# Greenhill R1 – 1NC v Presentation AB

## 1

#### The standard is maximizing expected well-being. Prefer it:

#### [2] Util is a lexical pre-requisite to any other framework-threats to bodily security and life preclude the ability for moral actors to effectively utilize and act upon other moral theories since they are in a constant state of crisis that inhibit the ideal moral conditions which other theories presuppose – so, util comes first and my offense outweighs theirs under their own framework.

#### [3] Pleasure and pain are the starting point for moral reasoning—they’re our most baseline desires and the only things that explain the intrinsic value of objects or actions

Moen 16, Ole Martin (PhD, Research Fellow in Philosophy at University of Oslo). "An Argument for Hedonism." Journal of Value Inquiry 50.2 (2016): 267.

Let us start by observing, empirically, that **a widely shared judgment about intrinsic value** and disvalue **is that pleasure is intrinsically valuable and pain is intrinsically disvaluable**. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels**, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” **are** here **understood inclusively**, as encompassing anything hedonically positive and anything hedonically negative. 2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store**, I might ask: “What for**?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. **The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good**. 3 As Aristotle observes: “**We never ask** [a man] **what** his **end is in being pleased, because we assume that pleasure is choice worthy in itself**.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that **if something is painful, we have a sufficient explanation of why it is bad**. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value**. Although **pleasure and pain thus seem to be good candidates for intrinsic value and disvalue**, several objections have been raised against this suggestion: (1) that pleasure and pain have instrumental but not intrinsic value/disvalue; (2) that pleasure and pain gain their value/disvalue derivatively, in virtue of satisfying/frustrating our desires; (3) that there is a subset of pleasures that are not intrinsically valuable (so-called “evil pleasures”) and a subset of pains that are not intrinsically disvaluable (so-called “noble pains”), and (4) that pain asymbolia, masochism, and practices such as wiggling a loose tooth render it implausible that pain is intrinsically disvaluable. I shall argue that these objections fail. Though it is, of course, an open question whether other objections to P1 might be more successful, I shall assume that if (1)–(4) fail, we are justified in believing that P1 is true itself a paragon of freedom—there will always be some agents able to interfere substantially with one’s choices. The effective level of protection one enjoys, and hence one’s actual degree of freedom, will vary according to multiple factors: how powerful one is, how powerful individuals in one’s vicinity are, how frequent police patrols are, and so on. Now, we saw above that what makes a slave unfree on Pettit’s view is the fact that his master has the power to interfere arbitrarily with his choices; in other words, what makes the slave unfree is the power relation that obtains between his master and him. The difﬁculty is that, in light of the facts I just mentioned, there is no reason to think that this power relation will be unique. A similar relation could obtain between the master and someone other than the slave: absent perfect state control, the master may very well have enough power to interfere in the lives of countless individuals. Yet it would be wrong to infer that these individuals lack freedom in the way the slave does; if they lack anything, it seems to be security. A problematic power relation can also obtain between the slave and someone other than the master, since there may be citizens who are more powerful than the master and who can therefore interfere with the slave’s choices at their discretion. Once again, it would be wrong to infer that these individuals make the slave unfree in the same way that the master does. Something appears to be missing from Pettit’s view. If I live in a particularly nasty part of town, then it may turn out that, when all the relevant factors are taken into account, I am just as vulnerable to outside interference as are the slaves in the royal palace, yet it does not follow that our conditions are equivalent from the point of view of freedom. As a matter of fact, we may be equally vulnerable to outside interference, but as a matter of right, our standings could not be more different. I have legal recourse against anyone who interferes with my freedom; the recourse may not be very effective—presumably it is not, if my overall vulnerability to outside interference is comparable to that of a slave— but I still have full legal standing.68 By contrast, the slave lacks legal recourse against the interventions of one speciﬁc individual: his master. It is that fact, on a Kantian view—a fact about the legal relation in which a slave stands to his master—that sets slaves apart from freemen. The point may appear trivial, but it does get something right: whereas one cannot identify a power relation that obtains uniquely between a slave and his master, the legal relation between them is undeniably unique. A master’s right to interfere with respect to his slave does not extend to freemen, regardless of how vulnerable they might be as a matter of fact, and citizens other than the master do not have the right to order the slave around, regardless of how powerful they might be. This suggests that Kant is correct in thinking that the ideal of freedom is essentially linked to a person’s having full legal standing. More speciﬁcally, he is correct in holding that the importance of rights is not exhausted by their contribution to the level of protection that an individual enjoys, as it must be on an instrumental view like Pettit’s. Although it does matter that rights be enforced with reasonable effectiveness, the sheer fact that one has adequate legal rights is essential to one’s standing as a free citizen. In this respect, Kant stays faithful to the idea that freedom is primarily a matter of standing—a standing that the freeman has and that the slave lacks. Pettit himself frequently insists on the idea, but he fails to do it justice when he claims that freedom is simply a matter of being adequately (and reliably) shielded against the strength of others. As Kant recognizes, the standing of a free citizen is a more complex matter than that. One could perhaps worry that the idea of legal standing is something of a red herring here—that it must ultimately be reducible to a complex network of power relations and, hence, that the position I attribute to Kant differs only nominally from Pettit’s. That seems to me doubtful. Viewing legal standing as essential to freedom makes sense only if our conception of the former includes conceptions of what constitutes a fully adequate scheme of legal rights, appropriate legal recourse, justiﬁed punishment, and so on. Only if one believes that these notions all boil down to power relations will Kant’s position appear similar to Pettit’s. On any other view—and certainly that includes most views recently defended by philosophers—the notion of legal standing will outstrip the power relations that ground Pettit’s theory.

#### [6] Extinction outweighs

Pummer 15 [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

## 2

#### The member nations of the World Trade Organization except for the United States ought to [reduce intellectual property protections for medicines].

#### The United States ought to [reduce intellectual property protections for medicines] through a supreme court decision by petitioning the PTAB and getting a formal ruling from APJs.

#### APJs have the authority to rule on intellectual property---the CP solves case.

Mosier 21 [Kevin; 8/9/21; “*Supreme Court Finds Constitutional Violation in Patent Challenges, But Provides Quick Fix*,” JDSupra, <https://www.jdsupra.com/legalnews/supreme-court-finds-constitutional-4702991/>] Justin

For those familiar with inter partes review—or IPR, as it is known—the recent Supreme Court decision in U.S. v. Arthrex was much anticipated because it carried with it the potential to upend the entire IPR system. IPR has been popular with patent challengers and trial court defendants since 2012, when the America Invents Act (“AIA”) took effect. Any person or entity may challenge the validity of a patent by petitioning the Patent Trial and Appeals Board (“the PTAB”). Although IPR petitioners are limited as to the grounds for invalidity they may present, IPR remains an efficient alternative to district court litigation on issues that can overlap with an IPR petition. If the PTAB determines there is a reasonable likelihood that the petitioner would prevail on least one of the patent claims challenged in the petition, the PTAB will institute the petition and hold a trial-like proceeding to determine whether the challenged claims are invalid. Active litigations concerning the same patent are often stayed, that is, put on ice, pending results of the IPR. IPRs are conducted by a panel of administrative patent judges (“APJs”) who are appointed by the Secretary of Commerce. Arthrex, a maker of surgical equipment, argued that APJs are “principal officers” under the Constitution because they wield significant authority and lack meaningful oversight. If APJs are principal officers, they must be appointed by the President and confirmed by the Senate. A Supreme Court holding that APJs are principal officers could have theoretically invalidated all IPR decisions and dramatically altered the IPR system. The lower appellate court—the Federal Circuit—had already determined that APJs are principal officers, but sought to remedy the constitutional concerns in a way that preserved the IPR system. As we wrote at the time, the Federal Circuit reinterpreted statutory limitations on at-will removal of APJs, rendering APJs “inferior officers” who do not need to be appointed by the President and confirmed by the Senate. Although the Supreme Court agreed with the Federal Circuit that the AIA as written caused the APJs to be principal officers, it reversed the Federal Circuit’s decision. The majority opinion held that the root of the constitutional violation was the lack of review authority by a superior officer. The court fixed this problem by bestowing upon the Director of the United States Patent and Trademark Office the unilateral authority to review all IPR decisions so that APJs are properly classified as inferior officers. U.S. v. Arthrex is highly significant for patent owners and IPR petitioners. First and foremost, patent owners who hoped that the IPR system would be scrapped or at least significantly altered did not get their wish. IPR has survived the day and will likely remain as popular as ever with patent challengers and parties accused as infringers. IPR litigants who were hoping for a new hearing before a new panel of APJs did not get their wish either: the Supreme Court made clear that this decision does not entitle prior litigants to new hearings. This decision does, however, present litigants with a vehicle to request that the Director review an IPR determination. All IPR determinations are subject to review and possibly modification or reversal by the Director. Previously, a final written decision by the PTAB was subject to a request for rehearing and then potentially an appeal to the Federal Circuit. Now, as explained in a PTAB Q&A, a party may request either a Director review or panel rehearing, but not both. The Director may also choose to review a final written decision on his or her own initiative. Like a panel rehearing, the Director’s review is appealable to the Federal Circuit. So what next? For now, not much will change aside from potentially greater influence being wielded by the Director. The Supreme Court did not issue guidelines for this additional avenue of review. The decision in Arthrex is notable for providing a simple, direct fix to a constitutional infirmity and not the sea change that those sympathetic to Arthrex’s cause were hoping for.

#### Circumvention is inevitable---the aff is unconstitutional and companies use that as a sword to prevent loss of IP.

Brown 21 [Delphine; 7/21/21; Partner in the firm's Litigation Practice Group, and a member of its Intellectual Property Practice Team. With over twenty years of trial experience, Delphine's practice focuses on complex intellectual property and technology cases, with extensive experience in the life sciences industry. Delphine has served as lead counsel for several global pharmaceutical companies in Hatch-Waxman litigation and trials involving dozens of drug products, dosage forms and delivery systems. Delphine’s lead counsel expertise also includes patent litigation involving biotech, medical device, computer hardware and software, design and business method patents, and counseling of established and emerging biotechnology companies regarding intellectual property, regulatory and litigation issues. Delphine has served as lead trial counsel in complex trademark and copyright infringement, misappropriation of trade secrets, and unfair competition cases. Delphine believes that the key to being the best litigator and trial lawyer is always keeping her "eyes on the prize" which she defines with her clients as accomplishing both legal victory and strategic objectives to get the client back to running its business as quickly as possible. A corporate client once remarked to Delphine's parents at her birthday party that "if Delphine wasn't such a good lawyer, we wouldn't have become such great friends." Delphine has three decades of experience representing both U.S. and foreign corporations in federal and state courts nationwide in pretrial proceedings, trials and appeals, and in arbitration proceedings. Delphine frequently publishes thought leadership and speaks on intellectual property issues. Delphine received her bachelors degree from Princeton University and her J.D. from St. John's University School of Law. In her spare time, she serves on the boards of several private foundations, and the CT Selection Committee for the Princeton Prize in Race Relations, as well as a USA swimming official. Delphine also enjoys skiing, golf, tennis and classic wood boats; “*Powerhouse Points: Will TRIPS Waiver of IP Protection for COVID-19 Vaccines Serve Global Need*,” Freeborn, <https://www.freeborn.com/perspectives/powerhouse-points-will-trips-waiver-ip-protection-covid-19-vaccines-serve-global-need>] Justin

Despite the current U.S. administration’s apparent support for waiving IP protection for COVID-19 vaccines, the response in the U.S. to the proposed broader waiver would most certainly involve intense lobbying by pharmaceutical companies to reverse or severely narrow its effect. The U.S. Congress has already introduced legislation to require Congressional approval of any waiver, and prohibit the use of federal funds to support a waiver.[vi] If the U.S. government seeks to enforce a TRIPS waiver, the takings clause of the Fifth Amendment to the U.S. Constitution could be used by U.S. companies as a sword to prevent the loss of intellectual property rights without compensation. In addition, compulsory licenses issued by foreign governments to U.S.-based pharmaceutical companies would be the subject of jurisdictional challenges and lack effective enforcement mechanisms.

## 3

#### Bipartisan infrastructure bill passing now but PC is needed – there is no margin for error.

Kapur et al 9/8 [Sahil, Frank Thorp, and Leigh Ann Caldwell; 9/8/21; Sahil Kapur is a national political reporter for NBC News, Frank Thorp V is a producer and off-air reporter covering Congress for NBC News, managing coverage of the Senate, Leigh Ann Caldwell is an NBC News correspondent; “*Democrats plow 'full speed ahead' on sweeping Biden budget, despite tensions*,” <https://www.nbcnews.com/politics/congress/democrats-plow-full-speed-ahead-sweeping-biden-budget-despite-tensions-n1278722>] Justin

WASHINGTON — The top two Democrats said they’re pushing forward with President Joe Biden’s sweeping safety net expansion, as House committees circulate legislative text with hearings scheduled Thursday to start advancing major sections of the bill. “We're moving full speed ahead,” Senate Majority Leader Chuck Schumer told reporters on a call Wednesday. The New York Democrat effectively cast aside calls by Sen. Joe Manchin, D-W.Va., for a “strategic pause” in the process of crafting the bill, as he voiced concerns about inflation and debt in a recent op-ed for the Wall Street Journal. Schumer is navigating demands by Manchin, as well as Sen. Kyrsten Sinema, D-Ariz., to reduce the price tag that Democrats set at a maximum of $3.5 trillion in the budget resolution. “There are some in my caucus who believe $3.5 trillion is too much; there are some in my caucus who believe it's too little,” Schumer said. “We're going to work very hard to have unity, because without unity, we're not going to get anything.” Speaker Nancy Pelosi said Wednesday the House is moving forward at the $3.5 trillion level. But she left open the possibility of a lower final price tag before the bill becomes law, while promising that “we will get the job done” with “a great bill” that honors Biden’s vision. “We will have our negotiations,” Pelosi, D-Calif., said, when asked by NBC News if the House could pass a bill at a lower amount. “I don’t know what the number will be. We are marking at 3.5 [trillion]. ... We will pay for more than half, maybe all of the legislation.” The remarks by Schumer and Pelosi point to a complicated balancing act, facing a broad range of opinions from centrist lawmakers skeptical of the price tag to progressives who believe $3.5 trillion should be the minimum. Democratic leaders are also juggling an aggressive timeline by seeking to ready the bill by Sept. 27 — the self-imposed House deadline to vote on the separate infrastructure bill — to ensure progressives will support the latter. They are betting Manchin can ultimately be won over on the substance of the package. Lawmakers and committees are keeping options open in case the price tag needs to be cut: For instance, they’ve privately discussed setting some provisions to expire sooner. Manchin has been somewhat vague in his demands. He has not specified what price tag he would support or what provisions of the emerging bill he wants to cut. His office did not have a comment when asked those questions Wednesday. In June, he said on ABC's "This Week" that he wants to “make sure we pay for” the bill. A source close to Manchin said he is a big proponent of targeting benefits on the basis of income and capping them so the money reaches people who need it the most — principles he believes are critical for Democrats' proposals on community college subsidies and on home-based care provisions for the disabled and elderly. Manchin also has issues with the climate change proposals in the legislation, the source said. As chairman of the Senate Energy and Natural Resources Committee, Manchin has major influence over the climate provisions. His committee was instructed to write legislation costing $198 billion for a clean electricity payment program, consumer rebates to weatherize and electrify homes, the creation of financing for domestic manufacturing of clean energy and auto supply chain technologies and climate research. “He’s not opposed to the overall bill,” the source said. “He’s going to shape the bill to what he feels is closer to the needs. People shouldn’t read into it more than that.” Senate Budget Chair Bernie Sanders, I-Vt., has said if the safety net package does not pass, the $550 billion bipartisan infrastructure package — which Manchin co-wrote — will fail as well. He told reporters the $3.5 trillion level was too low. “To my mind, this bill, that $3.5 trillion, is already the result of a major, major compromise,” Sanders said. “And at the very least, this bill should contain $3.5 trillion.” Pelosi said slashing the cost would require making difficult policy choices. “We have to talk about: What does it take? Where would you cut?” she asked. “Child care? Family medical leave paid for? Universal pre-K? Home health care?” On Thursday, the House committees on ways and means and education and labor will hold hearings on major portions of the bill they released this week. That includes 12 weeks' paid family and medical leave for all workers; expanding Medicare to cover dental, vision and hearing benefits; universal pre-K for 3- and 4-year-olds; and two years' tuition-free community college. Republicans are unified against the effort, leaving Democrats to pass the bill alone under narrow majorities. The package can bypass a Senate filibuster. Senate Minority Leader Mitch McConnell, R-Ky., said Wednesday that he hopes Manchin and Sinema “will dig in their heels” against some of the tax increases Democrats are eyeing to finance the package. “It comes down to — in the Senate — to two people,” he said. “Either one of them could kill the whole bill. I don't expect that to happen,” he said. “Either one of them could make dramatic changes in it — that could happen. Or either one of them could basically make a few cosmetic changes and throw in the towel.”

#### Aff doesn’t solve but requires negotiations that saps PC.

Pooley 21 [James; Former deputy director general of the United Nations’ World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding; “Drawn-Out Negotiations Over Covid IP Will Blow Back on Biden,” Barron’s; 5/26/21; <https://www.barrons.com/articles/drawn-out-negotiations-over-covid-ip-will-blow-back-on-biden-51621973675>] Justin

The Biden administration recently announced its support for a proposal before the World Trade Organization that would suspend the intellectual property protections on Covid-19 vaccines as guaranteed by the landmark TRIPS Agreement, a global trade pact that took effect in 1995. The decision has sparked furious debate, with supporters arguing that the decision will speed the vaccine rollout in developing countries. The reality, however, is that even if enacted, the IP waiver will have zero short-term impact—but could inflict serious, long-term harm on global economic growth. The myopic nature of the Biden administration’s announcement cannot be overstated. Even if WTO officials decide to waive IP protections at their June meeting, it’ll simply kickstart months of legal negotiations over precisely which drug formulas and technical know-how are undeserving of IP protections. And it’s unthinkable that the Biden administration, or Congress for that matter, would actually force American companies to hand over their most cutting-edge—and closely guarded—secrets. As a result, the inevitable foot-dragging will cause enormous resentment in developing countries. And that’s the real threat of the waiver—precisely because it won’t accomplish either of its short-term goals of improving vaccine access and facilitating tech transfers from rich countries to developing ones. It’ll strengthen calls for more extreme, anti-IP measures down the road. Experts overwhelmingly agree that waiving IP protections alone won’t increase vaccine production. That’s because making a shot is far more complicated than just following a

recipe, and two of the most effective vaccines are based on cutting-edge discoveries using messenger RNA. As Moderna Chief Executive Stephane Bancel said on a recent earnings call, “This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist. And then even if all those things were available, whoever wants to do mRNA vaccines will have to, you know, buy the machine, invent the manufacturing process, invent creation processes and ethical processes, and then they will have to go run a clinical trial, get the data, get the product approved and scale manufacturing. This doesn’t happen in six or 12 or 18 months.” Anthony Fauci, the president’s chief medical adviser, has echoed that sentiment and emphasized the need for immediate solutions. “Going back and forth, consuming time and lawyers in a legal argument about waivers—that is not the endgame,” he said. “People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible.” Those claiming the waiver poses an immediate, rather than long-term, threat to IP rights also misunderstand what the waiver will—and won’t—do. The waiver petition itself is more akin to a statement of principle than an actual legal document. In fact, it’s only a few pages long. As the Office of the United States Trade Representative has said, “Text-based negotiations at the WTO will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The WTO director-general predicts negotiations will last until early December. That’s a lot of wasted time and effort. The U.S. Trade Representative would be far better off spending the next six months breaking down real trade barriers and helping export our surplus vaccine doses and vaccine ingredients to countries in need.

#### Infrastructure secures the grid against worsening and increasing cyberattacks.

Carney 21 [Chris; 8/6/21; Senior policy advisor at Nossaman LLC, former US Representative, former professor of political science at Penn State University; "*The US Senate Infrastructure Bill: Securing Our Electrical Grid Through P3s and Grants*," JDSupra, <https://www.jdsupra.com/legalnews/the-us-senate-infrastructure-bill-4989100/>] Justin

As we begin to better understand the main components of the Infrastructure Investment and Jobs Act that the US Senate is working to pass this week, it is clear that public-private partnerships ("P3s") are a favored funding mechanism of lawmakers to help offset high costs associated with major infrastructure projects in communities. And while past infrastructure bills have used P3s for more conventional projects, the current bill also calls for P3s to help pay for protecting the US electric grid from cyberattacks. Responding to the increasing number of cyberattacks on our nation’s infrastructure, and given the fragile physical condition of our electrical grid, the Senate included provisions to help state, local and tribal entities harden electrical grids for which they are responsible. Section 40121, Enhancing Grid Security Through Public-Private Partnerships, calls for not only physical protections of electrical grids, but also for enhancing cyber-resilience. This section seeks to encourage the various federal, state and local regulatory authorities, as well as industry participants to engage in a program that audits and assesses the physical security and cybersecurity of utilities, conducts threat assessments to identify and mitigate vulnerabilities, and provides cybersecurity training to utilities. Further, the section calls for strengthening supply chain security, protecting “defense critical” electrical infrastructure and buttressing against a constant barrage of cyberattacks on the grid. In determining the nature of the partnership arrangement, the size of the utility and the area served will be considered, with priority going to utilities with fewer available resources. Section 40122 compliments the previous section as it seeks to incentivize testing of cybersecurity products meant to be used in the energy sector, including SCADA systems, and to find ways to mitigate any vulnerabilities identified by the testing. Intended as a voluntary program, utilities would be offered technical assistance and databases of vulnerabilities and best practices would be created. Section 40123 incentivizes investment in advanced cybersecurity technology to strengthen the security and resiliency of grid systems through rate adjustments that would be studied and approved by the Secretary of Energy and other relevant Commissions, Councils and Associations. Lastly, Section 40124, a long sought-after package of cybersecurity grants for state, local and tribal entities is included in the bill. This section adds language that would enable state, local and tribal bodies to apply for funds to upgrade aging computer equipment and software, particularly related to utilities, as they face growing threats of ransomware, denial of service and other cyberattacks. However, under Section 40126, cybersecurity grants may be tied to meeting various security standards established by the Secretary of Homeland Security, and/or submission of a cybersecurity plan by a grant applicant that shows “maturity” in understanding the cyber threat they face and a sophisticated approach to utilizing the grant. While the final outcome of the Infrastructure Investment and Jobs Act may still be weeks or months away, inclusion of these provisions not only demonstrates a positive step forward for the application of federal P3s and grants generally, they also show that Congress recognizes the seriousness of the cyber threats our electrical grids face. Hopefully, through judicious application of both public-private partnerships and grants, the nation can quickly secure its infrastructure from cyberattacks.

#### Cyberattacks on the grid spiral to all-out nuclear conflict.

Klare 19 [Michael; November 2019; Professor emeritus of peace and world security studies at Hampshire College; “*Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation*,” Arms Control Association, <https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation>] Justin

Yet another pathway to escalation could arise from a cascading series of cyberstrikes and counterstrikes against vital national infrastructure rather than on military targets. All major powers, along with Iran and North Korea, have developed and deployed cyberweapons designed to disrupt and destroy major elements of an adversary’s key economic systems, such as power grids, financial systems, and transportation networks. As noted, Russia has infiltrated the U.S. electrical grid, and it is widely believed that the United States has done the same in Russia.12 The Pentagon has also devised a plan known as “Nitro Zeus,” intended to immobilize the entire Iranian economy and so force it to capitulate to U.S. demands or, if that approach failed, to pave the way for a crippling air and missile attack.13 The danger here is that economic attacks of this sort, if undertaken during a period of tension and crisis, could lead to an escalating series of tit-for-tat attacks against ever more vital elements of an adversary’s critical infrastructure, producing widespread chaos and harm and eventually leading one side to initiate kinetic attacks on critical military targets, risking the slippery slope to nuclear conflict. For example, a Russian cyberattack on the U.S. power grid could trigger U.S. attacks on Russian energy and financial systems, causing widespread disorder in both countries and generating an impulse for even more devastating attacks. At some point, such attacks “could lead to major conflict and possibly nuclear war.”14

#### Scientific consensus flows aff – nuke war leads to extinction and is the most probable impact scenario

Tegmark 17 Max Tegmark, 5-26-2017, "Why 3,000 Scientists Think Nuclear Arsenals Make Us Less Safe," Scientific American Blog Network, https://blogs.scientificamerican.com/observations/why-3-000-scientists-think-nuclear-arsenals-make-us-less-safe/, SJBE Max Erik Tegmark is a Swedish-American physicist and cosmologist. He is a professor at the Massachusetts Institute of Technology and the scientific director of the Foundational Questions Institute.

Delegates from most United Nations member states are gathering in New York next month to negotiate a nuclear weapons ban, and 30 Nobel Laureates, a former U.S. Secretary of Defense and over 3,000 other scientists from 84 countries have signed an [open letter](https://futureoflife.org/nuclear-open-letter/) in support. Why? We scientists like to geek out about probabilities, megatons and impact calculations, so we see the nuclear situation differently than many politicians and pundits. From the public debate, one might think that the cold war threat is over and that the most likely way to be killed by a nuke is by being attacked by Iran, North Korea or terrorists, but that’s not what nerdy number crunching reveals. Those media-dominating scenarios could potentially kill millions of people—except that Iran has no nukes and North Korea lacks missiles capable of reliably delivering their dozen or so Hiroshima-scale bombs. But scientific research has shown that a nuclear war between the superpowers might kill hundreds or potentially even thousands of times more people, and since it’s not a hundred times less likely to occur, the laws of statistics tell us that it’s the nuke scenario most likely to kill you. Why is superpower nuclear war so risky? First of all, massive firepower: there are more than [14,000 nuclear weapons](https://fas.org/issues/nuclear-weapons/status-world-nuclear-forces/) today, some of which are hundreds of times more powerful than North Korea’s and those dropped on Japan. Over 90 percent of these belong to Russia and the US, who keep thousands on hair-trigger alert, ready launch on minutes notice. A [1979 report by the US Government](https://www.princeton.edu/~ota/disk3/1979/7906/7906.PDF) estimated that all-out war would kill 28-88 percent of Americans and 22-50 percent of Soviets (150-450 million people with today’s populations). But this was before the risk of nuclear winter was discovered in the 1980’s.Researchers realized that regardless of whose cities burned, massive amounts of smoke could spread around the globe, blocking sunlight and transforming summers into winters, much like when asteroids or supervolcanoes caused mass extinctions in the past. A peer-reviewed analysis published by Robock et al (2007) showed cooling by about 20°C (36°F) in much of the core farming regions of the US, Europe, Russia and China (by 35°C in parts of Russia) for the first two summers, and about half that even a full decade later. Years of near-freezing summer temperatures would eliminate most of our food production. It is hard to predict exactly what would happen if thousands of Earth’s largest cities were reduced to rubble and global infrastructure collapsed, but whatever small fraction of all humans didn’t succumb to starvation, hypothermia or epidemics would probably need to cope with roving, armed gangs desperate for food. There are large uncertainties in Nuclear Winter predictions. For example, how much smoke is produced and how high up it rises would determine its severity and longevity. Given this uncertainty, there is no guarantee that most people would survive. It has therefore been argued that the traditional nuclear doctrine of Mutual Assured Destruction (MAD) be replaced by Self-Assured Destruction (SAD): even if one of the two superpowers were able to launch its full nuclear arsenal against the other without any retaliation whatsoever, nuclear winter might still assure the attacking country’s self-destruction. Recent research has suggested that even a limited nuclear exchange between India and Pakistan could cause enough cooling and agricultural disruption to endanger up to [2 billion people](https://hinwcampaignkit.org/section-4/section-4/), mostly outside the warring countries. The fact that nuclear powers are taking the liberty to endanger everyone else without asking their permission has led to growing consternation in the world’s non-nuclear nations. This has been exacerbated by a seemingly endless [series of near-misses](https://futureoflife.org/background/nuclear-close-calls-a-timeline/) in which nuclear war has come close to starting by accident, and leaders of many non-nuclear nations feel less than thrilled by the idea of being destroyed by something as banal as a malfunctioning early warning-system in a nation that they are not threatening. Such concerns prompted 185 non-nuclear nations to sign the 1970 Non-Proliferation-Treaty (NPT), promising to remain nuke-free in return for the nuclear nations phasing out theirs in accordance with NPT Article VI, whereby each party "undertakes to pursue negotiations in good faith on effective measures relating to cessation of the nuclear arms race at an early date and to nuclear disarmament, and on a Treaty on general and complete disarmament under strict and effective international control”. Nearly 50 years later, many of these "have-nots” have concluded that they were tricked, and that the "haves” have no intention of ever keeping their end of the bargain. Rather than disarming, the U.S. and Russia have recently announced massive investments in novel nuclear weapons. Russia has recently touted a cobalt-encased doomsday bomb reminiscent of the dark comedy "Dr. Strangelove,” and the U.S. plans to spend a trillion dollars replacing most of its nuclear weapons with new ones that are more effective for a first strike. Adding insult to injury, India, Pakistan and Israel have been allowed to join the nuclear club without major repercussions. "The probability of a nuclear calamity is higher today, I believe, that it was during the cold war," said former U.S. Secretary of Defense William J. Perry, who signed the open letter. This disillusionment from the “have-nots” prompted 123 of them to launch an initiative in the United Nations General Assembly, where the nuclear nations lack veto power. In late 2016, they voted to launch the aforementioned UN negotiations that may produce a nuclear weapons ban treaty this summer. But a ban obviously wouldn’t persuade the nuclear ``haves” to eliminate their nukes the next morning, so what’s the point of it? The way I see it, most governments are frustrated that a small group of countries with a minority of the world's population insist on retaining the right to ruin life on Earth for everyone else with nuclear weapons. Such “might makes right” policy has precedent. In South Africa, for example, the minority in control of the unethical Apartheid system didn't give it up spontaneously, but because they were pressured into doing so by the majority. Similarly, the minority in control of unethical nuclear weapons won't give them up spontaneously on their own initiative, but only if they're pressured into doing so by the majority of the world's nations and citizens. The key point of the ban is to provide such pressure by stigmatizing nuclear weapons. Nuclear ban supporters draw inspiration from the 1997 Ottawa treaty banning landmines. Although the superpowers still refuse to sign it, it created enough stigma that many people now associate mines not with national security, but with images of children who have had limbs blown off while playing in peace-time. This stigma caused leading arms manufactures to half production in response to investor pressure and dwindling demand. In 2014, the Pentagon announced that it was halting landmine use outside of the Korean peninsula. Today, the global landmine market has nearly collapsed, with merely a single manufacturer (South Korean Hanwa) remaining. The "have-not” negotiators hope that a nuclear ban treaty will similarly stigmatize nuclear weapons, persuading us all that we’re less safe with more nukes—even if they are our own. If this happens, it will increase the likelihood that the ``haves” trim their nuclear arsenals down to the minimum size needed for effective deterrence, reverting from SAD back to MAD and making us all safer. Here is the text of the letter. A list of some of the notable signatories follows. AN OPEN LETTER FROM SCIENTISTS IN SUPPORT OF THE UN NUCLEAR WEAPONS NEGOTIATIONS Nuclear arms are the only weapons of mass destruction not yet prohibited by an international convention, even though they are the most destructive and indiscriminate weapons ever created. We scientists bear a special responsibility for nuclear weapons, since it was scientists who invented them and discovered that their effects are even more horrific than first thought. Individual explosions can obliterate cities, radioactive fallout can contaminate regions, and a high-altitude electromagnetic pulse may cause mayhem by frying electrical grids and electronics across a continent. The most horrible hazard is a nuclear-induced winter, in which the fires and smoke from as few as a thousand detonations might darken the atmosphere enough to trigger a global mini ice age with year-round winter-like conditions. This could cause a complete collapse of the global food system and apocalyptic unrest, potentially killing most people on Earth – even if the nuclear war involved only a small fraction of the roughly 14,000 nuclear weapons that today’s nine nuclear powers control. As Ronald Reagan said: “A nuclear war cannot be won and must never be fought.” Unfortunately, such a war is more likely than one may hope, because it can start by mistake, miscalculation or terrorist provocation. There is a steady stream of accidents and false alarms that could trigger all-out war, and relying on never-ending luck is not a sustainable strategy. Many nuclear powers have larger nuclear arsenals than needed for deterrence, yet prioritize making them more lethal over reducing them and the risk that they get used. But there is also cause for optimism. On March 27 2017, an unprecedented process begins at the United Nations: most of the world’s nations convene to negotiate a ban on nuclear arms, to stigmatize them like biological and chemical weapons, with the ultimate goal of a world free of these weapons of mass destruction. We support this, and urge our national governments to do the same, because nuclear weapons threaten not merely those who have them, but all people on Earth.

## Case

### 1NC – General

#### Aff gets circumvented- powerful countries use bilateral agreements to force other countries to accept their IPR protections- its empirically proven

DC = developing country

NIT = Net Importers of Technology (this references developing countries)

NET = Net Exporters of Technology (countries with advanced economies)

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016./SJKS

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on October 20, 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory measure in connection with an IP issue; that this type of action seriously inhibited Brazil’s participation in the work of the Group, since ‘no country could be expected to participate in negotiations while experiencing pressures on the substance of its position’ (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment of the Punta del Este Declaration. ‘The United States action was an attempt to coerce Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round’ (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted, and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28). The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil’s economy would likely affect their co-operation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos and Braithwaite 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

### 1NC – WTO Jurisdiction

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

#### Recent evidence confirms

Hillman and Tippett 21 [Jennifer A; Senior fellow for trade and international political economy; Alex; Research associate for international economics, at the Council on Foreign Relations; “Europe and the Prospects for WTO Reform,” CFR; 3/10/21; <https://www.cfr.org/blog/europe-and-prospects-wto-reform>] Justin

The WTO has been in the clutches of a slow-moving crisis for years. At its heart are a series of disputes about the role of the WTO’s Appellate Body, the final arbiter in the WTO’s Dispute Settlement System. Today, the Appellate Body sits empty, severely undermining the capacity of the WTO to resolve trade disputes.

Since the start of the Trump administration, the United States has refused to appoint any new members to the body, effectively allowing countries to avoid compliance with WTO rulings. The primary driver of this drastic action has been American frustration at perceived judicial overreach. U.S. policymakers, starting with the George W. Bush administration, have repeatedly voiced their displeasure with Appellate Body decisions, contending that certain decisions have reached beyond the text of existing WTO agreements.

### 1NC – Trade Secret Deficit

#### Aff fails---trade secrets remain secrets and existing logistical hubs fail.

Banri Ito 21 [(Professor of Economics, Aoyama Gakuin University; Fellow, RIETI), 8/8/21, Impacts of the vaccine intellectual property rights waiver on global supply, <https://voxeu.org/article/impacts-vaccine-intellectual-property-rights-waiver-global-supply>] Justin

Regarding waivers of vaccine patents, there have been some voluntary initiatives. On 8 October, soon after South Africa and India proposed a waiver of the TRIPS agreement on 2 October 2020, Moderna, a US pharmaceutical company, expressed its intention not to exercise its patent rights on its COVID-19 vaccine.1 Although Moderna reached an agreement with South Korean pharmaceutical company Samsung Biologics on consignment production of the vaccine on 22 May 2021, so far there have been very few confirmed cases of efforts to reproduce Moderna's vaccine or of licenses being granted to other companies.

With respect to the COVID-19 vaccines developed by Pfizer (jointly with BioNTech of Germany) and Moderna, it appears that the whole body of relevant technical knowledge has not necessarily been patented but that some of the technical knowledge remains undisclosed as trade secrets. Patenting is only one means of ensuring ‘appropriability’, which refers to a company's capacity to secure profits from its own technological innovation. While patent information may make it possible for outsiders to achieve development results similar to those achieved by the patented technology through a similar method without infringing the patent right, keeping the technology undisclosed as a trade secret or incorporating complex processes into it may be an effective means of ensuring appropriability. Pharmaceuticals can easily be counterfeited through ‘reverse engineering’, which refers to a process in which the active ingredients of a drug are identified as a result of deformulation. Therefore, as a general rule, it is considered important to exclude the risk of counterfeiting through patenting.

While it is not clear how much of the relevant technological knowledge remains unpatented, there are apparently some technical reasons for not obtaining full patent protection. The Pfizer and Moderna vaccines use advanced technology based on messenger RNA (mRNA), representing the first case of practical application of such technology. Although I, a non-expert in this field, will refrain from going into further detail, it is highly likely that those vaccines cannot easily be counterfeited as their production requires complex production processes and unique technology.

Patenting involves public disclosure of technical knowledge, providing information on how to reproduce patented inventions. It has the function of lowering technology trade costs by clarifying property rights on technical knowledge. If the technical knowledge necessary for manufacturing a certain product remains undisclosed as a trade secret, it may not be recorded in a written or other tangible form, and it may become necessary to pass down the technical information as cumulative implicit knowledge. As a result, technology transfer may become difficult.

Perhaps in view of that risk, in April 2021, the World Health Organization (WHO) established a COVID-19 vaccine technology transfer hub as a scheme to promote the sharing of mRNA-based technology. However, there are no media reports to date indicating that technical knowledge has been provided through this scheme.2

### 1NC – Infrastructure Deficit

#### MRNA expert shortages.

Garde et al 21 [Damian Garde (National Biotech Reporter), Helen Branswell (Senior Writer, Infectious Disease)Matthew Herper (Senior Writer, Medicine, Editorial Director of Events), 5/6/21, 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/>] Justin

In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses.

That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines.

“There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting.

While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing.

“In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said.

#### Existing companies solve scale-up, but other companies don’t have the capabilities.

Lowe 21 [Derek; BA from Hendrix College and PhD in organic chemistry from Duke before spending time in Germany on a Humboldt Fellowship on his post-doc. He’s worked for several major pharmaceutical companies since 1989 on drug discovery projects against schizophrenia, Alzheimer’s, diabetes, osteoporosis and other diseases; 2/2/21; Myths of Vaccine Manufacturing; <https://www.science.org/content/blog-post/myths-vaccine-manufacturing>] Justin

Ah, but now we get back to Step Four. As Neubert says, "Welcome to the bottleneck!" Turning a mixture of mRNA and a set of lipids into a well-defined mix of solid nanoparticles with consistent mRNA encapsulation, well, that's the hard part. Moderna appears to be doing this step in-house, although details are scarce, and Pfizer/BioNTech seems to be doing this in Kalamazoo, MI and probably in Europe as well. Everyone is almost certainly having to use some sort of specially-built microfluidics device to get this to happen - I would be extremely surprised to find that it would be feasible without such technology. Microfluidics (a hot area of research for some years now) involves liquid flow through very small channels, allowing for precise mixing and timing on a very small scale. Liquids behave quite differently on that scale than they do when you pour them out of drums or pump them into reactors (which is what we're used to in more traditional drug manufacturing). That's the whole idea. My own guess as to what such a Vaccine Machine involves is a large number of very small reaction chambers, running in parallel, that have equally small and very precisely controlled flows of the mRNA and the various lipid components heading into them. You will have to control the flow rates, the concentrations, the temperature, and who knows what else, and you can be sure that the channel sizes and the size and shape of the mixing chambers are critical as well.

These will be special-purpose bespoke machines, and if you ask other drug companies if they have one sitting around, the answer will be "Of course not". This is not anything close to a traditional drug manufacturing process. And this is the single biggest reason why you cannot simply call up those "dozens" of other companies and ask them to shift their existing production over to making the mRNA vaccines. There are not dozens of companies who make DNA templates on the needed scale. There are definitely not dozens of companies who can make enough RNA. But most importantly, I believe that you can count on one hand the number of facilities who can make the critical lipid nanoparticles. That doesn't mean that you can't build more of the machines, but I would assume that Pfizer, BioNTech, Moderna (and CureVac as well) have largely taken up the production capacity for that sort of expansion as well.

And let's not forget: the rest of the drug industry is already mobilizing. Sanofi, one of the big vaccine players already (and one with their own interest in mRNA) has already announced that they're going to help out Pfizer and BioNTech. But look at the timelines: here's one of the largest, most well-prepared companies that could join in on a vaccine production effort, and they won't have an impact until August. It's not clear what stages Sanofi will be involved in, but bottling and packaging are definitely involved (and there are no details about whether LNP production is). And Novartis has announced a contract to use one of its Swiss location for fill-and-finish as well, with production by mid-year. Bayer is pitching in with CureVac's candidate.

#### LICs statistically cannot mass produce vaccines.

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

Supply is one thing but actually getting shots into arms is a huge undertaking for any country. According to a review of low and middle income countries’ readiness to implement vaccine campaigns conducted by the World Bank, 95 per cent have developed national plans and 82 per cent have worked out which groups should be vaccinated first. However, crucial gaps remain. Only 59 per cent have plans to train vaccinators and less than half (48 per cent) have implemented communications strategies to encourage people to take up vaccines. While low and middle income countries are used to delivering childhood vaccines, so have cold chain systems in place, a mass vaccine campaign for adults is a very different beast, says Mamta Murthi, vice president for human development at the World Bank. “This is a very different population – adults may be at work, at home, they may be unwilling to travel or not be able to come to vaccine centres,” she says.

#### The aff ignores insufficient infrastructure, materials, and “know how” needed to expand vaccine supply- even if IPR were waived there’s no scale up

Santos Rutschman 21 Santos Rutschman, Ana (Professor of Law, St. Louis University) and Julia Barnes-Weise (Executive Director of the Global Healthcare Innovation Alliances Accelerator a non-profit organization spun out of a program in Public Policy at Duke University, and a Senior Consultant to the Coalition for Epidemic Preparedness Innovations. She is a lawyer, global health policy consultant, entrepreneur and Certified Licensing Professional). "The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal." Bill of Health (2021) (2021)./SJKS

Second, even if all types of legal restrictions on the use of vaccine technology were lifted — or had never existed in the first place — there is simply not enough infrastructure (manufacturing facilities and equipment) nor raw materials (the components needed to manufacture and deliver vaccines) to produce and distribute COVID-19 vaccines as predicted under current waiver proposals. We have long faced a global vaccine manufacturing problem that will not be fully resolved during the current pandemic. In the case of vaccines that need to be kept at ultra-cold temperatures, these problems intensify. One of us (Barnes-Weise) has been involved in the contractual negotiations for the development, manufacturing and transfer of technology related to COVID-19 vaccines. In addition to the informational gaps described above, COVID-19 vaccine manufacturers are most concerned about how well the recipients of the technology transfer will understand and be able to implement such knowledge in making vaccines of the necessary quality. Shortages do not merely affect materials necessary to manufacture vaccines and facilities adequate to manufacture the vaccines; they also affect the availability of personnel qualified to instruct the licensee and recipient of this information. Sending an employee of this caliber out of the original manufacturing site to a partner site risks reducing the capacity of the first site. And remote instruction, necessitated by the pandemic, has its own shortcomings. In relation to the patents on the vaccines themselves, most of the concerns that the vaccine manufacturers express are around the protection of their vaccine platforms for the purposes of making future or non-COVID-19 vaccines. Moderna shared information about its [patents](https://www.modernatx.com/patents) in summer 2020. The manufacturers, as evidenced by the number of licenses to manufacture granted to date, are eager to [find](https://www.reuters.com/article/us-health-coronavirus-lonza-moderna/lonza-gets-licence-to-make-ingredients-for-moderna-vaccine-idUSKBN2B72BB) [partners](https://www.bloomberg.com/news/articles/2021-01-27/sanofi-to-make-millions-of-biontech-pfizer-s-covid-vaccine-doses) with the [capabilities](https://www.fosunpharma.com/en/news/news-details-3801.html) to expand production. It is not to their benefit to produce an inadequate supply of a highly sought-after vaccine. However, even willingness to transfer patented vaccine technology has faced numerous practical hurdles to date: 1) infrastructural limitations; 2) scarcity of raw materials; 3) concerns about licensees having the ability to actually manufacture effective vaccines in light of the infrastructural and product scarcity, even in situations in which there might be no informational gaps. A patent waiver would not address any of the practical concerns currently at the root of tech transfer negotiations involving COVID-19 vaccine technology. Compounding these problems is the fact that, should a waiver be issued, there is no legal mechanism that can compel the transfer of certain types of know-how or trade secrets should a company be unwilling to license its intellectual property — which, again, at this point in the pandemic, is not a problem we have observed. Finally, it is important to keep in mind that a waiver would be temporary: supporters of current waiver proposals should consider what will happen once demand for vaccines begins diminishing and fewer manufacturers remain on the market. Moreover, they should consider the legal and practical uncertainty that a waiver would introduce, as it is unclear how technology transfer between companies would cease (or continue) once the waiver expires.

#### The aff institutes no plan for administering vaccines- lack of infrastructure and hesitancy mean shots don’t end up in arms- but it creates vaccine hesitancy that turns case.

Adler 21 [David; Writer on Industrial Policy, author of The New Economics of Liquidity and Financial Frictions and co-editor of the anthology The Productivity Puzzle: Restoring Economic Dynamism, both published by the CFA Institute Research Foundation. He is also an adviser on industrial strategy at the Common Good Foundation in the United Kingdom; 7/20/21; To Vaccinate the World, Supply Is Only Half the Issue, Foreign Policy, <https://foreignpolicy.com/2021/07/20/wto-trips-waiver-vaccine-equity-distribution-covid-pandemic/>] Justin

Administering shots in the arm was another story. This was primarily left up to the states. Initially, Operation Warp Speed planned to have the U.S. Defense Department administer shots in the arms, but state and local authorities complained of the [militarization of vaccine administration](https://www.astho.org/Federal-Government-Relations/Correspondence/ASTHO-Joins-Comments-Operation-Warp-Speed-Leaders/) and took over this function. For whatever the reason—lack of resources, lack of planning, [poor communication](https://www.astho.org/Press-Room/Nations-Health-Officials-Call-for-Greater-Collaboration-and-Communication-with-Federal-Government/09-02-20/) from the federal government—the states had trouble administering the vaccines on time. As of Jan. 15, more than 31 million doses had been “distributed” but only around 12 million doses had been “administered.” Over time, and with bolstered support from the incoming Biden administration, rollout rapidly improved. Nonetheless, vaccine hesitancy remains a major point of resistance to more widespread immunization in the United States.

These rollout problems found in the United States are amplified many times when it comes to global rollout. The Biden administration discovered this first hand when it attempted to donate 80 million doses from domestic U.S. supply to the rest of the world in June but fell well short of this target. White House press secretary Jen Psaki said, “what we found to be the biggest challenge is not actually the supply—we have plenty of doses to share with the world—but this is a herculean logistical challenge. And we’ve seen that as we’ve begun to implement.” She pointed to the distributional challenges associated with storing vaccines at the proper temperature as well as the need for needles and syringes.

As Psaki’s comments show, there is more to vaccinating the world than just increasing supply. Even if there are vaccine shortages at this moment, limited vaccine supply may not be a binding constraint by year end. Serum Institute of India, the world’s largest vaccine manufacturer, has announced it will begin [exporting later this year](https://www.reuters.com/world/india/indias-serum-institute-start-export-covid-19-vaccine-by-year-end-2021-05-18/), implying India should have adequate vaccine supply by then. Pfizer/BioNTech has [pledged to deliver](https://www.voanews.com/covid-19-pandemic/pfizer-biontech-pledge-2-billion-vaccine-doses-poor-nations) 2 billion doses to low- and middle-income countries. AstraZeneca is continuing to scale up production.

Nonetheless, the Biden administration’s signature international COVID-19 policy, the [TRIPS waiver](https://crsreports.congress.gov/product/pdf/IN/IN11662), is a supply side move—but one unlikely to lead to any actual increase in supply. This waves intellectual property protections for COVID-19 vaccines to further foreign production. The [U.K.](https://www.gov.uk/government/news/wto-trips-council-june-2021-uk-statements) and [German](https://www.dw.com/en/germany-rejects-us-push-to-waive-covid-vaccine-patents/a-57453453) governments have viewed it skeptically and can block it. Also, as has been widely noted, manufacturing involves trade secrets and supply chain issues that go well beyond intellectual property (IP) rights. Less widely noted is the fact that the Johnson & Johnson, AstraZeneca, and Novavax vaccines have already been [licensed to Indian manufacturers](https://www.statnews.com/2021/05/05/india-vaccine-heist-shoddy-regulatory-oversight-imperil-global-vaccine-access/), so it is not clear to what degree IP rights are really hindering additional foreign production.

Therefore, the TRIPS waiver can be seen as essentially a political or even theatrical gesture, well removed from the messy world of vaccine distribution and administration. It appealed to a domestic audience hostile to Big Pharma and an international audience of countries like India and South Africa whose industrial policies have long called for limitations on IP rights.

The Biden administration’s policies keep evolving, and newer proposals are likely to show more immediate results. The United States has pledged to buy 500 million U.S. produced doses of the Pfizer/BioNTech vaccine over the next year and donate them to low-income countries. Many financing initiatives have been announced. But U.S. plans of how to tackle the critical last mile and get the vaccines into people’s arms have not been as clearly fleshed out, with the United States mostly taking a hands-off approach.

Administering vaccines requires a global rollout plan. After all, as the truism goes, a global pandemic demands a global response. However, this phrase is open to interpretation, with vaccine nationalism typically cloaked in globalist rhetoric. Many in the United States are deeply uncomfortable with a U.S.-led pandemic effort and hear the statement to mean that globalist institutions should take the lead. In other countries, the phrase can mean something very different. For instance, when European Commission President Ursula von der Leyen floated the idea of a “vaccine export transparency mechanism” to block vaccine exports from the EU to the U.K., she said it was for the “global common good.” These various meanings are somehow aligned in discouraging any U.S. unilateralism and pose challenges to a more active U.S. involvement in a global rollout.

The primary global initiative to ensure all countries have access to COVID-19 vaccines is COVAX, co-convened by the Coalition for Epidemic Preparedness Innovations, the vaccine alliance Gavi, and the World Health Organization. Gavi oversees procurement but does not have an on-the-ground presence for administering vaccines. This is left up to the health ministries of developing countries and other partners. The coalition’s key partner responsible for delivering vaccines is UNICEF. UNICEF is a children’s agency whose mission is helping every child thrive all over the world. However, it is the elderly who are most at risk for COVID-19. Ultimately, COVAX has rollout capabilities but limited bandwidth and resources when it comes to vaccine administration.

The United States has these resources, including deep expertise in both vaccine distribution and administration. Operation Warp Speed showed the Defense Department can manage the complex ultra-cold logistics required for mRNA vaccine distribution. The Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) have knowledge of vaccine administration—although addressing a global pandemic would be a “stretch goal.” The United States could use its personnel and expertise to help solve the global rollout problem, either on its own or in a partnership with multilateral institutions, such as COVAX.

This is not to imply the United States, with its declining life expectancy, necessarily has a better health system than other afflicted countries—only that it has rollout knowledge it learned the hard way. The key lesson is the last mile is the hardest part to roll out. Rather than having vaccine supplies arrive and only then start training, it is better to have mass vaccination sites up and running and already fully staffed. The United States could offer technical guidance and materials necessary for rollouts, including refrigeration, ancillary kits, and having enough needles on hand. USAID could offer advice on how a country could improve its vaccine readiness plan.

Addressing vaccine hesitancy is also critical to a successful rollout. The reasons behind vaccine hesitancy are complex and vary by country and population. Hence, responses need to be country specific but will typically require a massive communications effort. Where is the global effort? Where is the global planning for this effort?

Tackling these global, last-mile challenges faces huge domestic roadblocks in the United States. It would require making global rollout a top U.S. foreign-policy priority, necessitating the planning, financing, and personnel of something akin to the Marshall Plan. It would be expensive. It involves industrial planning, which still has negative overtones in the United States. Which agency in the U.S. government should coordinate such a plan? The State Department? The Defense Department? The National Institute of Health? The CDC? The White House COVID-19 Response Team? Perhaps the most divisive question is if the United States should lead such an effort or follow the WHO’s directives.

But none of this is relevant because there is no domestic political pressure for pursuing such an approach, unlike the TRIPS waiver. This is because nonprofit activism is still primarily focused on supply and eliminating vaccine hoarding by rich countries. True global vaccine equity requires a broader definition and effort beyond just manufacturing more supply, namely creating a global rollout plan and deploying the health resources necessary to get shots into people’s arms.

The end result is the United States is hesitant to find more concrete ways to get involved with a global rollout beyond just pledging more vaccine supplies or money. It is hesitant to directly intervene to help the worst afflicted poor countries distribute and administer vaccines. And vaccine hesitancy, in whichever form it takes, can be deadly.

#### The aff doesn’t scale up fast enough to solve covid and distracts us from the root cause – prefer statistics.

Taylor 21 [Andrea; Andrea leads a portfolio of global innovation programs focused on evaluation, scaling, and adaptation of healthcare innovations to address critical access and quality challenges. Her work with the Duke Global Health Innovation Center and Innovations in Healthcare drive evidence-based recommendations for scaling transformative models of care, adapting models into new contexts, and facilitating system change. She is the research lead for the Launch and Scale project’s COVID-19 workstream, analyzing global data on vaccines, partnerships, and therapeutics to combat the pandemic. She led design and research for the USAID-funded Social Entrepreneurship Accelerator at Duke (SEAD) and the development of several publications for the recent evaluation of the Saving Lives at Birth program, with USAID and GCC. Before joining Duke University in 2012, Andrea was on faculty at the University of North Carolina at Chapel Hill School of Social Work, where she conducted research on health and economic policy innovation. Prior to this, she worked for the US Department of Health and Human Services, where she co-designed programs to build capacity for mental health policy and care delivery in countries coming out of violent conflict. She holds a master’s degree in Social Service Administration (social work) from the University of Chicago; “CAN THE TRIPS WAIVER SAVE THE WORLD? WEEKLY COVID VACCINE RESEARCH UPDATE,” Duke; 5/7/21; <https://dukeghic.org/2021/05/07/can-the-trips-waiver-save-the-world/>] Justin

We are not optimizing the capacity we already have

Calls for the TRIPS waiver are based on the assumption that IP is holding up global production. Our review of the evidence, however, does not support this.

Our data on vaccine manufacturing show that most Covid-19 vaccines using traditional platforms, such as viral vector and inactivated virus, did use tech transfer deals to set up global manufacturing networks. AstraZeneca has agreements in place to manufacture Covid-19 vaccine in 16 countries, Novavax and Sputnik V in 11 countries, Sinovac in 6 countries. But many of these manufacturing partners (particularly those in middle-income countries) are delayed in starting or operating at only partial capacity because knowledge transfer is difficult and raw materials are in short supply.

For mRNA vaccines, like Moderna and Pfizer-BioNTech, the picture is even more complicated. Very few manufacturers (and none in LMICs) are equipped to manufacture mRNA vaccine, with or without access to intellectual property.

Setting up manufacturing takes longer than we think

Starting from scratch to set up new manufacturing through access to IP is not an immediate fix. And right now, we need to be focused on an immediate fix. Retrofitting or building new plants takes a long time. Running test batches, quality checks, audits and regulatory approval of manufacturing sites also takes a long time.

### 1NC – AT: Patent

#### Patents can’t solve the vaccine problem- they don’t have enough info and manufacturers shield key replication information

Santos Rutschman 21 Santos Rutschman, Ana (Professor of Law, St. Louis University) and Julia Barnes-Weise (Executive Director of the Global Healthcare Innovation Alliances Accelerator a non-profit organization spun out of a program in Public Policy at Duke University, and a Senior Consultant to the Coalition for Epidemic Preparedness Innovations. She is a lawyer, global health policy consultant, entrepreneur and Certified Licensing Professional). "The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal." Bill of Health (2021) (2021)./SJKS

In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem. First, we are still left with a significant informational problem: as many [commentators](https://science.sciencemag.org/content/369/6506/912) have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine. From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere.

### 1NC – Raw Material 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.

#### Raw materials take years to scaleup.

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

But perhaps the strongest argument against waivers is this: in October Moderna, one of the producers of new mRNA vaccines, actually offered an IP waiver. No-one has yet taken it up. Instead, “the biggest obstacle is raw materials,” says Dr Richard Torbett, chief executive of the Association of the British Pharmaceutical Industry. “All of the companies are saying we could produce more if we only had more glass vials, or filters, or bio bags.” Again, this is a daunting challenge – the Pfizer vaccine, for example, has 260 ingredients that come from 60 companies in 19 different countries. Many of these products are highly specialised and it will take many months, perhaps years, to ramp production of them up. “We’re very likely to see continued shortages that set back some of the vaccine producers for several months,” says Rasmus Bech Hansen, chief executive of Airfinity, adding that it is becoming harder for manufacturers with new jabs to secure the needed supplies – CureVac is already facing this problem, for example. The third challenge is perhaps harder to tackle. Vaccines are biological products and the manufacturing process does not always go smoothly. According to Airfinity, 1.73bn doses have been distributed worldwide, far short of the 4.5bn initially projected by big pharma. An overambitious manufacturing target is largely to blame for the gap. [AstraZeneca’s row with Europe](https://www.telegraph.co.uk/news/2021/05/09/eu-says-wont-renew-astrazeneca-contract-pivots-towards-pfizers/), for instance, was triggered by a lower yield at factories than hoped. Meanwhile Russia has produced only around 42m doses – compared to 400m from AstraZeneca and Pfizer – amid difficulties producing the second dose of Sputnik V, which uses different adenoviruses in the first and second shot.

#### 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.