# 2NR

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# 1AC

## Offs

### 1

#### Interp – reductions are permanent

Reynolds 59. Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway. The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency. Aside from the practical aspect indicating permanency other indicia point to the same conclusion. From 1924 (L. 1924, ch. 619) to 1947 (L. 1947, ch. 841) a provision appeared in the Civil Service Law which read substantially as follows: "If the pension of a beneficiary is reduced for any reason, the amount of such reduction shall be transferred from the pension reserve fund to the pension accumulation fund during that period that such reduction is in effect." (See L. 1924, ch. 619, § 2 [Civil Service Law, § 58, subd. 4]; L. 1947, ch. 841 [Civil Service Law, § 66, subd. e].) This provision reappears in the 1955 Retirement and Social Security Law as subdivision f of section 24. This provision is useful for interpretative purposes. Since it prescribes that moneys not paid because of reduction should be transferred back to the accumulation fund the conclusion is inescapable that such reductions were meant to be permanent. If temporary suspensions were intended this bookkeeping device would result in a false picture of the funds, i.e., the reserve fund would be depleted when it would contain adequate funds to meet eventual payments 57\*57 to present pensioners. Likewise, the accumulation fund would be improperly inflated with respect to the present pensioners. Section 64 of the Retirement and Social Security Law (§ 85 under the 1947 act) provides that any disability pension must be reduced by the amount payable pursuant to the Workmen's Compensation Law if applicable. In Matter of Dalton v. City of Yonkers (262 App. Div. 321, 323 [1941]) this court interpreted "reduce" to mean "offset" in holding that under then section 67 (relating to Workmen's Compensation benefits as do its successors sections 85 and 64), pensions were to be offset by compensation benefits. This is merely another indication that "reduce" means a diminishing of the pension pursuant to a given formula rather than a mere recoverable, temporary suspension during the time other benefits or salaries are being received by the pensioner. (Also, cf., Retirement and Social Security Law, § 101 [§ 84 under the 1947 act].)

#### Violation –

#### Negate –

#### 1] Limits and topic lit – their model allows adding on infinite random suspensions to IP protections, anything from conditioning IP protections on human rights to monopolistic tendencies – the core of the debate is reducing IP protections, not temporarily suspending them

#### 2] Precision—they justify the aff arbitrarily doing away with words in the resolution – nothing stops them defending telemedicine or big pharma bad next

#### Voters:

#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### 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.

#### Drop the debater – they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to

#### Use competing interps – reasonability invites arbitrary judge intervention since we don’t know your bs meter

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance, b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms, c) baiting – incentivizes good debaters to be abusive, bait theory, then collapse to the 1AR RVI,

#### Evaluate T before 1AR theory – magnitude – T affects a larger portion of the debate since the aff advocacy determines every speech after it

### 2

#### The United States federal government should:

#### - substantially increase production and global distribution of necessary medicines during pandemics

#### - cooperate with allies to achieve increased production and global distribution of necessary medicines during pandemics

#### 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.

#### The US should take the lead – otherwise, China and Russia will use vaccine diplomacy to advance foreign policy goals. The counterplan alone solves and reinvigorates US leadership.

Gayle et al 21. [(HELENE GAYLE is President and CEO of the Chicago Community Trust and has served in global health and development roles with CARE, the Centers for Disease Control and Prevention, and the Bill & Melinda Gates Foundation. GORDON LaFORGE is a Senior Researcher at Princeton University and a lecturer at Arizona State University’s Thunderbird School of Global Management. ANNE-MARIE SLAUGHTER is CEO of New America and former Director of Policy Planning at the U.S. State Department) “America Can—and Should—Vaccinate the World,” Foreign Affairs, March 19, 2021. <https://www.foreignaffairs.com/articles/united-states/2021-03-19/america-can-and-should-vaccinate-world>] TDI

These initiatives come not a moment too soon. In tackling the **worst global crisis** of a lifetime, the **United States has so far been upstaged**. Russia and China have aggressively marketed and distributed their vaccines to foreign countries, **largely to advance foreign policy goals**. Russia is using the jab to bolster its image and investment prospects and to drive a wedge between EU countries. China is donating doses to gain leverage in territorial disputes and expand its influence under the Belt and Road Initiative. Both Moscow and Beijing have **moved to undercut the United States in its own backyard by supplying vaccines to Latin America.** The Biden administration is right to want to take the lead in vaccinating the world, for a host of reasons both self-interested and altruistic. But it should not fall into the trap of trying to beat Russia and China at their own game—handing out vaccines to specific countries based on their geostrategic importance and the amount of attention they are receiving from rival powers. Rather, **Biden should pursue** abroad the sort of “all in” unity approach that he has proclaimed at home. His administration should focus less on strategic advantage than on vaccinating the largest number of people worldwide in the shortest amount of time. In so doing, the United States would **concentrate on what the world’s peoples have in common—susceptibility to this and many other viruses**—regardless of the nature of their governments. ALL IN AND ALL OUT The United States has successfully mobilized its own and international resources to respond to regional crises in the past. In 2003, President George W. Bush started the U.S. President’s Emergency Plan for AIDS Relief, the largest global health program focused on a single disease in history. PEPFAR brought together U.S. agencies, private companies, and local civil society groups to help sub-Saharan Africa and Southeast Asia get the AIDS crisis under control, saving millions of lives. In 2004, a tsunami in the Indian Ocean caused more than 220,000 deaths and billions in damage, and the United States led an urgent, similarly inclusive humanitarian relief and recovery effort that rescued victims, hastened reconstruction, and built lasting goodwill in South and Southeast Asia. Biden can improve on Bush’s precedent by going global, and he has already taken steps toward doing so. Under President Donald Trump, the United States refused to participate in the COVID-19 Vaccine Global Access (COVAX) Facility, an international partnership that aims to guarantee COVID-19 vaccine access for the entire world. The Biden administration reversed this stance immediately and contributed $4 billion, making the United States the largest donor to the effort. Still, even if COVAX meets the ambitious target of delivering two billion doses to developing nations by the end of 2021, it will be able to vaccinate only 20 percent of those countries’ populations. Just imagine, however, what could happen if Washington were to treat COVID-19 as the equivalent of the enemy in a world war or the pandemic as a global version of the regional AIDS and Ebola epidemics of years past. Imagine, in other words, what all-out mobilization would look like if the **United States treated the COVID-19 pandemic like the global threat** that it is. The Biden administration is right to want to take the lead in vaccinating the world. Washington would lead a multilateral, whole-of-society effort to help COVAX vaccinate the world. The government would activate the military and call upon allies in the G-7 and NATO for a major assistance operation that speeds the flow of vaccine supplies and strengthens delivery systems. As it has pledged to do in the Quad summit deal, the U.S. government would use the State Department, U.S. Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and other civilian agencies and development programs to help countries with their national vaccination programs. And it would enlist companies, nonprofits, and civil society organizations to help increase vaccine production, raise funding, and provide technical assistance to foreign counterparts. The U.S. government should undertake exactly such an effort, right now: an all-out response for an all-in global vaccination campaign. Such a campaign would advance U.S. economic and security interests and **reboot American global leadership** after years of decline. Rather than perpetuate the transactional, friend-by-friend vaccine diplomacy of China and Russia, a U.S.-led vaccine effort could **invigorate a new multilateralism** that is more pragmatic and inclusive than the twentieth-century international order and better adapted to tackling twenty-first-century global threats. Washington would do well to remember that if COVID-19 does come back, authoritarian governments will be able to lock down their populations more quickly and effectively than democracies will, so even in competitive terms, America’s best bet really is to eradicate the novel coronavirus. The United States has a momentous **opportunity to prove both that democracy can deliver** and that American ideals truly are universal. By offering a model of global cooperation that draws on a far wider range of resources than any one government can provide, the United States can lead a vaccine effort that builds on the strengths of its **open and pluralist society.** President Biden would demonstrate unequivocally that the United States is not only “back” but looking—and **leading—far ahead.**

#### 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

### 3

#### 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

#### Infrastructure passes now due to Biden and Pelosi involvement – Biden PC and tight timetables makes the margin for error literally ZERO

Elliott 9-16 (Philip Elliott is a Washington Correspondent for TIME. Before joining TIME in early 2015, he spent almost a decade at The Associated Press, where he covered politics, campaign finance, education and the White House. He is a graduate of the E.W. Scripps School of Journalism at Ohio University, September 16, 2021, accessed on 9-17-2021, Time, "Democrats Face a Grueling Two Weeks as Infighting Erupts Over Infrastructure", https://time.com/6098810/house-democrats-reconciliation/)//babcii

House Democrats yesterday finished penning a 2,600-page bill that **finally outlines the specifics** of their ambitious “soft” infrastructure plan that won’t attract a single Republican vote. But no one was really rushing to Schneider’s for bottles of bubbly. For a party ready to spend $3.5 trillion to fund its social policy agenda, there were plenty of glum faces on Capitol Hill. In fact, one key piece of the legislation—a deal that would finally let Medicare negotiate lower prices with drug companies—fell apart in the Energy and Commerce Committee when three Democrats voted against it. It found resurrection a short time later when Leadership aides literally plucked it from the Energy and Commerce team and delivered it to the Ways and Means Committee for its approval instead. Even there, though, one Democrat voted against it, saying the threat it posed to pharmaceutical companies’ profits would doom it in the Senate. “Every moment we spend debating provisions that will never become law is a moment wasted and will delay much-needed assistance to the American people,” Rep. Stephanie Murphy of Florida later argued. Put another way? Brace **for some nasty politics** over the next two weeks as House Speaker Nancy Pelosi tries to get this bill to a vote before the budget year ends on Sept. 30. And those 2,600 pages had better be recyclable. Democrats can **only afford three defectors** if they want to usher this bill into law, **and they’re perilously close to failure**. So far, five centrist Democrats in the House have said they prefer a scaled-back version of the Medicare component. But if Pelosi gives the five centrists that win, she risks losing the support of progressives who are already sour that things like a punitive wealth tax and the end to tax loopholes aren’t present in the current version of the bill. As it stands now, letting Medicare negotiate drug prices would save the government about $500 billion over the next decade. The scaled-back version doesn’t have an official cost, but a very similar version got its score in the Senate last year: roughly $100 billion in savings. Because Democrats are using a budgeting loophole to help them avoid a filibuster and pass this with bare majorities, that $400 billion gap matters a lot more than on most bills. Scaling back the Medicare savings means they would also have to scale back their overall spending on the bill—a big line in the sand for progressives who say they’ve already compromised too much. All of this, of course, comes as President Joe Biden and his top aides in the White House have been trying to get Senate **centrists onboard**. Just yesterday, he **met separately with Sens. Kyrsten Sinema and Joe Manchin**, fellow Democrats who have expressed worries about the $3.5 trillion price tag but have been vague about what exactly they want to cut back on. With the Senate evenly divided at 50-50, and Vice President Kamala Harris in position to break the ties to Democrats’ victories, any shenanigans from those two independent thinkers scrambles the whole package. Oh, and that other bipartisan infrastructure plan that carries $550 billion in new spending? It’s still sitting on the shelf in the House. Pelosi said she’d bring it to the floor only when the bigger—and entirely partisan—bill was ready. And there’s plenty of grumbling about that package, too. If this is all beginning to sound like a scratched record that keeps repeating, it’s because this has become something of a pattern here in Washington. Things look pretty grim for legislation in town these days, despite Democrats controlling the House, the Senate and the White House. Their margin for error **is literally zero**, and so hiccups from a half-dozen centrists can forewarn a doomed agenda. So far, Pelosi has been a master of holding the line on crucial votes and has managed to maneuver her team to victories, including on an earlier pandemic relief package that passed with only Democratic votes. Now she’s trying again, but the clock is ticking, and $3.5 trillion is an eye-popping sum of money that rivals the spending the United States unleashed to close out World War II.

#### Attacks on pharmaceutical profits triggers Mod Dem Backlash – it disrupts unity.

Cohen 9-6 Joshua Cohen 9-6-2021 "Democrats’ Plans To Introduce Prescription Drug Pricing Reform Face Formidable Obstacles" <https://www.forbes.com/sites/joshuacohen/2021/09/06/democrats-plans-to-introduce-prescription-drug-pricing-reform-face-obstacles/?sh=37a269917395> (independent healthcare analyst with over 22 years of experience analyzing healthcare and pharmaceuticals.)//Elmer

There’s considerable uncertainty regarding passage with a simple majority of the 2021 massive budget reconciliation bill. Last week, Senator Joe Manchin called on Democrats to pause pushing forward the budget reconciliation bill. If Manchin winds up saying no to the bill, this would scuttle it as the Democrats can’t afford to lose a single Senator. And, there’s speculation that provisions to reduce prescription drug prices may be watered down and not incorporate international price referencing. Additionally, reduced prices derived through Medicare negotiation may not be able to be applied to those with employer-based coverage. While the progressive wing of the Democratic Party supports drug pricing reform, **several key centrist Democrats** in both the House and Senate appear to be **uncomfortable** **with** particular aspects of the budget reconciliation bill, including a potential deal-breaker, namely the potential **negative impact of drug price controls on the domestic pharmaceutical industry**, as well as long-term patient access to new drugs. A paper released in 2019 by the nonpartisan Congressional Budget Office found that the proposed legislation, H.R. 3, would reduce global revenue for new drugs by 19%, leading to 8 fewer drugs approved in the U.S. between 2020 and 2029, and 30 fewer drugs over the next decade. And, a new report from the CBO reinforces the message that drug pricing legislation under consideration in Congress could lead to fewer new drugs being developed and launched. **Intense lobbying efforts from biopharmaceutical industry groups** **are underway**, **warning of** what they deem are **harms from price controls in** the form of diminished patient **access to new innovations**. The argument, based in part on assumptions and modeling included in the CBO reports, asserts that price controls would dampen investment critical to the biopharmaceutical industry’s pipeline of drugs and biologics. **This** won’t sway most Democrats, but has been a traditional talking point in the Republican Party for decades, and **may convince some centrist Democrats to withdraw backing** of provisions **that** in their eyes **stymie pharmaceutical innovation.** If the budget reconciliation bill would fail to garner a majority, a pared down version of H.R. 3, or perhaps a new bill altogether, with Senator Wyden spearheading the effort, could eventually land in the Senate. But, a similar set of provisos would apply, as majority support in both chambers would be far from a sure thing. In brief, Democrats’ plans at both the executive and legislative branch levels to introduce prescription **drug pricing reform** **encounter challenges** which may prevent impactful modifications from taking place.

#### Sinema specifically jumps ship.

Hancock and Lucas 20 Jay Hancock and Elizabeth Lucas 5-29-2020 "A Senator From Arizona Emerges As A Pharma Favorite" <https://khn.org/news/a-senator-from-arizona-emerges-as-a-pharma-favorite/> (Senior Correspondent, joined KHN in 2012 from The Baltimore Sun, where he wrote a column on business and finance. Previously he covered the State Department and the economics beat for The Sun and health care for The Virginian-Pilot of Norfolk and the Daily Press of Newport News. He has a bachelor’s degree from Colgate University and a master’s in journalism from Northwestern University.)//Elmer

Sen. Kyrsten **Sinema formed** a **congressional caucus to raise** “**awareness of the benefits of personalized medicine**” in February. Soon after that, employees of **pharmaceutical companies** **donated** $35,000 to her campaign committee. Amgen gave $5,000. So did Genentech and Merck. Sanofi, Pfizer and Eli Lilly all gave $2,500. Each of those companies has invested heavily in personalized medicine, which promises individually tailored drugs that can cost a patient hundreds of thousands of dollars. **Sinema** is a first-term Democrat from Arizona but has nonetheless **emerged as a pharma favorite in Congress** as the industry steers through a new political and economic landscape formed by the coronavirus. She is a **leading recipient of pharma campaign cash** even though she’s not up for reelection until 2024 and lacks major committee or subcommittee leadership posts. For the 2019-20 election cycle through March, political action committees run by employees of drug companies and their trade groups gave her $98,500 in campaign funds, Kaiser Health News’ Pharma Cash to Congress database shows. That stands out in a Congress in which a third of the members got no pharma cash for the period and half of those who did got $10,000 or less. The contributions give companies a chance to cultivate Sinema as she restocks from a brutal 2018 election victory that cost nearly $25 million. Altogether, pharma PACs have so far given $9.2 million to congressional campaign chests in this cycle, compared with $9.4 million at this point in the 2017-18 period, a sustained surge as the industry has responded to complaints about soaring prices. Sinema’s pharma haul was twice that of Sen. Susan Collins of Maine, considered one of the most vulnerable Republicans in November, and approached that of fellow Democrat Steny Hoyer, the powerful House majority leader from Maryland. It all adds up to **a bet by drug companies that** the 43-year-old **Sinema**, first elected to the Senate in 2018, **will** gain influence in coming years and **serve as an industry ally** in a party that also includes many lawmakers harshly critical of high drug prices and the companies that set them.

#### Pharma backlash 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.

#### Infrastructure investment beats China in the tech-race

Anderson 2/22 [(Norman, Chairman & CEO of CG/LA Infrastructure, a firm focused on global infrastructure project development, driving productivity across countries, and maximizing the benefits of infrastructure for people in the U.S. and around the world) “The Biden Infrastructure Plan - 5 Actions To Jolt Us Awake, Now,” *Forbes*, 2-22-2021, <https://www.forbes.com/sites/normananderson/2021/02/22/the-biden-infrastructure-plan5-actions-to-jolt-us-awake-now/?sh=1d72f17b2ebd>] TDI

The Focus Needs to be on Creating Project Results. Producing immediate results is necessary for our political system - how does this work, when the average highway project takes 9.5 years to move through the approval process, and 4.5 years after that for results - say cars, or autonomous trucks, zipping down the freeway? Lucky for us we are not starting from scratch - we have an enormous pent-up backlog of projects that can start showing results… this year.

By results I don’t just mean creating new and well-paying jobs, or saving the thousands of struggling professional service firms that are in danger of turning off their computers, rather what I mean is addressing the Administration’s priorities in the way that infrastructure professionals think about investment (yes, these people exist - and they are as smart as economists!):

* Brownfield projects - you can revitalize Army Corps reservoirs, or put 5G on interstate highways, or authorize the Gateway tunnel, or make rural broadband really fast, right now, tomorrow,
* Greenfield projects - infrastructure is a ‘thinking short, thinking long’ business, so while you are speeding up investment in ultra high voltage transmission lines, you can also get moving on the Brent Spence Bridge, and by the end of 2024 you can get butts in seats on the Dallas/Houston high speed rail project, and the Great Lakes Basin highway project, and
* New Infrastructure - this is the low-hanging fruit, and the battlefield between China and the U.S. for global influence, period. Largely private, and almost wholly environmentally friendly, this is where our economy has tremendous strengths that we are not seeing. It’s also the battlefield - AI, Machine Learning, 5G, Autonomy, High Voltage Transmission, along with high speed rail - that is critical to the achievement of every single goal that our country can set for the future.

Every infrastructure person - and every citizen - across the country can tell you the five projects that they’d like to see happen. The map above is a 500 project stimulus map that my firm, CG/LA infrastructure, created by polling people around the country. Why not engage citizens now, and show results this year, picking up steam in 2022 and in 2023? Infrastructure is 5G/AI and Electrification, and it Needs a Budget. The infrastructure of the future is going to be as different as cellular is from fixed line telephony, and that future is coming at us extremely fast… The 2020’s will be a decade of disruption - the greatest period of disruption in 100 years or more. We can either continue our course, and try and weather the storm, or we can make the kind of strategic investments that will allow us to lead - with enormous environmental and equity benefits, coupled with the kind of productivity increases that come from rapid innovation. There couldn’t be a bigger difference between the way that China is going about new infrastructure creation, with their top down, devil may care about the individual approach, and our celebration of the individual. The problem - in democracies around the world - is that we are absent, and so China is winning. Leaders Set Goals, Achieve Goals - and Create Trust. Who is in charge of infrastructure? Without an infrastructure office it is hard to tell, and this is a fatal flaw problem. The presidency needs to to bring everyone together to discuss what world we want to create, what our infrastructure vision going forward will look like. This needs to happen fast - and then we need to set goals that we all agree to: projects completed, time to project approvals, life expectancy, reduction of traffic congestion, reduction in carbon by sector, even increases in infrastructure equity. I am a business guy - everything is opportunity. Then we (all of us) need to row hard in the same direction, and achieve those goals. Action This Day. If we can get this right, the results for all of us will be extraordinary - domestic growth, environmental leadership and an injection of strength into the global democratic model. Unimaginable things can quickly be envisioned, and developed, including the return of manufacturing (advanced and distributed manufacturing) to our newly digitized and electrified heartland. Infrastructure can bring us together, but it is a very heavy lift - as in war, the first thing a president things about in the morning, and the last thing he thinks about before going to bed at night.

#### Chinese tech leadership leads to nuclear war

Kroenig 18 (Matthew, Deputy Director for Strategy, Scowcroft Center for Strategy and Security Associate Professor of Government and Foreign Service, Georgetown University) “Will disruptive technology cause nuclear war?” *BAS*, Nov 12, 2018, <https://thebulletin.org/2018/11/will-disruptive-technology-cause-nuclear-war>

Recently, analysts have argued that emerging technologies with military applications may undermine nuclear stability (see here, here, and here), but the logic of these arguments is debatable and overlooks a more straightforward reason why new technology might cause nuclear conflict: by upending the existing balance of power among nuclear-armed states. This latter concern is more probable and dangerous and demands an immediate policy response. For more than 70 years, the world has avoided major power conflict, and many attribute this era of peace to nuclear weapons. In situations of mutually assured destruction (MAD), neither side has an incentive to start a conflict because doing so will only result in its own annihilation. The key to this model of deterrence is the maintenance of secure second-strike capabilities—the ability to absorb an enemy nuclear attack and respond with a devastating counterattack. Recently analysts have begun to worry, however, that new strategic military technologies may make it possible for a state to conduct a successful first strike on an enemy. For example, Chinese colleagues have complained to me in Track II dialogues that the United States may decide to launch a sophisticated cyberattack against Chinese nuclear command and control, essentially turning off China’s nuclear forces. Then, Washington will follow up with a massive strike with conventional cruise and hypersonic missiles to destroy China’s nuclear weapons. Finally, if any Chinese forces happen to survive, the United States can simply mop up China’s ragged retaliatory strike with advanced missile defenses. China will be disarmed and US nuclear weapons will still be sitting on the shelf, untouched. If the United States, or any other state acquires such a first-strike capability, then the logic of MAD would be undermined. Washington may be tempted to launch a nuclear first strike. Or China may choose instead to use its nuclear weapons early in a conflict before they can be wiped out—the so-called “use ‘em or lose ‘em” problem. According to this logic, therefore, the appropriate policy response would be to ban outright or control any new weapon systems that might threaten second-strike capabilities. This way of thinking about new technology and stability, however, is open to question. Would any US president truly decide to launch a massive, bolt-out-of-the-blue nuclear attack because he or she thought s/he could get away with it? And why does it make sense for the country in the inferior position, in this case China, to intentionally start a nuclear war that it will almost certainly lose? More important, this conceptualization of how new technology affects stability is too narrow, focused exclusively on how new military technologies might be used against nuclear forces directly. Rather, we should think more broadly about how new technology might affect global politics, and, for this, it is helpful to turn to scholarly international relations theory. The dominant theory of the causes of war in the academy is the “bargaining model of war.” This theory identifies rapid shifts in the balance of power as a primary cause of conflict. International politics often presents states with conflicts that they can settle through peaceful bargaining, but when bargaining breaks down, war results. Shifts in the balance of power are problematic because they undermine effective bargaining. After all, why agree to a deal today if your bargaining position will be stronger tomorrow? And, a clear understanding of the military balance of power can contribute to peace. (Why start a war you are likely to lose?) But shifts in the balance of power muddy understandings of which states have the advantage. You may see where this is going. New technologies threaten to create potentially destabilizing shifts in the balance of power. For decades, stability in Europe and Asia has been supported by US military power. In recent years, however, the balance of power in Asia has begun to shift, as China has increased its military capabilities. Already, Beijing has become more assertive in the region, claiming contested territory in the South China Sea. And the results of Russia’s military modernization have been on full display in its ongoing intervention in Ukraine. Moreover, China may have the lead over the United States in emerging technologies that could be decisive for the future of military acquisitions and warfare, including 3D printing, hypersonic missiles, quantum computing, 5G wireless connectivity, and artificial intelligence (AI). And Russian President Vladimir Putin is building new unmanned vehicles while ominously declaring, “Whoever leads in AI will rule the world.” If China or Russia are able to incorporate new technologies into their militaries before the United States, then this could lead to the kind of rapid shift in the balance of power that often causes war. If Beijing believes emerging technologies provide it with a newfound, local military advantage over the United States, for example, it may be more willing than previously to initiate conflict over Taiwan. And if Putin thinks new tech has strengthened his hand, he may be more tempted to launch a Ukraine-style invasion of a NATO member. Either scenario could bring these nuclear powers into direct conflict with the United States, and once nuclear armed states are at war, there is an inherent risk of nuclear conflict through limited nuclear war strategies, nuclear brinkmanship, or simple accident or inadvertent escalation. This framing of the problem leads to a different set of policy implications. The concern is not simply technologies that threaten to undermine nuclear second-strike capabilities directly, but, rather, any technologies that can result in a meaningful shift in the broader balance of power. And the solution is not to preserve second-strike capabilities, but to preserve prevailing power balances more broadly. When it comes to new technology, this means that the United States should seek to maintain an innovation edge. Washington should also work with other states, including its nuclear-armed rivals, to develop a new set of arms control and nonproliferation agreements and export controls to deny these newer and potentially destabilizing technologies to potentially hostile states. These are no easy tasks, but the consequences of Washington losing the race for technological superiority to its autocratic challengers just might mean nuclear Armageddon.

### 5

#### Biotech industry strong now – new innovation and R&D coming

Cancherini et al. 4/30 [Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company] “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide> //ajs

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### Strong IPR is key to innovation – empirics and FDI

Ezell and Cory 19 [Stephen Ezell, BS from School of Foreign Service at Georgetown, VP of global innovation policy at Information Technology and Innovation Foundation. Nigel Cory, MA in public policy from Georgetown, BA in international business from Griffith University, Associate Director of trade policy at Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies.] “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> TG

* FDI – foreign direct investment

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that countries with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### COVID incentivizes engineered bioterror- extinction

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

#### WTO wavier will lead to spillover

Hopkins 5/7 (Jared S. Hopkins, [ New York-based reporter for The Wall Street Journal covering the pharmaceutical industry, including companies such as Pfizer Inc. and Merck & Co. He previously was a health-care reporter at Bloomberg News and an investigative reporter at the Chicago Tribune], 5-7-2021, “U.S. Support for Patent Waiver Unlikely to Cost Covid-19 Vaccine Makers in Short Term “, WSJ, accessed: 8-26-2021, https://www.wsj.com/articles/u-s-support-for-patent-waiver-unlikely-to-cost-covid-19-vaccine-makers-in-short-term-11620414260) ajs

The Biden administration’s unexpected support for temporarily waiving Covid-19 vaccine patents won’t have an immediate financial impact on the companies making the shots, industry officials and analysts said.

Yet the decision could mark a shift in Washington’s longstanding support of the industry’s valuable intellectual property, patent-law experts said. A waiver, if it does go into effect, may pose long-term risks to the vaccine makers, analysts said.

Moderna Inc., Pfizer Inc. and other vaccine makers weren’t counting on sales from the developing countries that would gain access to the vaccine technology, analysts said. If patents and other crucial product information behind the technology is made available, it would take at least several months before shots were produced, industry officials said.

Yet long-term Covid-19 sales could take a hit if other companies and countries gained access to the technologies and figured out how to use it. Western drugmakers could also confront competition sooner for other medicines they are hoping to make using the technologies.

A World Trade Organization waiver could also set a precedent for waiving patents for other medicines, a long-sought goal of some developing countries, patient groups and others to try to reduce the costs of prescription drugs.

“It sets a tremendous precedent of waiving IP rights that’s likely going to come up in future pandemics or in other serious diseases,” said David Silverstein, a patent lawyer at Axinn, Veltrop & Harkrider LLP who advises drugmakers. “Other than that, this is largely symbolic.”

Countries including India and South Africa want to open up the intellectual property to help spur more production of shots for developing nations where cases have been surging. Many of these countries have limited doses, while the U.S. and other developed countries enjoy far greater supplies and vaccinated more of their populations

The U.S., which for years has defended drug-company patents, said Wednesday it supported a temporary waiver, surprising the pharmaceutical industry and other countries. Vaccine maker stocks fell on the news, though they have since shaved some of the losses.

## Case

### Vaccine Diplomacy

#### US doesn’t support it – plan looks like it’s following on

Lazare 20 (Sarah Lazare, [], 12-8-2020, “U.S. Says It Supports a Covid Vaccine Patent Waiver, But Document Reveals It Is Dragging Feet at WTO“, In These Times, accessed: 9-19-2021, https://inthesetimes.com/article/world-trade-organization-trips-waiver-council-proposal-patents-vaccines) ajs

On September 14, the United States declined to support as-is a proposal at the World Trade Organization (WTO), put forward by South Africa and India in October 2020, to suspend key intellectual property rules that relate to the Covid-19 vaccine. While the United States expressed frustration about ​“lost momentum” around negotiations over the intellectual property waiver, global health advocates say they are disappointed that the Biden administration has declined to take an active role in pushing such negotiations forward.

### Pandemics

#### 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.

#### IPR hasn’t harmed access – 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.

### WTO Legitmacy

#### The US has structurally undermined WTO legitimacy

Baschuk 2/22 [(Bryce, reporter for Bloomberg Economics based in Geneva, Switzerland, has been published in Bloomberg, the Washington Times, United Press International and National Public Radio) “Biden Picks Up Where Trump Left Off in Hard-Line Stances at WTO,” Bloomberg, 2/22/2021] TDI

President Joe Biden’s administration dashed hopes for a softer approach to the World Trade Organization by pursuing a pair of his predecessor’s strategies that critics say risk undermining the international trading system.

The U.S. delegation to the WTO, in a statement Monday obtained by Bloomberg, backed the Trump administration’s decision to label Hong Kong exports as “[Made in China](https://www.bloomberg.com/news/articles/2020-10-30/hong-kong-takes-formal-wto-action-on-u-s-made-in-china-order)” and said the WTO had no right to mediate the matter because the organization’s rules permit countries to take any action to protect their “essential security interests.”

“The situation with respect to Hong Kong, China, constitutes a threat to the national security of the United States,” the U.S. delegation said. “Issues of national security are not matters appropriate for adjudication in the WTO dispute-settlement system.”

Prior to 2016, WTO members generally steered clear of defending their trade actions on the basis of national security because doing so could encourage other nations to pursue protectionist policies that have little or nothing to do with hostile threats.

That changed in 2018, when the Trump administration triggered a cold war-era law to justify tariffs on foreign imports of steel and aluminum. In response, a handful of U.S. trade partners, including Canada, the EU, and China filed disputes at the WTO and a ruling in those cases is expected later this year.

Since then, more nations -- including Saudi Arabia, India, Russia and others -- have cited the WTO’s national-security exemption in regional trade fights, leading trade experts to warn that such cases could erode the organization’s ability to mediate disputes.

The Biden administration on Monday said the U.S. has consistently argued that national-security disputes are not subject to WTO review because it would infringe on a member’s right to determine what is in its own security interests.

In spite of the U.S. objection, the WTO granted Hong Kong’s dispute inquiry and will establish a panel of experts to deliberate the matter and render a decision, which could take two to three years.

At the same meeting, the Biden administration said it would not agree to appoint new members to the WTO’s appellate body, a seven-member panel of experts who until 2019 had the final say on trade disputes involving billions of dollars worth of international commerce.

The Biden administration said it could not do so because the U.S. “continues to have systemic concerns” with the functioning of the appellate body as have all previous administrations over the past 16 years.

Though the statement was not entirely unexpected, it confirms America’s bipartisan frustration with the functioning of the WTO appellate body and the new administration’s willingness to block new panelists until changes can be agreed.

Once Katherine Tai is confirmed as the U.S. Trade Representative, her office “looks forward to working with” WTO Director-General Ngozi Okonjo-Iweala to tackle the problems with WTO dispute settlement, including the unresolved issues over appellate-body overreach, USTR spokesman Adam Hodge said in an email. “These are long-standing, bipartisan concerns that we hope our trading partners will work with us to address,” he said.

The Trump administration broke precedent when it refused to consider any nominees to fill vacancies on the panel until there weren’t enough to sign off on new rulings. As a result, the WTO’s dispute-settlement system has been critically damaged because WTO members are now free to veto any adverse dispute rulings by appealing them into a legal void created by the appellate body’s paralysis.