# SO21 – Yale R5 – 1N v Strake HZ

## 1

#### Interpretation: The affirmative must only reduce intellectual property protections.

#### Reduce means make smaller, Cambridge:

<https://dictionary.cambridge.org/us/dictionary/english/reduce> //LHP AV

**to** become or to **make** **something** become **smaller** **in** size, amount, **degree**, importance, etc.:

#### Violation: They use patent term extensions which are the same length. Either a] the extension is extra T or b] they don’t reduce at all because it’s the same length – their ev below

Pandemic-related patent term extensions could be given for a period of time that the compulsory license is in force. With current pandemic projections of six months to two years for sufficient distribution, providing a patent term extension is reasonable and in line with the time period of many patent term extensions. Given that most pharmaceutical patents are prosecuted in multiple countries, this provides an incentive to participate in a limited waiver program.

#### Vote neg:

#### 1] Semantics –

#### A] jurisdiction – you don’t have the jurisdiction as per the tournament invite to vote on nontopical affs – outweighs because it constrains your ballot

#### B] stasis – anything else justifies the aff not talking about the topic – next it’ll be tech sharing, vaccine transfers, or ip extensions because it’s in the topic area which decks neg prep

#### 2] Ground – all NCs and DAs are based on the incentives of long patent terms, so they destroy any comparative disadvantage

#### 3] Preempt normal means args –

#### A] Normal means doesn’t license the aff to be nontopical – find a better solvency advocate

#### B] your own author says it’s a third option and a novel proposal – not normal nor necessary to be topical

#### [

#### TVA – Read any aff that only reduces IP protections for medicines – like trips plus.

#### Fairness is a voter

#### a] they concede the authority of fairness by agreeing to tournament procedures and speech times

#### b] fairness is a procedural constraint—if they had 10 minutes to say fairness bad and I only had 1 minute to defend it, they would win because it was structurally unfair to begin with.

#### Drop the debater (a) deter future abuse – empirically confirmed with aprioris and (b) dropping the arg on T is incoherent because it is dropping the aff advocacy so its functionally the same.

#### No RVI’s – (a)

#### chilling effect – aff is dangerous on theory because they get to prep a long counterinterp in the 1ar and then get the 2ar to collapse, weigh, and contextualize - negs would always be disincentives from reading theory against good theory debaters which leads to infinite abuse so it outweighs time skew and

#### (b) they’re illogical - “I’m fair vote for me” doesn’t make any sense - logic comes first on theory since all args need to make sense in order to be evaluable.

#### Competing interpretations – a] reasonability is arbitrary since it relies upon judge opinion which outweighs since it’s terminally unfair – it relies on something completely out of control and b] reasonability collapses into competing interpretations since you need to justify why your brightline is better than competing ones.

T over 1ar theory –

## 2

#### CP Text: Resolved: Member Nations of the World Trade Organization should increase Public/Private partnerships between IP owners of the Covid-19 vaccine and the government – we control solvency – they only make the problem worse – Brown 21:

Brown, Delphine. “Powerhouse Points: Will Trips Waiver of Ip Protection for Covid-19 Vaccines Serve Global Need?” Powerhouse Points: Will TRIPS Waiver of IP Protection for COVID-19 Vaccines Serve Global Need?-News | Freeborn & Peters LLP, 2021, www.freeborn.com/perspectives/powerhouse-points-will-trips-waiver-ip-protection-covid-19-vaccines-serve-global-need. // LHP PS

**The TRIPS waiver proposals have been under discussion for over eight months with no end in sight, and will likely fall prey to months, if not years, of legal challenges if approved.** Additionally, despite India and China developing mRNA vaccine candidates, **when one considers the intellectual property landscape for mRNA vaccines, a handful of pharmaceutical companies still hold half of the patent applications. Though a TRIPS waiver might free up untapped capacity for increased vaccine production to meet the huge unmet need, it seems that government and private sector partnerships could be forged much more expeditiously and result in the desired rapid ramp up of COVID-19 vaccine production.** For example, **Moderna and Samsung Biologics recently announced an agreement for fill-and-finish manufacturing of Moderna’s COVID-19 vaccine**.[[vii]](https://www.freeborn.com/perspectives/powerhouse-points-will-trips-waiver-ip-protection-covid-19-vaccines-serve-global-need" \l "_edn7" \o ") When the IP waiver concept was first proposed last October, **Moderna agreed not to enforce its COVID-19 related patents during the pandemic. But despite Moderna’s voluntary waiver of its IP rights, no other company has stepped up to manufacture the Moderna vaccine.** **The most significant obstacle to COVID-19** vaccine supply is not just the IP rights that companies have obtained, or are pursuing, but rather the **lack of raw materials and manufacturing facilities to produce the vaccines.** Currently, **there are shortages of raw materials and equipment used to make vaccines and biological products. Unlike drug manufacturing, vaccine production processes are extremely complex and difficult to develop without support from current manufacturers. Additional manufacturers would need to have oracquire skilled expertise in mRNA technology and create or reconfigure manufacturing sites.** **Manufacturing vaccines requires additional processing steps and testing to assure quality and consistency**. **Manufacturing vaccines will also likely use the patented technology of other companies, who have not waived their IP rights.** **Investment in manufacturing is also an important piece of the solution. Whether existing companies can retool facilities and jump start manufacturing or new facilities need to be created through investment will be outcome determinative**. **There is little doubt that the waiver proposals would at the very least up-end the existing incentives, including the prospect of future pharmaceutical innovation and development of products, that resulted in the rapid development and approval of COVID-19 vaccines**. Moreover, **the TRIPS waiver proposals may not have the desired effect of boosting COVID vaccine production and availability of mRNA vaccines.** On the other hand, **recent attempts at voluntary licensing and technology transfer agreements related to adenovirus vector technology have resulted in increased vaccine production and availability.** **A TRIPS waiver may not be as effective for more complex vaccine production.** **Scaling up COVID-19 vaccine production is not a one-size-fits-all proposition**. Ensuring equitable availability and delivery complicates the matter further. Coordination and collaboration will be required within a complex network of investing in technology transfer, contracting existing and new manufacturing facilities, sourcing materials, and pooling procurement facilities. **The negotiators and drafters of any TRIPS waiver have a difficult task to craft it into the cornerstone of an effective solution to the known problems of unmet need, and supply and availability, while also anticipating issues yet to arise concerning sustainability of supply, intellectual property rights for COVID-19 tests and treatments, and sharing of research**. The next several months will determine whether a TRIPS waiver can be successfully negotiated, practically implemented, and make a timely and effective difference in COVID-19 vaccine availability.

## 3

#### Biden’s infrastructure bill will pass through reconciliation but absolute Dem Unity is key.

* Turns Structural Violence

Pramuk and Franck 8-25 Jacob Pramuk and Thomas Franck 8-25-2021 "Here’s what happens next as Democrats try to pass Biden’s multitrillion-dollar economic plans" <https://www.cnbc.com/2021/08/25/what-happens-next-with-biden-infrastructure-budget-bills-in-congress.html> (Staff Reporter at CNBC)//Elmer

WASHINGTON — **House Democrats just patched up a party fracture** **to take a critical step forward with a mammoth economic agenda**. But the **path ahead could get trickier** as party leaders try to thread a legislative needle to pass more than $4 trillion in new spending. **In** the **coming weeks**, **Democrats** **aim to approve** a $1 trillion bipartisan **infrastructure** plan and up to $3.5 trillion in investments in social programs. Passing both **will require a heavy lift**, as leaders will need to **satisfy** **competing demands of centrists** wary of spending **and progressives** who want to reimagine government’s role in American households. The House is leaving Washington **until Sept. 20** after taking key steps toward pushing through the sprawling economic plans. The chamber on Tuesday approved a $3.5 trillion budget resolution and advanced the infrastructure bill, as House Speaker Nancy Pelosi, D-Calif., promised centrist Democrats to take up the bipartisan plan by Sept. 27. The Senate already passed the infrastructure legislation, so **a final House vote would send it to Biden’s desk for his** signature. Now that both chambers have passed the budget measure, **Democrats can move without Republicans** to push through their spending plan **via reconciliation**. Party leaders want committees to write their pieces of the bill by Sept. 15 before budget committees package them into one massive measure that can move through Congress. Committees could start marking up legislation in early September. Party leaders **face a challenge** in coming up with a bill that will satisfy centrists who want to trim back the $3.5 trillion price tag and progressives who consider it the minimum Congress should spend. As **one defection in the Senate** — **and four in the House** — **would sink legislation,** **Democrats have to satisfy a diverse range of views** to pass their agenda. “We write a bill with the Senate because it’s no use doing a bill that’s not going to pass the Senate, in the interest of getting things done,” Pelosi told reporters on Wednesday. Given the magnitude of the legislation, passing it quickly could prove difficult. To appease congressional progressives who have prioritized passage of the budget bill, Democrats could move to pass both proposals at about the same time. While Pelosi gave a Sept. 27 target date to approve the infrastructure plan, the commitment is not binding. Still, she noted Wednesday that Congress needs to pass the bill before surface transportation spending authorization expires Sept. 30. “We have long had an eye to having the infrastructure bill on the President’s desk by the October 1, the effective date of the legislation,” she wrote in a separate letter to Democrats on Wednesday. Democrats say the bills combined will provide a jolt to the economy and a lifeline for households. Supporters of the Democratic spending plan, including Pelosi and Senate Budget Committee Chair Bernie Sanders, I-Vt., have cast it as the biggest expansion of the U.S. social safety net in decades. “This is a truly historic opportunity to pass the **most transformative** and consequential **legislation for families** in a century, and will stand alongside the New Deal and Great Society as pillars of **economic security**,” Pelosi wrote to colleagues Wednesday. The plan would **expand Medicare**, **paid leave** and child care, extend enhanced household tax credits and encourage **green energy adoption**, **while hiking taxes on corporations and the wealthy**. Democrats hope to sell a wave of new support for families as they campaign to keep control of Congress in next year’s midterms. Those elections, though, have helped to generate staunch opposition on the other side of the aisle. The GOP has cited the trillions in new spending and the proposed reversal of some of its 2017 tax cuts in trying to take down the Democratic budget bill. Republicans and some Democrats have in recent weeks said that another $4.5 trillion in fiscal stimulus could not only boost economic growth but have the adverse effect of fueling inflation.

#### Pharma backlashes to the Plan – they’re aggressive lobbyists and will do anything to preserve patent rights.

* Turns Case – Waters down the Plan due to lobbying
* Optional Card – still thinking on if its necessary [note from Elmer]

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### They choose Infrastructure as backlash – they bill costs Pharma millions – lobbyists can derail the Agenda.

Brennan 8-2 Zachary Brennan 8-2-2021 "How the biopharma industry is helping to pay for the bipartisan infrastructure bill" <https://endpts.com/how-the-biopharma-industry-is-helping-to-pay-for-the-bipartisan-infrastructure-bill/> (Senior Editor at Endpoint News)//Elmer

Senators on Sunday finalized the text of **a massive, bipartisan infrastructure bill** that contains little **that might** **impact the biopharma industry** other than two ways the legislators are planning to pay for the $1.2 trillion deal. On the one hand, senators are **seeking to** further **delay** a **Trump-era Medicare** Part D **rule** **related to drug rebates**, this time until 2026. Senators claim the rule could end up saving about $49 billion (and that number increased this week to $51 billion), but the PBM industry has attacked it as it would remove rebates from a safe harbor that provides protection from federal anti-kickback laws. The **pharmaceutical industry**, however, is in favor of the rule and **opposes this latest delay** as it continues to point its finger at the PBM industry for the rising cost of out-of-pocket expenses. Debra DeShong, EVP of public affairs at PhRMA, said via email: Despite railing against high drug costs on the campaign trail, lawmakers are threatening to gut a rule that would provide patients meaningful relief at the pharmacy. If it is included in the infrastructure package, this proposal will provide health insurers and drug middlemen a windfall and turn Medicare into a piggybank to fund projects that have nothing to do with lowering out-of-pocket costs for medicines. This would be an unconscionable move that robs patients of the prescription drug savings they deserve to help fill potholes and fund other infrastructure projects. The **other provision** **in the infrastructure bill**, which is estimated to save about $3 billion, **would save money for Medicare** **on discarded medications** from large, single-use drug vials. **Manufacturers will be required to pay refunds** for such discarded drugs, and each manufacturer will be subject to periodic audits on the refunds issued. If manufacturers don’t comply, HHS can fine them the refund amount that they would have paid plus 25%. Drugs that will be excluded from these refund payments include radiopharmaceuticals or imaging agents, as well as those that require filtration during the drug preparation process. So do these two pay-fors mean that the pharma industry is getting off without any serious drug pricing reforms? Not quite, according to Alex Lawson, executive director of Social Security Works. Lawson told Endpoints News in an interview that he still fully expects major drug pricing reforms to make their way through Congress between now and the end of September as Sen. Ron Wyden (D-OR) refines his plan, part of an early fall spending package. Senate Majority Leader Chuck Schumer has promised both the infrastructure and spending package will pass before the Senate leaves for August recess. At the very least in terms of drug pricing provisions, expect to see a combination of the Wyden bill he co-wrote with Sen. Chuck Grassley (R-IA) last year, alongside further Medicare negotiations, Lawson said. “Talk is still optimistic,” Lawson said on the prospects of a drug pricing deal getting done, while noting that **pharmaceutical** company **lobbyists** are **swarming Capitol Hill** at the moment because of **not just drug pricing plans**, but **tax provisions** and the **TRIPS waiver** that the biopharma industry is worried about. “These are **challenges to their entire existence**, **so they’re willing to protect them at any cost**,” Lawson said, noting the target for drug pricing is about $500 billion in savings. As the House has jetted off to enjoy what might be an abbreviated summer recess, the Senate has just this week to get its work done, unless its recess is cut short too. “There’s a **real possibility** that **the whole thing blows up** and we get nothing on either side,” Lawson said.

#### Democrat Senators in Big Pharma’s pocket derails the Plan.

Sirota 8-23 David Sirota 8-23-2021 "Dem Obstructionists Are Bankrolled By Pharma And Oil" <https://www.dailyposter.com/dem-obstructionists-are-bankrolled-by-pharma-and-oil/> (an American journalist, columnist at The Guardian, and editor for Jacobin. He is also a political commentator and radio host based in Denver. He is a nationally syndicated newspaper columnist, political spokesperson, and blogger)//Elmer

The **small group of conservative Democratic lawmakers** that has been **threatening to** help Republicans **halt** **Democrats’ budget package** have **raked in more than $3 million from donors in the pharmaceutical** and fossil fuel **industries** that could see reduced profits if the plan passes. As the House reconvenes today to tackle the budget reconciliation process, nine Democrats legislators have been promising to kill their party’s $3.5 trillion budget bill until Congress first passes a separate, smaller infrastructure spending measure, which has garnered some Republican support and which some environmental advocates say would exacerbate the climate crisis. Indeed, an ExxonMobil lobbyist was recently caught on tape saying the company had worked to strip climate measures out of the infrastructure bill. “**We will vote against a budget resolution** if the infrastructure package isn’t brought up first,” Democratic **Rep**. Josh **Gottheimer** **told** the Washington Post this weekend, **though** the American Prospect reported on Sunday that “**several**” of the **legislators** now **indicated they could back down**. **In the narrowly divided House**, **obstructionism from these** conservative Democrats **could decouple the infrastructure** and budget **measures** from one another. Many believe that would kill the latter by letting conservative Democrats in the Senate such as Kyrsten Sinema (D-Ariz.) and Joe Manchin (D-W.Va.) get the infrastructure bill they want without having to provide the votes necessary to enact the much larger and more progressive budget measure. “If we were to pass the bipartisan [infrastructure] bill first, then we lose leverage,” Democratic Rep. Ritchie Torres (NY) told the Wall Street Journal. Along with Gottheimer, the eight other Democrats who have threatened to obstruct the budget bill are Carolyn Bordeaux (Ga.), Ed Case (Hawaii), Jim Costa (Calif.), Henry Cuellar (Texas), Jared Golden (Maine), Vicente Gonzalez (Texas), Kurt Schrader (Ore.), and Filemon Vela (TX). The U.S. Chamber of Commerce — Washington’s most powerful corporate lobby group — has been airing digital ads thanking the nine Democrats for their maneuvers. Eight of the nine Democrats represent congressional districts won by President Joe Biden, who supports the reconciliation package. Big Pharma’s Big Allies The reconciliation bill is still being negotiated, and many Democratic lawmakers — including those in key swing districts — are pushing for it to include long-promised legislation to allow Medicare to use its enormous purchasing power to negotiate lower prices for prescription drugs. The **pharmaceutical industry** has **aggressively lobbied against the initiative**, which the Congressional Budget Office has estimated would save Medicare $345 billion in medicine costs. The nine House Democrats threatening to derail the reconciliation bill have raked in nearly $1.2 million from donors in the pharmaceutical and health products industries, according to data compiled by OpenSecrets. Among them are two of the Democratic Party’s **top recipients of health care industry money**: **Gottheimer** ($228,186) **and Schrader** ($614,830). Schrader’s third biggest career donor is Pfizer’s political action committee, and his former chief of staff is now a registered lobbyist for the Pharmaceutical Researchers and Manufacturers Association, the pharmaceutical industry’s main lobbying group. Both Gottheimer and Schrader signed a letter earlier this year slamming Democratic leaders’ legislation to lower prescription drug prices. Eight out of the nine Democrats threatening to kill the budget bill also declined to sponsor Democrats’ standalone legislation to let Medicare negotiate lower drug prices. In the Senate, Sinema’s renewed threat to vote down a final reconciliation bill came after she received $519,000 from donors in the pharmaceutical and health products industries.

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

## Case

### ADV 1

#### Impact turn – Heg is net destabilizing which internal link turns all your impact card warrants – empirically confirmed, Cambanis 12

[Thanassis - Fellow at The Century Foundation and Professor at Columbia University’s School of International and Public Affairs “The lonely superpower,” <http://bostonglobe.com/ideas/2012/01/22/the-lonely-superpower/FRkSf1s5n9lXku4VqvEtqJ/story.html>]

Now, however, with a few decades of experience to study, a young international relations theorist at Yale University has proposed a provocative new view: American dominance has destabilized the world in new ways, and the United States is no better off in the wake of the Cold War. In fact, he says, a world with a single superpower and a crowded second tier of distant competitors encourages, rather than discourages, violent conflict--not just among the also-rans, but even involving the single great power itself. In a paper that appeared in the most recent issue of the influential journal International Security, political scientist Nuno P. Monteiro lays out his case. America, he points out, has been at war for 13 of the 22 years since the end of the Cold War, about double the proportion of time it spent at war during the previous two centuries. “I’m trying to debunk the idea that a world with one great power is better,” he said in an interview. “If you don’t have one problem, you have another.” Sure, Monteiro says, the risk of apocalyptic war has decreased, since there’s no military equal to America’s that could engage it in mutually assured destruction. But, he argues, the lethal, expensive wars in the Persian Gulf, the Balkans, and Afghanistan have proved a major drain on the country. Even worse, Monteiro claims, America’s position as a dominant power, unbalanced by any other alpha states actually exacerbates dangerous tensions rather than relieving them. Prickly states that Monteiro calls “recalcitrant minor powers” (think Iran, North Korea, and Pakistan), whose interests or regime types clash with the lone superpower, will have an incentive to provoke a conflict. Even if they are likely to lose, the fight may be worth it, since concession will mean defeat as well. This is the logic by which North Korea and Pakistan both acquired nuclear weapons, even during the era of American global dominance, and by which Iraq and Afghanistan preferred to fight rather than surrender to invading Americans. Of course, few Americans long for the old days of an arms race, possible nuclear war, and the threat of Soviet troops and missiles pointed at America and its allies. Fans of unipolarity in the foreign policy world think that the advantages of being the sole superpower far outweigh the drawbacks -- a few regional conflicts and insurgencies are a fair price to pay for eliminating the threat of global war. But Monteiro says that critics exaggerate the distinctions between the wars of today and yesteryear, and many top thinkers in the world of security policy are finding his argument persuasive. If he’s right, it means that the most optimistic version of the post-Cold War era -- a “pax Americana” in which the surviving superpower can genuinely enjoy its ascendancy -- was always illusory. In the short term, a dominant United States should expect an endless slate of violent challenges from weak powers. And in the longer term, it means that Washington shouldn’t worry too much about rising powers like China or Russia or the European Union; America might even be better off with a rival powerful enough to provide a balance. You could call it the curse of plenty: Too much power attracts countless challenges, whereas a world in which power is split among several superstates might just offer a paradoxical stability. From the 1700s until the end of World War II in 1945, an array of superpowers competed for global influence in a multipolar world, including imperial Germany and Japan, Russia, Great Britain, and after a time, the United States. The world was an unstable place, prone to wars minor and major. The Cold War era was far more stable, with only two pretenders to global power. It was, however, an age of anxiety. The threat of nuclear Armageddon hung over the world. Showdowns in Berlin and Cuba brought America and the Soviet Union to the brink, and the threat of nuclear escalation hung over every other superpower crisis. Generations of Americans and Soviets grew up practicing survival drills; for them, the nightmare scenario of thermonuclear winter was frighteningly plausible. It was also an age of violent regional conflicts. Conflagrations in Asia, Africa, and Latin America spiraled into drawn out, lethal wars, with the superpowers investing in local proxies (think of Angola and Nicaragua as well as Korea and Vietnam). On the one hand, superpower involvement often made local conflicts far deadlier and longer than they would have been otherwise. On the other, the balance between the United States and the USSR reduced the likelihood of world war and kept the fighting below the nuclear threshold. By tacit understanding, the two powers had an interest in keeping such conflicts contained. When the Soviet Union began its collapse in 1989, the United States was the last man standing, wielding a level of global dominance that had been unknown before in modern history. Policy makers and thinkers almost universally agreed that dominance would be a good thing, at least for America: It removed the threat of superpower war, and lesser powers would presumably choose to concede to American desires rather than provoke a regional war they were bound to lose. That is what the 1991 Gulf War was about: establishing the new rules of a unipolar world. Saddam Hussein invaded Kuwait, Monteiro believes, because he miscalculated what the United States was willing to accept. After meeting Saddam with overwhelming force, America expected that the rest of the world would capitulate to its demands with much less fuss. Monteiro compared the conflicts of the multipolar 18th century to those of the Cold War and current unipolar moment. What he found is that the unipolar world isn’t necessarily better than what preceded it, either for the United States or for the rest of the world. It might even be worse. “Uncertainty increases in unipolarity,” Monteiro says. “If another great power were around, we wouldn’t be able to get involved in all these wars.” In the unipolar period, a growing class of minor powers has provoked the United States, willing to engage in brinkmanship up to and including violent conflict. Look no further than Iran’s recent threats to close the Strait of Hormuz to oil shipping and to strike the American Navy. Naturally, Iran wouldn’t be able to win such a showdown. But Iran knows well that the United States wants to avoid the significant costs of a war, and might back down in a confrontation, thereby rewarding Iran’s aggressive gambits. And if (or once) Iran crosses the nuclear threshold, it will have an even greater capacity to deter the United States. During the Cold War, on the other hand, regional powers tended to rely on their patron’s nuclear umbrella rather than seeking nukes of their own, and would have had no incentive to defy the United States by developing them. Absent a rival superpower to check its reach, the United States has felt unrestrained, and at times even obligated, to intervene as a global police officer or arbiter of international norms against crimes such as genocide. Time and again in the post-Cold War age, minor countries that were supposed to meekly fall in line with American imperatives instead defied them, drawing America into conflicts in the Balkans, Somalia, Haiti, Iraq, and Afghanistan. This wasn’t what was supposed to happen: The world was supposed to be much safer for a unipolar superpower, not more costly and hazardous.

#### American primacy and challenging revisionist powers to force their decline encourages revisionary lashout – “use it or lose it” means their impacts are triggered – this is comparatively more likely than a revisionary challenge,

### Solvency/Turns

#### [1] The proposed waiver won’t solve because of how complicated it would be to mandate disclosure and transfer of trade secrets—the plan is insufficient to trigger the advantages, Donahoe

<https://www.natlawreview.com/article/waiver-ip-protections-covid-19-vaccines-still-under-consideration-wto>, 24 Aug 2021, Donahoe, Casey D.

While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. Katherine Tai, the U.S. Trade Representative, has not publicly committed to any position beyond waiving patent protections in particular. [Karpan 2021-07-01] Moderna has temporarily waived its COVID-19 vaccine patent rights, but the vaccine is still protected, at least in the U.S. and EU by regulatory marketing exclusivity. [Collins 2021-06-11] **With respect to patents, existing TRIPS flexibilities already allow for countries to issue compulsory licenses for domestic production in the face of public health crises and, under additional criteria, compulsory licenses for export.** But proponents of the waiver argue that the existing processes, which can require country-by-country and case-by-case negotiations and litigation with the vaccine developers and may be limited to public uses, are too time-consuming and inconvenient to mount an effective response, particularly where thickets of IP protection cover single vaccines. [Labonte 2021-01-09, The Conversation]; [Public Citizen, tradewatch.org] In fact, compulsory licensing to exporting manufacturers under Article 31b is has only been successfully used once in the past twenty years, [Public Citizen, tradewatch.org] when Canada issued a compulsory license authorizing the manufacture and export of an AIDS medication to Rwanda. [WTO 2007-10-04] Additionally, multiple countries may be involved in the pipeline for manufacturing a single packaged vaccine to be distributed in a country in need. Further, one key advantage to a unanimously agreed-upon waiver over attempting to utilize existing TRIPS flexibilities, would be that countries could more comfortably exploit the waiver without the threat of trade complaints or sanctions from other nations. [Lopez 2021-05-07] Proponents of the waiver point to alleged U.S. and European retaliatory trade measures against nations that have attempted to use existing TRIPS flexibilities to skirt IP protections. [Public Citizen, tradewatch.org] While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. **However, even if patent protection were not an issue, manufacturing and distribution of the vaccines would remain a substantial obstacle to achieving global immunity.** [Paton 2021-05-07 Bloomberg] **Aspects of vaccine manufacturing and regulation raise further issues of what TRIPS calls “undisclosed information,” encompassing trade secrets and know-how. Such undisclosed information may be particularly crucial in scaling up manufacture in a commercially viable fashion**. [Garrison 2020-12-16]. Article 39 of TRIPS requires members to protect the confidentiality of undisclosed information, including data submitted to regulatory agencies for marketing approval of pharmaceuticals. **As related to vaccines, undisclosed information could include clinical data** (e.g., related to effectivity, including negative results), **manufacturing processes, medical formulas, cell lines, genomic information, technical designs and specifications, instruction manuals, process controls and monitoring, quality control procedures, technical training, working practices, etc.** [Garrison 2020-12-16]; [Levine 2020-07-10]; [Eakin 2021-05-25 Law360] **The Pfizer and Moderna vaccines,** in particular, are expected to be **extremely difficult to replicate** given **they rely on new mRNA technology.** The WTO touts the COVID-19 Clinical Research Coalition, which aims to provide a platform for voluntary data-sharing, and the WHO-backed COVID-19 Technology Access Pool (C-TAP), which provides a platform for technology developers to bundle intellectual property rights, knowledge, and data into non-exclusive licenses with each other and with multiple quality-assured manufacturers, as examples of voluntary efforts to fill-in the know-how gap. [WTO Report 2020-10-15] In general, the voluntary transfer of know-how between two parties is highly contractually stipulated, usually allowing the licensor strict control over the dissemination of its know-how and protecting rights to improvements and developments that may derive from the collaboration, some of which might be patentable in themselves. [Bracho 2021-05-24 Bloomberg]. **The proposed waiver**, though, **wades into relatively unchartered territory of compulsory transfers of undisclosed information. Likely the biggest threat felt by vaccine manufacturers is that the compulsory transfer of undisclosed information will not simply diminish their return on investments in COVID19 vaccines, but would jeopardize entire proprietary technological platforms that support a wide range of potential products.** Such giveaways would likely impact small-to-medium sized enterprises especially, which account for approximately 75% of US COVID-19 treatments, and particularly small university spin-outs, which are highly depend on IP for valuation. [Balfour 2021-06-30] As details of a waiver have not yet been hammered out, it remains unclear exactly who might have access to such undisclosed information (e.g., the general public or only generic manufacturers) and the mechanisms by which such transfers would be achieved. Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. [Labonte 2021-01-09, The Conversation**] The most obvious means would be for regulatory agencies to disclose data and manufacturing protocols submitted by vaccine manufacturers that they are ordinarily required to keep confidential.** In fact, the issue of data confidentiality has already been raised in the U.S. as an obstacle to developing a competitive generic biologics market, with some pointing to the Federal Pesticide Act (FPA) as a successful model which allows more free dissipation of regulatory data by the EPA. [Heled 2019] There are some exemptions to confidentiality of data supplied to regulatory drug agencies implemented in the U.S. and Europe, particularly where public funding helped finance the underlying research. For example, for research funded by the U.S. government, the Bayh-Dole Act provides some additional licensing provisions to the government which could potentially extend to some know-how; however, these provisions are largely untested and may be contractually restricted. [Collins 2021-06-11]. **But there is no precedent for compulsory transfer of confidential information in general**. [Levine 2020-07-10] **Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. Additionally, knowledge holders may be located outside the jurisdiction of a member state desiring to compel transfer,** [Garrison 2020-12-16] **and waiving an obligation for member states to protect undisclosed information does not necessarily compel other member states to do so.  Notably, India, one of the waiver proponents that actually has substantial pharmaceutical manufacturing capacity, does not even presently require submission of test data for marketing approval.**  [Haugen 2020-12-01]  **Compulsory disclosure of undisclosed information is further complicated by the fact that the knowledge holders for manufacturing a single vaccine may be dispersed across multiple entities and/or even multiple jurisdictions, particularly where a supply chain of highly technical components is utilized or certain processes are outsourced to contractor entities.**  [Garrison 2020-12-16]  **The legislative levers that might be needed to fully enforce compulsory disclosure of undisclosed information or that could be pulled to halt executive branch action, as well as the lawsuits that might be filed would seem likely to stall any grand gestures of governmental action related to undisclosed information.** [Eakin 2021-05-25 Law360]  **For instance, compulsory disclosures would likely spurn allegations of violating the Takings Clause of the Fifth Amendment**, although the Supreme Court had found previously in *Ruckelshaus v. Monsanto Co*. that the FPA had not done so [Heled 2019].  Still, compulsory disclosure facilitated by regulatory agencies may not be sufficient to fill the knowledge gap for the successful manufacture of the vaccines, leaving room for countries to consider other creative avenues.  Brazil, for instance, has proposed one of a kind legislation which would tie patent rights to the compulsory disclosure of all information needed to make COVID-19 vaccines.  [Eakin 2021-05-25 Law360] Opponents argue that **bottlenecks in manufacturing capacity and supplies would stymie the effect of the waiver, despite the transfer of undisclosed information, and that even with full technology transfer, it would take months or years for factories to come up to speed on vaccine production.**  [Leonard 2021-05-06, Bloomberg]; [Paton 2021-05-07 Bloomberg]  **Manufacturing capacity is particularly limited for mRNA-based vaccines and there’s not even necessarily a sufficient population of people with expertise capable of manufacturing them.**  [Karpan 2021-05-11 Law360]  **Some also warn that redistributing crucial supplies to manufacturers without existing capabilities to manufacture the high-quality vaccines with regulatory approval would actually hinder vaccine distribution efforts.**  [Karpan 2021-05-11 Law360]; [Lima 2021-05-08 Bloomberg]; [Paton 2021-05-07 Bloomberg]  Even manufacturing facilities with access to all IP rights are experiencing production delays from regulatory reviews.  [Baschuck 2021-05-06]  Opponents also resound that such efforts to undermine IP rights will only discourage future innovation, including research that targets new variants of the coronavirus.  [Bacchus 2020-12-16 Cato Institute];  [Paton 2021-05-07 Bloomberg] The large divide between fervid proponents of the waiver and even those who have expressed some mild support suggests any significant compromise may be some time coming.  Many view the waiver controversy any way as less of a problem-driven exercise and more of an opportunity for the usual players to debate both the power of big pharma in the U.S.  [Collins 2021-06-11] and the stifling effects IP protections can have on the least developed nations around the world.  Also, the angst amongst some proponents of the waiver, some believe, may stem more from policies of vaccine nationalism than of TRIP impediments. [Clarke 2021-04-22 Lexology] Regardless, the decisions reached at the WTO during this crisis are likely to shape future policy discussions for years to come.

#### [2] Waivers won’t solve the actual problem. Supply will be a non-issue by years end. The TRIPS waiver is a theatrical gesture aiming to let rich economies off the hook for actually solving the problem, Adler

<https://foreignpolicy.com/2021/07/20/wto-trips-waiver-vaccine-equity-distribution-covid-pandemic/>, July 20, 2021

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**](https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/21/press-briefing-by-press-secretary-jen-psaki-june-21-2021/)**, “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. **The TRIPS waiver can be seen as essentially a political or even theatrical gesture.** 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](https://foreignpolicy.com/2021/07/16/biden-africa-covid-19-ship-millions-vaccines/), and newer proposals are likely to show more immediate results. The United States has [pledged](https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/) 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](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort) 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](https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_221)” 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](https://www.gavi.org/covax-facility?gclid=Cj0KCQjwub-HBhCyARIsAPctr7wD6lbQwpflk8lliN12KxEUIUL9NkbdH7NgZ3UTkYqdsLWgG380utMaAqtvEALw_wcB), 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](https://www.gavi.org/our-alliance/operating-model) 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](https://www.unicef.org/) 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](https://www.amnesty.org/en/latest/news/2021/06/g7-support-for-pharma-monopolies-putting-millions-of-lives-at-risk/) and [eliminating vaccine hoarding](https://www.oxfamamerica.org/press/cnn-rich-countries-are-hoarding-covid-19-vaccines-and-leaving-developing-world-behind-peoples-vaccine-alliance-warns/) 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.

#### Turns case – enables rich countries to politically justify not putting additional effort into int. COVID vaccinations.