy of a patented technology. n123 However, patent protection is relatively ineffective for [\*766] patented drugs because counterfeiters do not copy the active ingredient and usually replace it with a cheaper ingredient. n124 Additionally, generic drug manufacturers, who often manufacture drugs after the patent term expires, have no recourse through the patent system. n125 By contrast, trademarks seek to protect exactly what counterfeiters target: brand recognition. For this reason, Konski argues that trademark protection is the most valuable type of intellectual property that can be used to combat counterfeiting. n126 A pharmaceutical company may obtain a trademark on the color or shape of pills as well as brand names, designs, and symbols. n127 This allows pharmaceutical manufacturers, including generic drug companies, to register and protect all unique aspects of their products. In contrast to most patent lawsuits, in many countries the trademark owner can have counterfeit goods, documents, and equipment immediately seized after bringing suit. n128 Furthermore, if a person knowingly infringes a trademark in the process of trafficking counterfeit drugs, criminal sanctions are increased from a maximum of three years in prison to a maximum of ten years in prison. n129 In addition, obtaining and enforcing trademark rights is typically much less costly and time-consuming than patent prosecution and infringement actions. n130 This unique combination makes trademarks particularly well suited as a first line of defense for drug manufacturers. Copyrights only protect works of authorship such as literary, musical, dramatic, pictorial, graphic, sculptural, cinematic, and architectural works. n131 As a result, only package inserts may be protected and are of little use in preventing the drug from reaching the public. n132 In the world of counterfeit drugs, that amounts to virtually no protection. Thus, in addition to educating customers, pharmaceutical companies can best protect their intellectual property and ensure maximum punishments for criminals by maintaining strong trademarks.

#### Next is harmonization. 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.

# Case

### No Solvency

#### 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.”

### Solvency and Case Turn

#### List of supply shortages – there is no way the aff solves, but they decrease available vaccines.

[Laurie Garrett 21, (Columnist at Foreign Policy and former senior fellow for global health at the Council on Foreign Relations). 5/7/21, Stopping Drug Patents Has Stopped Pandemics Before, Foreign Policy, <https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/>] Justin

The vaccines aren’t easy to make. Manufacturing errors in a Maryland Emergent BioSolutions factory caused an 86 percent plummet in Johnson & Johnson vaccine supplies in early April. Complex steps in the process of isolating, purifying, preserving, storing, and delivering COVID-19 immunizations are each error-prone and require long lists of specialized chemicals and machinery.

The world is in the grips now of pipette tips shortages—used to suck out chemicals and viral samples from test tubes in key steps of vaccine making. Syringes are in short supply, prompting vaccinators to toss vaccine supplies for lack of means to administer them. The sterile containers used to hold vaccines are running out. From the earliest days of the 2020 pandemic, the sorts of protective gear and machinery vaccine researchers and makers require have been in short supply, exacerbated by trade tensions between the United States and China. Swabs used for COVID-19 testing and all aspects of equipment cleaning in sterile conditions are held up in a grotesque family dispute in Maine. There aren’t enough centrifuge tubes made worldwide to spin down cell samples. Moderna and Pfizer are constantly scrambling to find the ingredients used to make the microscopic fatty balls, called liposomes, that house the mRNA molecules and carry them safely into the bloodstream. Even the nucleic acids used to construct mRNA and a long list of special enzymes used to purify those samples are in horribly short supply, largely because their use overlaps with the manufacture of COVID-19 tests. Because such delicate chemicals and proteins must be handled at deep-freeze temperatures and transported swiftly for immediate use, the entire supply chain is vulnerable to the simplest of catastrophes: weather at an airport, a car crash that blocks truck traffic, power outages, or competition for cargo space.

Although waiving TRIPS requirements on COVID-19 vaccines is a spectacular, historic gesture, would-be generic makers worldwide will soon discover their efforts are stymied not by patents but for want of Avanti Polar Lipids’ liposome ingredients, Flexsafe RM special bags to hold liquid vaccines in bulk, phosphate-buffered saline solution, Distearoylphosphatidylcholine for liposome-making, 5’ cap for mRNA made by TriLink BioTechnologies, RNA polymerases—the list goes on, and on, and on. As the number of would-be vaccine makers grows, so will demand for thousands of such items, putting pressure on companies that are, in many cases, mom-and-pop operations. Worse, pressure on supplies critical for COVID-19 vaccine making is already resulting in a production loss of vital medicines for other diseases.

#### The aff causes a scramble for limited resources by manufacturers with no experience – turns case.

Breuninger 21 [Kevin; Specialist at CNBC; “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues,” CNBC; 5/7/21; <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] Justin

“Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague letter posted on LinkedIn. “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.”

Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients.

“Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote.

He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.”

“It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote.

“Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.

#### Prevents distribution---causes vaccine hesitancy.

Newey et al 21 [Sarah Newey*;* Anne Gulland*;* Jennifer Rigby, (GLOBAL HEALTH SECURITY CORRESPONDENTS at the telegraph) *and* Samaan Lateef (Reporting IN INDIA) 6/1/21, Vaccinating the world: the obstacles hindering global rollout – and how to overcome them, Telegraph, <https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/>] Justin

[Vaccine hesitancy has also reared its head](https://www.telegraph.co.uk/global-health/science-and-disease/hesitancy-hard-wired-us-indulge-now-peril/), with concerns around rare blood clots linked to the AstraZeneca and J&J vaccines hitting public confidence in Africa. The Democratic Republic of Congo sent 1.3m unwanted doses to countries including Togo and Senegal before they expired in late June, while Malawi destroyed 20,000 unused shots last month as hesitancy hit rollout. “There were some assumptions in the public health community that this is such a bad pandemic... that this will change people’s minds if they were ever hesitant about vaccines,” Prof Heidi Larson, director of the Vaccine Confidence Project, told a Devex event. “Well, it hasn’t really – in fact, the groups and the questioning around vaccines and some of the anti sentiments have actually escalated.” There are also growing concerns that the AstraZeneca and J&J vaccines may be viewed as the “cheap relation” compared to the new mRNA vaccines produced by Pfizer and Moderna. Given the former make up the bulk of Covax’s supply and are far easier to distribute in the developing world, this is a substantial hurdle. “The AstraZeneca row has significantly impacted confidence – not just across Africa, but around the world,” says Dr Ayoade Alakija, co-chair of the Africa Union Vaccine Delivery Alliance. “But there is no choice here [to pick a different vaccine].” However, back in Kumasi, Mr Nyarko says it is supply rather than confidence that is currently undermining his district’s roll out. And with no clear picture on when more shots will arrive, he’s left with few options. “All we can do for now is pray that Ghana can secure another batch,” he says. “We are praying that the UK and Europe will help us.

### Pharma Retaliation

#### 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 – Turns Case and makes the situation far worse

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

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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.

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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.