## 1

### T Medicines – Vaccines

#### **Interp – “medicines” treat or cure, whereas vaccines prevent – o/w on specificity since it’s about the COVID vaccine**

Vecchio 7/22 (Christopher Vecchio, [CFA, Senior Strategist,], 7-22-2021, “Delta Variant Concerns Won't Cripple Markets, US Economy“, DailyFX, accessed: 8-9-2021, https://www.dailyfx.com/forex/video/daily\_news\_report/2021/07/22/market-minutes-delta-variant-concerns-wont-cripple-markets-us-economy.html) ajs

Let’s stick to the facts. The COVID-19 vaccines are not medicines, which by definition “treat or cure diseases.” Vaccines “help prevent diseases,” an important distinction. Why does this matter? Because data coming out of some of the world’s developed economies with high adult vaccination rates suggest that the vaccines are working as intended: tail-risks have been reduced, with hospitalizations and deaths falling relative to the recent spike in infections (which have been occurring primarily among the unvaccinated at this point). Put another way, vaccines are like a Kevlar vest for the immune system; while they don’t make you bulletproof, they dramatically increase the odds of surviving an adverse event.

#### Vaccines are medical interventions – not medicines

Elbe 10 (Stefan Elbe, [director of the Centre for Global Health Policy and a professor of international relations at the University of Sussex. He is the author of Strategic Implications of HIV/AIDS, Security and Global Health, and Virus Alert: Security, Governmentality, and the AIDS Pandemic.], 5-3-2010, “Security and Global Health” Polity Press, accessed: 8-9-2021, https://books.google.com/books?id=PKMoMJrSsksC) ajs

Yet here too we must be careful not to overlook other types of medical intervention simultaneously pursued by the 'social' arm of modern medicine at the population level. Vaccines in particular continue to be particularly important medical interventions that repeatedly surface in a variety of different health security delib- erations. Strictly speaking, vaccines are not medicines because they consist of small concentrations of disease-causing microbes (or their derivatives) used to enhance a person's immuno-response to a future infection. As a public health measure, vaccines have therefore also been largely sidelined in the existing medicalization literature. Yet, generally speaking, vaccines too can be considered as medical inter- ventions. That is certainly how the World Health Organization views them, pointing out that 'vaccines are among the most important medical interventions for reducing illness and deaths' available today (WHO 2009a). Whereas pills and other therapies mark the tools of clinical medicine, vaccines play a crucial part in the arsenal of 'social' medicine and public health. Developing and rolling out of new vaccines against a range of current (and future) diseases therefore represents further evidence of how the rise of health security is also encouraging security to be practised through the introduction of new medical interventions in society.

#### Violation – their plan - “The United States of America ought to reduce intellectual property protections for the COVID-19 vaccine”

#### Negate –

#### 1] Limits – expanding the topic to preventative treatment or medical interventions allows anything from surgery to medical devices to education strategies or mosquito repellent to prevent malaria. Destroys core generics like innovation which are exclusive to disease curing – core of the topic is about proprietary information. A big case list with no unifying generics destroy neg prep – disincentivizes in depth topic research and leaves the neg behind.

#### 2] Precision – WHO definitively outweighs on common usage and quals and views vaccines as medical interventions which proves we’re right and consistent with topic lit – debates should mirror international medical consensus.

#### Voters:

#### Competing interpretations—it tells the negative what they do and do not have to prepare for. Reasonability is arbitrary and unpredictable, inviting a race to the bottom and we’ll win it links to our offense.

#### Drop the debater to deter future abuse and because the 2N doesn’t get new disads to whole rez so it’s permanently skewed.

#### No RVIs – a) baiting – incentivizes good debaters to be abusive, bait theory, then collapse to the 1AR RVI, b) topic ed – prevents 1AR blipstorm scripts and allows us to get back to substance after resolving theory

#### Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### T comes before 1AR theory – a) norms – we only have a couple months to set T norms but can set 1AR theory norms anytime, b) magnitude – T affects a larger portion of the debate since the aff advocacy determines every speech after it

#### 1AR theory is skewed towards the aff – a) the 2NR must cover substance and over-cover theory, since they get the collapse and persuasive spin advantage of the 3min 2AR, b) their responses to my counter interp will be new, which means 1AR theory necessitates intervention. Implications – a) reject 1AR theory since it can’t be a legitimate check for abuse, b) drop the arg to minimize the chance the round is decided unfairly, c) use reasonability with a bar of defense or the aff always wins since the 2AR can line by line the whole 2NR without winning real abuse

## 2

### Infrastructure

#### Infrastructure is making halting progress via reconciliation – Dem unity is key

Litvan 9/2 [Laura] “Manchin Jolts Democrats by Urging ‘Pause’ on $3.5 Trillion Bill,” Bloomberg, September 2, 2021, <https://www.bloomberg.com/news/articles/2021-09-02/manchin-tells-democrats-to-pause-on-biden-s-3-5-trillion-plan> TG

Senator Joe Manchin is demanding a “strategic pause” in action on President Joe Biden’s economic agenda, potentially imperiling the $3.5 trillion tax and spending package that Democratic leaders plan to push through Congress this fall.

The West Virginia Democrat, a linchpin vote in the evenly divided Senate, said at an event in his home state on Wednesday and in a Thursday Wall Street Journal op-ed that rising inflation and a soaring national debt necessitate a go-slow approach and a “significantly” smaller plan than the one Democratic leaders and the White House have endorsed.

“By placing a strategic pause on this budgetary proposal, by significantly reducing the size of any possible reconciliation bill to only what America can afford and needs to spend, we can and will build a better and stronger nation for all our families,” Manchin said in the op-ed.

Manchin’s resistance to the core of Biden’s economic plan caps a politically painful month for a White House that has grappled with a chaotic withdrawal from Afghanistan, a resurgent pandemic and a massive hurricane that cut a path of death and damage from Louisiana to New York.

In comments Wednesday at an event hosted by the West Virginia Chamber of Commerce, the moderate Democrat said his party should “hit the pause button.” Lawmakers, he said, have too many other pressing issues before them, including heightening national security concerns after the Taliban takeover of Afghanistan.

“Let’s sit back. Let’s see what happens. We have so much on our plate,” he said.

Manchin’s comments come as Democratic leaders and committee chairs in the Senate and House work out the specifics of the economic package, with a goal of moving it through Congress soon after lawmakers return from a recess later this month. All members of the Senate Democratic caucus would have to back the measure for it to get the 51 votes needed to pass, with Vice President Kamala Harris providing the tie-breaking vote.

A spokesman for Senate Majority Leader Chuck Schumer didn’t immediately respond to a request for comment about Manchin’s request, and White House Press Secretary Jen Psaki did not immediately provide a comment.

The chair of the Congressional Progressive Caucus, Representative Pramila Jayapal, replied “Absolutely not” on Twitter to Manchin’s idea of a pause.

The spending package also is facing obstacles in the House. Democrats can only afford three defections in that chamber if Republicans are united in opposition, and some moderate Democrats also are balking at the size of the package being drawn up.

Manchin also called on the House to pass within a few weeks a Senate-passed $550 billion bipartisan infrastructure bill. House Speaker Nancy Pelosi has promised progressives in the chamber that she will marry that legislation with the much bigger Democrat-only tax-and-spending package, although moderates have been promised an infrastructure vote by late September.

#### Pharma fights the plan and wins – sparks backlash and turns case

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

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 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.

#### Democrats in pharma’s pocket derails the plan and infrastructure.

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.

#### Comprehensive infrastructure investment is key to all facets of the economy

Condon 2/21 [(Christopher, overing the Treasury and U.S. economic policy at Bloomberg News, with Erik Wasson) “Biden’s Economic Legacy at Stake as Next Package Takes Shape,” *Bloomberg*, 2-21-2021, <https://www.bloomberg.com/news/articles/2021-02-21/biden-s-economic-legacy-at-stake-with-next-package-taking-shape>] TDI

The next phase of President Joe Biden’s legislative agenda is fast taking shape, with an economic-recovery package that will potentially far surpass his $1.9 trillion virus-relief plan in size, complexity and overall ambition. The White House and congressional Democrats are busy plotting strategy for the proposal, which could be unveiled next month, kicking off a legislative process that may culminate by August. The centerpiece will be possibly the biggest infrastructure-spending commitment since the New Deal -- including roads, bridges and rural broadband internet. Progressives are eyeing much more, such as an expansion of Obamacare and a public-sector jobs program, along with tax measures including an increase in the capital-gains levy. But stuffing it with too many controversial proposals could threaten its approval or force it to be broken up, and put in peril the Democrats’ thin majorities in the 2022 midterm elections. Still, Democrats see a narrow opening to forge Biden’s legacy: not just restoring the U.S. economy to its pre-pandemic state, but reversing the trend of sluggish growth in recent years with the most far-reaching measures in decades. U.S. economy has put up more moderate growth in the 2000s versus heydays Biden’s virus-relief package is “going to help us get us back on the growth pattern we were on before,” said Virginia Representative Don Beyer, who, as incoming chair of the Joint Economic Committee, is a leading Democratic macroeconomic-policy voice. “The genius of the second plan is that it gives us the opportunity to punch GDP up above the long-term trend,” he said in an interview. During his campaign, Biden proposed $2 trillion for economic rebuilding, a step up from the $1.5 trillion level proposed in the House last year, which Democrats are now calling a “floor.” China Card Biden is aiming to succeed where Donald Trump and other predecessors have failed, when funding disputes stymied measures that economists say are vital to boosting long-term productivity. The president is selling the package as a way to counter China, which has deployed public investment not only to boost its own growth but to build global influence as well. As challenging as it may be to enact, such arguments may make the core infrastructure piece likely to be the easiest component to get through Congress. Bipartisan support for improved highway, transit, waterway and flood-mitigation work is strong, while deficit concerns are at the lowest level in decades. There’s also a Sept. 30 deadline in Congress for reauthorizing surface-transportation funding -- offering a ready-made vehicle for pursuing infrastructure measures. “Much of our infrastructure is nearing the end of its useful design life,” said Thomas Smith, executive director of the American Society of Civil Engineers, which will issue its latest quadrennial report card on U.S. infrastructure on March 3. “We’ve neglected it for far too long, and we’ve watched other countries continue to invest and continue to move ahead of the United States.” The ASCE’s last assessment, in 2017, was a D+. Back then, it estimated the U.S. needed $4.5 trillion in infrastructure spending over the following 10 years. With about $2.5 trillion in estimated outlays already in train, that left a $2 trillion gap -- which Biden’s proposal could largely fill. Congressional Budget Office figures indicate that a $1.5 trillion package would be equivalent to all federal spending on transportation and water infrastructure in the 14 years through 2017. The Senate Environment and Public Works Committee plans a hearing on transportation investment on Wednesday, when Michigan Governor Gretchen Whitmer, a Democrat, and Maryland Governor Larry Hogan, a Republican, are scheduled to testify. But infrastructure could become ensnared by a push among liberal lawmakers to tack on a raft of other items, from creating a government-run health insurance plan and making unionization easier, to a pathway to citizenship for undocumented immigrants and a carbon tax. Political Risk Meanwhile, House moderates in swing districts are facing the perils of redistricting ahead of the midterms, and could insist on limiting the scope of the bill to rein in its cost and limit partisan battles. Fights could also emerge over formulas for divvying up the money among states and cities. Congressional Progressive Caucus Chair Pramila Jayapal said Thursday her large cohort of House Democrats will decide in the coming weeks which elements to advocate in the package -- including whether to use it as an opportunity to roll back Trump’s tax cuts for the wealthy. Jayapal’s group was instrumental in attaching to the pandemic-relief plan an increase in the hourly minimum wage to $15, something that’s become easily the most controversial potential holdup for that bill. The progressive caucus has proposed a $2 trillion infrastructure bill, and is already advocating that it include expanded child and elder care. The question of funding, whether by raising taxes or issuing more debt, also looms large, and many Republicans are set to be vociferous in opposing much of the plan. Senate Finance Committee Chairman Ron Wyden is expected to propose tax hikes, including equalizing ordinary income and capital-gains levies for those making more than $1 million a year and ending the deferral of capital gains. He’d also change international tax provisions in the 2017 tax law and close the carried-interest loophole, according to a Democratic aide. Some lawmakers favor raising the federal gasoline tax -- now 18.4 cents a gallon and 24.4 cents for diesel -- for the first time since 1993, though Wyden in 2019 expressed opposition to the idea, calling it regressive. Treasury Secretary Janet Yellen, who argues that deficit spending makes more sense with interest rates historically low, said on CNBC last week that “certainly part of the package, the parts that are permanent, will be paid for in order to not raise long-term deficits.” While the yield on 10-year Treasury notes has risen markedly in recent weeks, Friday’s level of 1.34% is far below the 50-year average of about 6.16%. U.S. government's borrowing costs are historically low “There’s a lot of appetite to do something this year,” said Jeff Davis, a senior fellow at the Eno Center for Transportation. “But there seems to be no appetite to pay for it.” Despite all the hurdles, Biden has a strong hand. Upgrading and maintaining infrastructure acts as its own stimulus, unleashing real demand for equipment makers, materials suppliers and, most importantly, workers. Nucor Corp., Cleveland-Cliffs Inc. and U.S. Steel Corp., the country’s three largest steel producers, have been lobbying through their industry groups since the election to persuade lawmakers to back whatever infrastructure package the Biden administration puts forth. Productivity Potential Such spending would also be a huge boon for Caterpillar Inc., one of the world’s largest machinery makers, which attributed a drop in North American construction-equipment sales to weaker demand for pipelines and road construction. There’s also the potential for a long-term payoff, if investments translate into productivity gains -- such as savings on shipping and commuting costs when roads, rails and ports are improved, or avoiding the kind of power-grid failures on display this month in Texas. “We cannot throw all fiscal discipline to the wind, but the standards for fiscal prudence have indeed changed in light of the global decline in the normal structure of interest rates,” said David Wilcox, a senior fellow at the Peterson Institute for International Economics, and a former Federal Reserve and Treasury official. “If the rate of return on an investment exceeds your borrowing cost, it makes sense to do that investment, and with lower borrowing costs, more investments today can clear that bar.”

#### Post-COVID economic rebound secures geopolitical dominance---the alternative is global conflict, EU collapse and Chinese authoritarian dominance

Kempe 20 [(Frederick, best-selling author, prize-winning journalist and president & CEO of the Atlantic Council, one of the United States’ most influential think tanks on global affairs. He worked at The Wall Street Journal for more than 25 years as a foreign correspondent, assistant managing editor and as the longest-serving editor of the paper’s European edition.) “Op-ed: How the US can win the post-coronavirus race for global dominance,” CNBC, 4-18-2020, https://www.cnbc.com/2020/04/18/op-ed-how-us-can-win-the-post-coronavirus-race-for-global-dominance.html] TDI

Place your bets for the coming race to growth. It will be an epic contest among the world’s most significant economies, with generational and geopolitical consequences. For context, think back to what the United States accomplished after World War II, when it rose as an economic power to shape a better world. The post-COVID19 race could determine whether the U.S. rebounds in a manner that allows it to retain the mantle of global leadership. More likely for the moment, Beijing could leverage its first-mover advantage – alongside a faster economic recovery across Asian markets – accelerating the trend toward a Chinese-centric globalization. Elsewhere, as President Macron [argued](https://www.ft.com/content/3ea8d790-7fd1-11ea-8fdb-7ec06edeef84) this week to the Financial Times, the coming months could determine whether the European Union collapses as a political and economic project. The days ahead also could trigger a dangerous widening of the economic gap between emerging markets and the developed world – with escalating conflict and surging migration. It may seem premature to reflect on which of the globe’s economies is likely to have the most robust and lasting economic comeback – and with what geopolitical impact. After all, this was a week in which the International Monetary Fund [projected](https://www.imf.org/en/Publications/WEO/Issues/2020/04/14/weo-april-2020) a 3% contraction in global GDP for 2020, the most dramatic drop since the Great Depression. Yet it is the details behind that dismal forecast that should raise concerns within the U.S. and Europe. Their steeper economic decline and slower recovery could lay the seeds for a long-lasting shift of global tectonic plates to China’s advantage. The IMF projected a U.S. economic decline of about 6% in 2020 and a contraction of the eurozone of 7.5%. That compares to projected Chinese economic growth for 2020 of 1.2% after a first quarter real decline of 6.7% – far less than the 10%-plus dip many experts had expected. The only group of countries in the world projected to be in positive territory are East Asian, at roughly 1%. Even if one accepts that Chinese coronavirus fatalities likely are greater than their public figures and that the growth decline is likely larger, that doesn’t change the potential for a scenario that Deloitte and Salesforce this week [referred to](https://www2.deloitte.com/global/en/pages/about-deloitte/articles/covid-19/covid-19-scenarios-and-impacts-for-business-and-society-world-remade.html) as “Sunrise in the East.” Describing this scenario, as one of four possibilities they list, they write, “The global center of power shifts decisively east as China and other East Asian nations take the reigns as primary powers on the world stage and lead global coordination of the health system and other multilateral institutions.” That comes with the broader acceptance of greater surveillance mechanisms as part of the public good, a faster recovery of East Asian countries with less economic impact from COVID19, and a significant ramping up of Chinese foreign direct investment to burnish its global reputation. Still, the U.S. has a host of incumbent advantages that could serve it well if it uses its economic recovery to also strengthen its infrastructure, if it reverses runaway unemployment quickly, if it can tame political polarization and, most significantly, if it rediscovers its taste for collaborative global leadership. In the economic race, no advantage is greater than the dollar. China may be the world’s second largest economy, but the Chinese yuan [makes up](https://asiatimes.com/2019/12/yuan-globalization-remains-a-long-way-off/) only 2% of global payments and reserves while the dollar [accounts](https://asiatimes.com/2019/12/yuan-globalization-remains-a-long-way-off/) for roughly two thirds of foreign exchange reserves. The dollar [underpins](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) four-fifths of global supply chains. The Economist [reckons](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) China could chip away at U.S. economic advantages through three underestimated strengths of its own: as a trusted debtor, an attractive creditor, and increasingly as a tech partner. As a debtor, China’s $13 trillion bond market is the world’s second largest and [has weathered the crisis well](https://www.ft.com/content/41044876-6ab4-11ea-a3c9-1fe6fedcca75). Chinese debt [returned](https://www.cbsnews.com/news/china-cuts-us-treasury-debt-holding-by-13/) 1.3% in the first quarter, vastly better than the 15.5% [decline](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) for other emerging market bonds. Over the same period, the Chinese market added $8.5 billion (60 billion yuan) in net inflows. As a creditor, China has remained willing and generous, an approach that served the U.S. well after World War II. For example, it [declared](https://www.ft.com/content/5f296d54-d29e-4e87-ae7d-95ca6c0598d5) its willingness to back a G20 deal to suspend bilateral loan repayments by poorer countries, a sizable benefit also at its own cost. On the tech front, few countries were as ready as China for money and people to go entirely online. Tencent and Ant Financial have more than a billion users each for their digital wallets, and they are expanding rapidly throughout Asia. OneConnect, an offshoot of China’s largest insurer, provides financial institutions in sixteen Asian countries with cloud-based services. So, what other advantages can the United States leverage in this race? Never underestimate the brittleness of an authoritarian country under stress. Its broad censorship, it’s opaque legal system, and the nature of its surveillance state are hardly models to emulate. Beyond that, Japanese Prime Minister Shinzo Abe is not alone [in proposing](https://asia.nikkei.com/Editor-s-Picks/China-up-close/Xi-fears-Japan-led-manufacturing-exodus-from-China) that his country relocate high-value supply chains from China. If many countries do the same, the manufacturing foundation of China’s economy could erode. The Financial Times’ Gideon Rachman [adds](https://www.ft.com/content/2e8c8f76-7cbd-11ea-8fdb-7ec06edeef84) that the global trust in the dollar is just one of two built-in U.S. advantages that are difficult to dislodge. The other? “Where, outside your home country, would you most like your children to go to university or to work?” he writes. Most significant in this race would be if the United States regained its appetite for political and economic leadership as the world’s premier “convening power.” That need not be done at the cost of China – or anyone else. The race still can be won if U.S. leaders see it as a marathon and recall that much of the world long embraced their global leadership because partners learned they were more likely to win as American partners. This economic rebound from COVID19 will be patchy and uneven. Being first out the gate will be significant, and that is likely to be China. Yet history has taught the United States that it’s victory will be longest lasting if it can achieved alongside partners and allies.

#### Nuclear war

Henricksen 17, emeritus senior fellow at the Hoover Institution (Thomas, “Post-American World Order,” *Hoover Institution*, <http://www.hoover.org/research/post-american-world-order>)

The tensions stoked by the assertive regimes in the Kremlin or Tiananmen Square could spark a political or military incident that might set off a chain reaction leading to a large-scale war. Historically, powerful rivalries nearly always lead to at least skirmishes, if not a full-blown war. The anomalous Cold War era spared the United States and Soviet Russia a direct conflict, largely from concerns that one would trigger a nuclear exchange destroying both states and much of the world. Such a repetition might reoccur in the unfolding three-cornered geopolitical world. It seems safe to acknowledge that an ascendant China and a resurgent Russia will persist in their geo-strategic ambitions. What Is To Be Done? The first marching order is to dodge any kind of perpetual war of the sort that George Orwell outlined in “1984,” which engulfed the three super states of Eastasia, Eurasia, and Oceania, and made possible the totalitarian Big Brother regime. A long-running Cold War-type confrontation would almost certainly take another form than the one that ran from 1945 until the downfall of the Soviet Union. What prescriptions can be offered in the face of the escalating competition among the three global powers? First, by staying militarily and economically strong, the United States will have the resources to deter its peers’ hawkish behavior that might otherwise trigger a major conflict. Judging by the history of the Cold War, the coming strategic chess match with Russia and China will prove tense and demanding—since all the countries boast nuclear arms and long-range ballistic missiles. Next, the United States should widen and sustain willing coalitions of partners, something at which America excels, and at which China and Russia fail conspicuously. There can be little room for error in fraught crises among nuclear-weaponized and hostile powers. Short- and long-term standoffs are likely, as they were during the Cold War. Thus, the playbook, in part, involves a waiting game in which each power looks to its rivals to suffer grievous internal problems which could entail a collapse, as happened to the Soviet Union.

## 3

### Future Pandemics CP

#### CP: During the next national public health emergency, the United States of America ought to reduce intellectual property protections for relevant medicines. The plan’s implemented through a TRIPS waiver for the US.

#### No solvency deficit – they didn’t read a Covid existential impact, and there’s no reason setting the precedent now vs next time is key.

## 4

### Distribution CP

#### The United States federal government should:

#### - substantially increase production and global distribution of the COVID-19 Vaccine

#### - cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.

#### That solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.

Hans Sauer 6-17 [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

## Case

### COVID Adv

#### 1] Can’t solve for local producers in developing countries.

USPTO “Protecting intellectual property rights (IPR) overseas” No Date <https://www.uspto.gov/ip-policy/ipr-toolkits> SM

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in other countries must apply for a patent in each of the other countries or in regional patent offices. Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country, in accordance with the requirements of that country. Similarly, local laws apply to trademark, copyrights, and other forms of intellectual property in each jurisdiction.

#### 2] Doesn’t solve import restrictions.

Kumar 21 [Rajeesh; Associate Fellow at the Institute, currently working on a project titled “Emerging Powers and the Future of Global Governance: India and International Institutions.” He has PhD in International Organization from Jawaharlal Nehru University, New Delhi. Prior to joining MP-IDSA in 2016, he taught at JamiaMilliaIslamia, New Delhi (2010-11& 2015-16) and University of Calicut, Kerala (2007-08). His areas of research interest are International Organizations, India and Multilateralism, Global Governance, and International Humanitarian Law. He is the co-editor of two books;Eurozone Crisis and the Future of Europe: Political Economy of Further Integration and Governance (London: Palgrave Macmillan, 2014); and Islam, Islamist Movements and Democracy in the Middle East: Challenges, Opportunities and Responses (Delhi: Global Vision Publishing, 2013); “WTO TRIPS Waiver and COVID-19 Vaccine Equity,” IDSA Issue Briefs; <https://idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721>]

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

#### 3] Only lets US companies manufacture but no companies in any other countries – none of their ev says one country worth of companies is enough to solve, cuz their whole aff is in a GLOBAL CONTEXT.

### WTO Cred Adv

#### Framing issue: Don’t let them spew some bs about normal means or shift – their plan text actor was explicitly the United States with no mention of the other hundred plus WTO countries. Anything else encourages 1AR shiftiness that makes the 2NR impossible cuz we don’t get new arguments.

#### 1] US waiver is incoherent

#### A] The US can’t waive TRIPS just for themselves because WTO proceedings require a consensus to allow anyone to waive TRIPS – that’s proven by their Meyer ev explicitly saying international consensus is key. Their aff isn’t that all countries do the plan nor is there US norm setting ev, so they can’t solve.

#### B] Countries can’t just assign themselves a waiver…AND all of their evidence is in the context of a GLOBAL TRIPS waiver which they definitely don’t solve.

Minnsen 7/6 Timo Minssen [Professor of Law at the University of Copenhagen (UCPH) and the Founder and Managing Director of UCPH's Center for Advanced Studies in Biomedical Innovation Law (CeBIL)], July 6, 2021, “The Prospects for an IP Waiver Under the TRIPS Agreement” <https://blog.petrieflom.law.harvard.edu/2021/07/06/the-prospects-for-an-ip-waiver-under-the-trips-agreement/> SM

Ultimately, however, the WTO is a member-driven institution, and agreement on a TRIPS waiver will require either consensus, or, if it were to go to a vote, a three-fourths majority in accordance with Article IX of the WTO Agreement. Currently, WTO members supporting the waiver simply don’t have the numbers to achieve this. About 123 WTO members would be needed if this went to a vote under Article IX of the WTO Agreement. Even optimistically, the current number of WTO members supporting the waiver is only half that total. In reality, when deciding on whether a consensus or majority approach will be sought, the Chair of the WTO General Council will have a great deal of discretion as to what will happen next. He will make that decision based on the information he receives from the Chair of the TRIPS Council, but there will be no vote taken at the TRIPS Council itself. Only the WTO Ministerial Conference (slated for November 30 – December 3 2021) can decide this. We do expect some sort of WTO Declaration on IP and COVID-19 to emerge by December 3, but whether this is anywhere close to current TRIPS waiver proposals remains to be seen. Watering down the current TRIPS waiver proposals to achieve a consensus or majority vote remains a very real possibility.

#### 2] The US unilaterally changing their laws to violate TRIPS without WTO consensus undermines WTO legitimacy – that’s a bigger internal link that turns the aff.

Patch 19 COLIN PATCH [J.D., Georgetown University Law Center (expected May 2021); B.A., Connecticut College (2016). “A Unilateral President vs. A Multilateral Trade Organization: Ethical Implications In The Ongoing Trade War” 2019, <https://www.law.georgetown.edu/legal-ethics-journal/wp-content/uploads/sites/24/2019/11/GT-GJLE190043.pdf> SM

One significant effect that the Trump administration’s actions will have on the WTO is to set a precedent that the global trading system can be bypassed altogether. As mentioned previously, one of the primary purposes of the WTO is to resolve trade disputes, and a large part of the WTO’s success is due to countries resorting to the DSB rather than settling disputes unilaterally.85 While the U.S. finds itself squarely in the type of trade dispute that the DSB was designed to resolve, the U.S. has chosen to utilize its domestic Section 301 legislation rather than bring a case at the WTO.86 Further, by imposing unilateral tariffs under Section 301, President Trump is undermining the spirit of the WTO and its various agreements by creating the precedent that disputes may be settled through internal domestic investigations and actions, rather than resort to the DSB. This presents a dangerous situation and threatens to undo over two decades of progress where the DSB served as the go-to neutral venue for settling complex disputes. The 12th Annual Report by the Subcommittee on Unfair Trade Policies and Measures of the WTO summarized this danger, saying “[t]he multilateral trading system is marked by countries observing international rules, including those provided by the WTO Agreement and its dispute settlement procedures. Disputes occurring within the system should be resolved by the available dispute settlement procedures, not through resort to unilateral measures.”87

Furthermore, by invoking Section 301, the Trump administration is acting in a manner that had already been strictly prescribed by the WTO. Specifically, the Trump administration’s use of Section 301 constitutes a violation of Article 23 of the DSU, which “explicitly prohibits Members from invoking unilateral measures that are not based on the WTO dispute settlement procedures.”88 President Trump imposed the Section 301 tariffs on China on July 6, 2018, before the U.S. had even requested the establishment of a panel at the WTO, which it did later on October 29, 2018. Because the U.S. had not received a panel report from the DSB authorizing unilateral action, the U.S. violated Article 23 of the DSU by imposing tariffs without the proper DSB authorization.

#### 3] Can’t solve – it’s perceived as a US action not a WTO action.

#### 4] Their ev highlights underlying tensions with China and WTO rules as a huge alt cause for US refusal to appoint anyone to the appellate body and WTO illegitimacy

1AC Meyer 21 6-18-21 – David Meyer is the Editor of CEO Daily and a senior writer on Fortune’s European team. Author of the digital rights primer, Control Shift: How Technology Affects You and Your Rights; “The WTO’s survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn”; Fortune, June 18, 2021. <https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/> //advay

Reform needs Top of the list is the WTO's Appellate Body, which hears appeals in members' trade disputes. It's a pivotal part of the international trade system, but Trump—incensed at decisions taken against the U.S. —blocked appointments to its seven-strong panel as judges retired. The body became completely paralyzed at the end of 2019, when two judges' terms ended and the panel no longer had the three-judge quorum it needs to rule on appeals. Anyone who hoped the advent of the Biden administration would change matters was disappointed earlier this year when the U.S. rejected a European proposal to fill the vacancies. "The United States continues to have systemic concerns with the appellate body," it said. "As members know, the United States has raised and explained its systemic concerns for more than 16 years and across multiple U.S. administrations." At her confirmation hearing in February, current U.S. Trade Representative Katherine Tai reiterated those concerns—she said the appellate body had "overstepped its authority and erred in interpreting WTO agreements in a number of cases, to the detriment of the United States and other WTO members," and accused it of dragging its heels in settling disputes. "Reforms are needed to ensure that the underlying causes of such problems do not resurface," Tai said. "While the U.S. [has] been engaging [with the WTO] it hasn't indicated it would move quickly on allowing appointments to the Appellate Body," says Bryan Mercurio, an economic-law professor at the Chinese University of Hong Kong, who opposes the vaccine waiver. "This is not a good sign. In terms of WTO governance, it's a much more important step than supporting negotiations on an [intellectual property] waiver." It's not just the U.S. that wants to see reform at the WTO. In a major policy document published in February, the EU said negotiations had failed to modernize the organization's rules, the dispute-resolution system was broken, the monitoring of countries' trade policies was ineffective, and—crucially—"the trade relationship between the U.S. and China, two of the three largest WTO members, is currently largely managed outside WTO disciplines." China is one of the key problems here. It became a WTO member in 2001 but, although this entailed significant liberalization of the Chinese economy, it did not become a full market economy. As the European Commission put it in February: "The level at which China has opened its markets does not correspond to its weight in the global economy, and the state continues to exert a decisive influence on China's economic environment with consequent competitive distortions that cannot be sufficiently addressed by current WTO rules." "China is operating from what it sees as a position of strength, so it will not be bullied into agreeing to changes which it sees as not in its interests," says Mercurio. China is at loggerheads with the U.S., the EU and others over numerous trade-related issues. Its rivals don't like its policy of demanding that Chinese citizens' data is stored on Chinese soil, nor do they approve of how foreign investors often have to partner with Chinese firms to access the country's market, in a way that leads to the transfer of technological knowhow. They also oppose China's industrial subsidies. Mercurio thinks China may agree to reforms on some of these issues, particularly regarding subsidies, but "only if it is offered something in return." All these problems won't go away if the WTO manages to come up with a TRIPS waiver for COVID-19 vaccines and medical supplies, Wallach concedes. "But," she adds, "the will and the good faith to tackle these challenges is increased enormously if the WTO has the experience of being part of the solution, not just an obstacle." Wallach points to a statement released earlier this month by Asia Pacific Economic Cooperation (APEC) trade ministers, which called for urgent discussions on the waiver. "The WTO must demonstrate that global trade rules can help address the human catastrophe of the COVID-19 pandemic and facilitate the recovery," the statement read in its section about WTO reform. Okonjo-Iweala's role The WTO's new director general, whose route to the top was unblocked in early 2021 with the demise of the Trump administration, is certainly keen to fix the problems that contributed to the early departure of her predecessor, Brazil's Robert Azevedo. "We must act now to get all our ambassadors to the table to negotiate a text" on the issue of an IP waiver for COVID vaccines, Ngozi Okonjo-Iweala, director general of the World Trade Organization, has said. Dursun Aydemir—Anadolu/Bloomberg/Getty Images Earlier this week, when the U.S. and EU agreed a five-year ceasefire in a long-running dispute over Boeing and Airbus aircraft subsidies, Okonjo-Iweala tweeted: "With political will, we can solve even the most intractable problems." However, Mercurio is skeptical about her stewardship having much of an effect on the WTO's reform process. "Upon taking [over she] stated it was time for delegations to speak to each other and not simply past each other, but at the recent General Counsel meeting delegations simply read prepared statements in what some have described as the worst meeting ever," he says. "On the other hand, Ngozi is very much someone who will actively seek solutions to problems, and in this way different to her predecessor. If the role of mediator is welcomed, she could have an impact not in starting discussions but in getting deals over the finish line."

### Solvency

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.17

#### Waiver greenlights counterfeit medicine – turns case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Squo solves – plan increases price of scarce materials and results in costly, ineffective facilities

Mcmurry-Heath 8/18 (Michelle Mcmurry-Heath, [physician-scientist and president and CEO of the Biotechnology Innovation Organization.], 8-18-2021, “Waiving intellectual property rights would harm global vaccination“, STAT, accessed: 8-19-2021, https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/) ajs

Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive.

Here’s why. Before Covid-19 emerged, the world produced at most [5.5 billion doses](https://www.barrons.com/articles/a-plan-to-break-the-vaccine-manufacturing-bottleneck-51621952245) of various vaccines every year. Now the world needs an additional [11 billion doses](https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-g7-summit---12-june-2021) — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease.

Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months.

The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit.

Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.

Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another [four to six months](https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/) to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available.

That’s slower than our current production rate. According to a report from Duke University’s [Global Health Innovation Center](https://launchandscalefaster.org/covid-19/vaccinemanufacturing), companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity.

Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid [$23.50 per dose](https://www.timesofisrael.com/israel-said-to-be-paying-average-of-47-per-person-for-pfizer-moderna-vaccines/) for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during [just two days of shutdowns](https://www.bmj.com/content/372/bmj.n281) in the country.

Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose.

Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. [COVAX](https://www.who.int/initiatives/act-accelerator/covax), the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year.

President Biden vowed to make America the world’s [“arsenal of vaccines.”](https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/05/17/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-4/) The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate [500 million more](https://www.npr.org/sections/goatsandsoda/2021/08/03/1023822839/biden-is-sending-110-million-vaccines-to-nations-in-need-thats-just-a-first-step) by the end of summer. Other countries are following the administration’s leadership and ramping up their donations.

#### Manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### Waivers fail – license agreements are key to access and scaling up vaccines

Crosby et al 21 [[Daniel Crosby](https://www.jdsupra.com/authors/daniel-crosby/), [Evan Diamond](https://www.jdsupra.com/authors/evan-diamond/), [Isabel Fernandez de la Cuesta](https://www.jdsupra.com/authors/isabel-fernandez-de-la-cuesta/), [Jamieson Greer](https://www.jdsupra.com/authors/jamieson-greer/), [Jeffrey Telep](https://www.jdsupra.com/authors/jeffrey-telep/), [Brian White](https://www.jdsupra.com/authors/brian-white/)] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### Squo solves – voluntary licensing and other initiatives

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3. Voluntary licensing and other initiatives are supporting access to COVID-19 vaccines Contrary to assertions the sponsors made at the TRIPS Council, pharmaceutical companies have been actively signing voluntary licensing agreements with various generic drug manufacturers to scale up the production of COVID-19 medication. For instance, Gilead’s antiviral drug named Remdesivir was approved for emergency use for COVID-19 treatment by the US Food and Drug Administration (FDA) and the European Medicines Agency in May 2020.35 As demand surged following the approvals for use in COVID-19, Gilead issued nonexclusive voluntary licences to generic producers based in India, Egypt and Pakistan in order to meet the growing demand for the product. Under the voluntary licensing agreements, these manufacturers receive the technology necessary to manufacture Remdesivir, as well as set their own prices for the generic drugs they produce. The arrangement allows the distribution of the drug in 127 countries, covering nearly all low-income and lower-middle-income countries.36 Another example of industry cooperation is the COVID-19 vaccine co-developed by AstraZeneca and University of Oxford. AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicence agreements with several generic drugs producers to increase the supply of future vaccine, including with the Serum Institute of India (one of the world’s largest vaccine producers),37 Fiocruz in Brazil,38 BioKangtai in China39 and R-Pharm in Russia,40 enabling the massive production of cheap generic vaccines and supply of over two billion doses to lower-middle-income countries once the vaccine is approved for sale in those countries.

Other initiatives set up in response to IP issues related to COVID-19 treatments and vaccines include the World Health Organization’s (WHO) COVID-19 Technology Access Pool (CTAP), launched to gather COVID-19 technology related patents and other kinds of intellectual properties, such as data, know-how and software.41 This Pool, similar to Medicines Patent Pool (MPP) – established to pool and distribute generic licences for HIV/AIDS-related treatments – aims to accelerate the scale-up of production of medical inventions to fight against COVID-19 and ensure they are available globally and equitably.42 To date, 39 WHO member states and 4 intergovernmental bodies have indicated their support43 and a coalition of 18 generic drugs manufacturers located in India, China, Bangladesh and South Africa have pledged to work together to accelerate access to millions of doses of new interventions for COVID-19 for lowand middle-income countries.

Another effort, the Access to Covid-19 Tools (ACT) Accelerator, has raised $5.8 billion from nearly forty countries and over 40 private and non-governmental sources for the deployment tests, treatments and vaccines. 44 COVAX, convened by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, is the vaccine pillar of the ACT and acts as a global initiative to pool procurement of safe and effective COVID-19 vaccines. The objective of this accelerator collaboration is to guarantee rapid and fair access to COVID-19 vaccines for every country in the world. As of January 2021, COVAX has agreements in place to access 2 billion doses of promising COVID-19 vaccine candidates, implying that all 190 participating economies are eligible to access effective and approved vaccines in the first half of 2021.45 At least 1.3 billion donor-funded doses will be made available to 92 low- and middle-income economies.46

With the advance of reasonably priced patented treatments and vaccines, as well as the widespread and growing use of non-exclusive voluntary licence agreements and several newly established global initiatives, it is not only unnecessary to waive IPRs to ensure access to affordable medicines for all populations around the world during the pandemic but also unwise as the waiver would stifle cooperative efforts and potentially lead to less availability of needed treatments and vaccines.

#### Existing mechanisms solve – domestic not international policy is the problem

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4. Existing mechanisms effectively safeguard public health

The international system was designed to deal with all circumstances – including global pandemics like COVID-19 – providing both incentives to industry to spend large amounts of time and money on research and development and tools for developing countries to leverage in their fight against COVID-19.

The rights and protections granted by the TRIPS Agreement must be read in the context of the objectives and principles of the agreement as set out in Article 7 and 8: Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights [shall be] in a manner conducive to social and economic welfare” while Article 8 states that WTO Members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” Read together, these two provisions should allow for a wide range of policy choices and health measures taken during a health crisis or emergency, such as the COVID-19 pandemic.47

Moreover, in the wake of the HIV/AIDS crisis, developing countries secured a major victory when WTO Members agreed to adopt the Doha Declaration on TRIPS and Public Health as part of the Doha Ministerial Declaration in November 2001. 48 The Doha Declaration, inter alia, reiterated that every WTO Member “has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” 49 Members could not agree, however, on how to resolve the issue of how Members with insufficient or no manufacturing capability could make use of the compulsory licensing provision set out in Article 31 of the TRIPS Agreement.50 This issue was resolved in August 2003, when Members adopted a waiver allowing such Members to import generic drugs under a compulsory licence from another country even if the required drugs are protected by patent in that third country. 51 In such a case, licences are required to be issued in both the importing and exporting countries. In 2017, the waiver became the first (and to date only) amendment to any WTO Agreement in the form of Article 31bis of the TRIPS Agreement. 52

Despite repeated assertions by leading non-governmental organizations (NGOs) that the TRIPS flexibilities such as the aforementioned compulsory licence regime are too complicated to use or that threats from developed countries restrict their use, a study by leading public health advocates found that the flexibilities “been used more frequently than commonly assumed and proven effective for procuring generic versions of essential medicines”. 53 More specifically, the study found extensive use of TRIPS flexibilities between 2001 and 2016, with the four leading flexibilities being (i) compulsory licensing (including public non-commercial use licensing); (ii) least-developed countries (LDCs) making use of the pharmaceutical transition measure54; (iii) parallel importation55; and (iv) the research exception.56 In total, the study identified 176 occurrences of possible use of TRIPS flexibilities by 89 countries, of which around 60% engaged in the use of compulsory or government use licences and over one-fifth involved the LDC pharmaceutical transition measure.57

The flexibilities described above have been proven effective in reducing the price of medicines by promoting generic competition and effectively ensuring equitable access to medical products for all. 58 This is especially the case with regards to compulsory licensing. For example, Malaysia’s use of compulsory licences in 2002 reduced the price of antiretrovirals to treat HIV/AIDS by up to 83% while Thailand’s granting of compulsory licences on five medicines (including antiretrovirals and medicines to treat cancer and coronary disease) between 2006 and 2008 contributed to a reduction in prices of up to 98 percent.59

Thus, while the sponsors to the proposal may argue a waiver is urgently needed given that the TRIPS flexibilities are not being fully utilized, the reality is that several developing countries and LDCs have made good use of the flexibilities and those that have not done so lack explicit provisions in their domestic legislation.6

Where available flexibilities have not been utilised, it is often the complicated and unworkable domestic framework which proves to be the stumbling block and not the international system. This point is perhaps illustrated best by reference to compulsory licensing. In Zimbabwe, for example, the institutional framework and capacity to effectively implement and take advantage of the TRIPS flexibility has been severely curtailed since the local regulations establish that a compulsory licence decision requires the approval of two government agencies: the Ministry of Health for medicines procurement and the Patent office for enquiry on the patent status of medicines. The lack of clarity and overlapping in roles and responsibilities leads to delayed access and, worse, a standstill.61 Even the Indian representative to the WTO placed some responsibility on the Members when he admitted that “many smaller countries were not able to fulfil the formalities required” to make use of available flexibilities.62

A final flexibility contained in the TRIPS Agreement is Article 73, which in relevant part allows a Member to take “any action which it considers necessary for the protection of its essential security interests… taken in time of war or other emergency in international relations.” Following precedent established in the Russia–Transit dispute,63 the WTO panel in Saudi Arabia–IPRs found that Article 73 is not self-judging.64 More specifically, the panel held that the mere invocation of Article 73 is justiciable and that it could proceed to assess:

a. whether the existence of a “war or other emergency in international relations” has been established…;

b. whether the relevant actions were “taken in time of” that war or other emergency in international relations; c. whether the invoking member has articulated its relevant “essential security interests” sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and d. whether the relevant actions are so remote from, or unrelated to, the “emergency in international relations” as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.65

While we cannot say for certain whether the COVID-19 pandemic would constitute an emergency in international relations, whether measures taken by WTO members to override IPRs may be considered necessary to protect their essential security interests, or if the presence of other provisions in the TRIPS Agreement addressing emergencies preclude Members from invoking Article 73, there is scholarly support that the provision could be used to justifiably override IPRs in this time of global health pandemic.66 The debate may indeed be academic as it extremely unlikely that any Member would file a WTO complaint and initiate dispute settlement against a developing country Member invoking Article 73.

What is clear is that instead of calling for an IP waiver a better way to ensure equitable distribution of vaccines during the pandemic and a more lasting sustainable and prodevelopment solution would be for developing countries to revise their domestic laws to allow better use of the flexibilities existing within the TRIPS Agreement.