# 1NC Set Col

## Framing

#### I value Morality, since the word “ought” in the resolution implies a moral obligation.

#### Value Criterion for this round is Maximizing Expected Well Being-This means we look to improve the lives of the most amount of people

#### Utilitarianism is the only moral philosophy available to governments

Goodin 95 – Professor of Philosophy at the Research School of the Social Sciences at the Australian National University (Robert E., Cambridge University Press, “Utilitarianism As a Public Philosophy” pg 63)

My larger argument turns on the proposition that there is something special about the situation of public officials that makes utilitarianism more plausible for them (or, more precisely, makes them adopt a form of utilitarianism that we would find more acceptable) than private individuals. Before proceeding with that larger argument, I must therefore say what it is that is so special about public officials and their situations that makes it both more necessary and more desirable for them to adopt a more credible form of utilitarianism. Consider, first the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices-public and private alike- are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, at **relatively poorly informed as to the effects that their choices will have on individuals, one by one**. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices. But that is all. That is enough to allow public policy makers to use the utilitarian calculus – if they want to use it at all – to choose general rules of conduct. Knowing aggregates and averages, they can proceed to calculate the utility payoffs from adopting each alternative possible general rule. But they cannot be sure what the payoff will be to any given individual or on any particular occasion. Their knowledge of generalities, aggregates and averages is just not sufficiently fine-grained for that.

## T - Extratopical

#### Interp: The affirmative may only defend that the member nations of the World Trade organization ought to reduce intellectual property protections for medicines. To clarify, they may defend a subset of the resolution, but they may not defend the member nations of the WTO adopting any other policy --

#### **Definition of IP**

WIPO 21 “What Is Intellectual Property (IP)?” Wipo.int, 2021, www.wipo.int/about-ip/en/. Accessed 19 Aug. 2021.

Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent

or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish. Publications What is IP? Understanding Copyright and Related Rights ǀ Understanding Industrial Property Types of intellectual property Copyright Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings. Patents A patent is an exclusive right granted for an invention. Generally speaking, a patent provides the patent owner with the right to decide how - or whether - the invention can be used by others. In exchange for this right, the patent owner makes technical information about the invention publicly available in the published patent document. Trademarks A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks date back to ancient times when artisans used to put their signature or "mark" on their products. Industrial designs An industrial design constitutes the ornamental or aesthetic aspect of an article. A design may consist of three-dimensional features, such as the shape or surface of an article, or of two-dimensional features, such as patterns, lines or color. Geographical indications Geographical indications and appellations of origin are signs used on goods that have a specific geographical origin and possess qualities, a reputation or characteristics that are essentially attributable to that place of origin. Most commonly, a geographical indication includes the name of the place of origin of the goods. Trade secrets Trade secrets are IP rights on confidential information which may be sold or licensed. The unauthorized acquisition, use or disclosure of such secret information in a manner contrary to honest commercial practices by others is regarded as an unfair practice and a violation of the trade secret protection.

#### Violation: They don’t support the World trade oragization AND they defend nationalizing medicine which doesn’t necessitate keeping IP

#### Determining semantics comes before other standards: The topic is the only stasis point we know before the round so it controls the internal link to engagement, and there’s no way to use ground if debaters aren’t prepared to defend it. If there’s no basis for it in the resolution it guts predictability and makes clash impossible

#### Limits - there are a finite amount of policy action reducing IPP for medicines, but an infinite number of extra-topical plans they can include in their advocacy. I can’t prepare good answers for a policy not included the resolution – this damages my education since I can’t engage with the affirmative and it skews the round in their favor.

#### Education is a voter a) it’s the only terminal impact of debate and the only independent good b) it allows for portable skills and knowledge which outweigh on real world applicability.

#### Fairness is a voter because it acts as a bright line that controls the internal link to education – without a certain level of fairness debate is impossible

#### Drop the debater on T - the round is skewed from the beginning because their advocacy excluded my ability to generate NC offense - dropping the debater will make people wary of being non-topical in the future.

#### Also drop the debater for not disclosing their 1AC positions on the LD wiki – it’s a prerequiste for my ability to enagage in the round AND they refused to send this aff preround

#### No RVIs – a) Winning for proving you aren’t bad for debate is illogical b) Chills checking abuse which incentivizes further abuse

#### T is an issue of C/I over reasonability – reasonability invites arbitrary judge intervention based on preference rather than argumentation and encourages a race to the bottom in which debaters will exploit a judge’s tolerance for questionable argumentation.

T is about setting clear standards and rules for future debates and therefore it doesn’t matter whether a debater was “reasonable” or whether their case outweighs theory in one instance.

T is a prior issue to being able to access case 1) they don’t get to leverage a non-topical AFF against us. 2) We have no way of knowing whether the 1AC is true prior to debating them and the lack of ability for us to engage fully because of extra topicality means they can’t way case 3) the 1AC's goals can't be met because they haven't been thoroughly vetted and refined-means vote neg for a better model of debate

## CP

#### CP text: United states and United Kingdom should nationalize the pharmaceutical industry and keep all intellectual property protections. The solvency advocates are their 1AC authors

## DA - WTO Backlash

#### Even small changes make pharma companies fear patent reform

**Asgari et al. 21** [Nikou Asgari, markets reporter for the Financial Times, Donato Paolo Mancini, FT's pharma reporter, and Hannah Kuchler, FT’s global pharmaceutical correspondent, 05-06-2021, "Pharma industry fears Biden’s patent move sets precedent," FT, https://amp.ft.com/content/f54bf71b-87be-4290-9c95-4d110eec7a90]/Kankee

Profits in the pharmaceutical industry are protected by a **fortress of patents** that **guarantee** drugmakers a stream of income until they expire. On Wednesday, Joe Biden broke with decades of US orthodoxy and made a crack in the wall. His administration’s decision to support a temporary waiver of Covid-19 vaccine patents prompted **instant outrage** in the pharmaceutical sector, which argues that the move rides roughshod over their intellectual property rights and will discourage US innovation while sending jobs abroad. “Intellectual property is the **lifeblood** of biotech, it’s like oxygen to our industry,” said Brad Loncar, a biotech investor. “If you take it away, you don’t have a biotech sector.” Biden’s top trade adviser Katherine Tai said that while the US government still “believes strongly” in intellectual property protections, it supported waiving patents for Covid-19 vaccines to help boost global production of jabs. The move comes as some countries, including India, struggle to tackle further waves of the virus even as others have rolled out successful vaccination campaigns that are driving down infections, hospitalisations and deaths. The waiver proposal was put forward at the World Trade Organization in October and has since been supported by more than 60 countries who say worldwide vaccine production must increase dramatically. Washington’s support marks a pivotal step in making the proposal a reality and Tai said the US would engage in negotiations to hammer out the details at the WTO. Tedros Adhanom Ghebreyesus, the WHO’s director-general, told the Financial Times the decision was a “**monumental moment**” in the fight against Covid-19. “I am not surprised by this announcement. This is what I expected from the administration of President Biden.” However, the pharma industry did not expect it; the US has tended to **fiercely protect** domestic companies’ intellectual property rights in trade disputes. Industry leaders described the decision as a heavy blow for innovation that would do little to boost global production because there is a shortage of manufacturing facilities and skilled employees. In an earnings call Thursday, Stéphane Bancel, chief executive of Moderna, said a patent waiver “will not help supply more mRNA vaccines to the world any faster in 2021 and 2022, which is the most critical time of the pandemic”. “There is no idle mRNA manufacturing capacity in the world,” he said. “The administration’s steps here are very unnecessary and damaging,” said Jeremy Levin, chair of biotech trade association Bio. “Securing vaccines rapidly will not be the result, and worse yet, it sets a principle that companies who invested in new tech will stand the risk of having that taken away.” Shares in the big makers of Covid-19 vaccines were hit by the announcement. Frankfurt-listed shares in BioNTech closed down 12 per cent on Thursday while Moderna and Novavax pared losses after tanking on Wednesday in New York, trading 2.4 per cent lower and 1 per cent lower, respectively. CanSino Biologics, a Chinese private company that developed a single-shot adenovirus-vectored vaccine with Chinese military researchers, fell 14 per cent on Thursday. Fosun Pharma, which has a deal to supply BioNTech vaccines in China, lost 9 per cent. Sven Borho, a managing partner at OrbiMed Advisors, a healthcare investment company, said pharma executives **feared** the administration’s move set a **precedent** that would make it easier to suspend patents in the future. “They are **worried** in the long term that this is a **foot in the door** — ‘OK, we did it with Covid-19, let’s do it with the next crisis, and the next one’,” he said. “And then suddenly it’s a cancer drug patent that needs to be invalidated. They fear it is a mechanism that sets the stage for actions in the future.” Peter Bach, director of Memorial Sloan Kettering’s Center for Health Policy and Outcomes, said there was a potential trade-off that pitted the imminent need to contain the pandemic against the risk that drugmakers would be more cautious when investing in pioneering therapies in the future.

#### The pharma industry will fight with the best lobbying that exists

**Huetteman 20** [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/]/Kankee

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.

#### Big pharma wins –Congress waters down the aff so de facto monopolies remain

**Florko and Facher 19** [Nicholas Florko, Stat News Washington correspondent, and Lev Facher, Stat News health and life sciences writer, 07-16-2019, “How pharma, under attack from all sides, keeps winning in Washington,” Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]/Kankee

It does not seem to matter how angrily President Trump tweets, how pointedly House Speaker Nancy Pelosi lobs a critique, or how shrewdly health secretary Alex Azar drafts a regulatory change. The pharmaceutical industry is still winning in Washington. In the past month alone, drug makers and the **army of lobbyists** they employ **pressured** a Republican senator not to push forward a bill that would have limited some of their intellectual property rights, according to lobbyists and industry representatives. They managed to water down another before it was added to a legislative package aimed at lowering health care costs. Lobbyists also convinced yet another GOP lawmaker — once bombastically opposed to the industry’s patent tactics — to publicly commit to softening his own legislation on the topic, as STAT reported last month. Even off Capitol Hill, they found a way to block perhaps the Trump administration’s most substantial anti-industry accomplishment in the past two years: a rule that would have required drug companies to list their prices in television ads. To pick their way through the policy minefield, drug makers have successfully deployed dozens of lobbyists and devoted **record-breaking sums** to their federal advocacy efforts. But there is also a seemingly new strategy in play: industry CEOs have targeted their campaign donations this year on a pair of vulnerable Republican lawmakers — and then called on them not to upend the industry’s business model. In more than a dozen interviews by STAT with an array of industry employees, Capitol Hill staff, lobbyists, policy analysts, and advocates for lower drug prices, however, an unmistakable disconnect emerges. Even though Washington has stepped up its rhetorical attacks on the industry, and focused its policymaking efforts on reining in high drug prices, the pharmaceutical industry’s time-honored lobbying and advocacy strategies have kept both lawmakers and the Trump administration from landing any of their prescription-drug punches. “**Big Pharma has replaced Big Tobacco** as the most powerful brute in the ranks of Washington power brokers,” Sen. Dick Durbin (D-Ill.) said in a statement to STAT. Durbin, who recently saw the industry successfully oppose his proposal to curtail some of the industry’s patent maneuvering, added that, “Pharma’s billions allow them to continue to rip off American families and taxpayers.” The industry doesn’t get all the credit; it has also benefited from a fractured Congress and discord between President Trump’s most senior health care advisers. PhRMA, the drug industry’s largest lobbying group here, declined to comment for this article. But industry leaders have broadly argued against efforts to rein in the industry’s practices in terms of price hikes and patents, making the case that that could irreparably stifle medical innovation. The battle is far from over, and industry representatives and lobbyists are quick to hypothesize that the worst, for them, is yet to come. They point to several ongoing legislative initiatives, including in the Senate Finance Committee, that could take more concerted direct aim at their pricing strategies in Medicare. They’re waiting, too, to see if House Democrats can cut a drug pricing deal with the White House to empower Medicare to negotiate at least some drug prices. Another pending regulation, loathed by drug makers, might tie their pricing decisions in Medicare to an index of international prices. They’ve also bemoaned the Trump administration’s decision last week to abandon a policy change that would have ended drug rebates — which, the pharmaceutical industry has said, could have given drug makers more space to lower their prices voluntarily. “We’re getting killed!” one pharma lobbyist told STAT. Of course, the Trump administration’s supposedly devastating decision to abandon that proposal simply maintains the status quo. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers.” n Valentine’s Day, Sen. Thom Tillis (R-N.C.) enjoyed a showering of love that is familiar in Washington: a flood of campaign contributions, many at the federal limit of $2,800 for a candidate or $5,000 for an affiliated political committee. One donation came from Pfizer’s CEO, Albert Bourla, who donated $5,000 to Tillis and another $10,000 to Sen. John Cornyn (R-Texas) and associated campaign committees. Another came from Kenneth Frazier, the top executive at Merck. The Tillis campaign committee eventually cashed checks from CEOs and other high-ranking executives at those companies as well as Amgen, Eli Lilly, Sanofi, and Bristol Myers-Squibb, plus two high-ranking officials at the advocacy group PhRMA. Six lobbyists at one firm that works with PhRMA, BGR, also combined to contribute $100,000 to a bevy of Republican lawmakers and the party’s campaign arms. Tillis raised an additional $64,500 from drug industry political action committees in the past quarter, according to disclosures released on Monday. A Pfizer spokeswoman declined to comment about Bourla’s contributions, and representatives for the other companies did not respond to STAT’s request for comment. Tills was one of few individual lawmakers — in many cases, the only one — to whom the executives had written personal checks during the current election cycle. While drug industry CEOs frequently contribute to political committees for congressional leadership, the breadth of executives who donated Tillis specifically is notable, particularly considering his outspoken role on pharmaceutical industry issues. While lobbyists pushed back on the notion that campaign contributions directly influence votes, the donations targeted so specifically to a particular candidate could be seen as a prime example of Washington’s system for rewarding loyalty and how industries protect their interests. The same PhRMA PAC that donated to Tillis has given generously in recent years: nearly $200,000 in the 2018 campaign cycle, roughly 58% of which was targeted toward Republicans. Drug industry PACs donated $10.3 million in total in that cycle, according to the Center for Responsive Politics. The figure two years before was even higher: a total of $12.2 million from industry-aligned PACs alone. It is no accident that the pharmaceutical industry has maintained its reputation among the nation’s **most powerful lobbies**, said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “Their access and influence goes beyond this Congress or even the administration,” Krumholz said in an interview, adding that she “was **struggling** to think of evidence” it had waned. Pharma has a reputation here for winning on policy — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s aggressive **interventions** to **water down** legislation. “In lots of ways they’re like the [National Rifle Association], because they have an **incredible power** to **squash** out any negative opinion, nor to feel any of the ill effects of those things,” said Pallavi Damani Kumar, an American University crisis communications professor who once worked in media relations for drug manufacturers. “It just speaks to how incredibly savvy they are.” Pharmaceutical industry lobbyists also successfully fought to keep another anti-drug industry patent proposal from Sen. Bill Cassidy (R-La.) and Dick Durbin (D-Ill.) out of a bipartisan drug pricing package moving through the Senate HELP Committee. The legislation would have allowed the FDA to approve cheaper versions of drugs, even when the more expensive product was protected by certain patents. Cassidy’s proposal never even made it into the HELP package. As the lobbyist who bemoaned the withdrawal of the rebate rule put it, Cassidy “simmered down” in the face of industry pressure. In recent weeks, the industry had targeted Cassidy in particular, in recent weeks, for fear he would break with many of his GOP colleagues to support a cap on some price hikes for drugs purchased under Medicare, a proposal so far pushed only by Democrats. “Sen. Cassidy doesn’t care what lobbyists think — he is going to do what’s best for patients,” said Ty Bofferding, a Cassidy spokesman. “Sen. Cassidy fought for the committee to include the REMEDY Act in the package, despite strong opposition from the pharmaceutical industry.” The committee eventually included half the bill’s provisions, he added, as well as four other pieces of legislation meant to prevent the industry from taking advantage of the patent system. The drug industry also notched a win by watering down another proposal in that package from Sen. Susan Collins (R-Maine) that would have blocked drug makers from suing over patents they didn’t disclose to the FDA. The version of the bill that actually made it into the package doesn’t block drug makers from suing, but instead directs the FDA to create a public list of companies that fail to disclose their patents. “This change is a big win for drug makers,” Michael Carrier, a Rutgers University professor and expert on patent gaming, told STAT. “Shaming is something drug makers don’t seem worried about.” Matthew Lane, the executive director of the Coalition Against Patent Abuse, likewise added that the altered bill “doesn’t seem to be doing much anymore.” Not all of the pharma-endorsed changes, however, are self-serving. Patent experts and federal regulators too had raised concerns with some of the bill being proposed. Cornyn’s patent bill was particularly controversial. “These provisions encourage ‘fishing expeditions’ by zealous bureaucrats, politically motivated by the popularity of efforts to reduce drug prices and garner the political benefits of being seen to be pursuing these ends,” Kevin Noonan, a patent lawyer at McDonnell Boehnen Hulbert & Berghoff wrote in a recent blog post, referring to the original Cornyn bill. Drug-pricing advocates said lobbyists have even managed to convince lawmakers to introduce some legislation they say has explicitly favored the drug industry, including intellectual property-focused legislation that would allow drug makers to patent human genes. That particular bill would “undo the bipartisan effort underway to fix pharma’s exploitation of the patent system,” said the Coalition Against Patent Abuse. And they were far from the only group raising concerns. The American Civil Liberties Union and more than 150 other groups wrote to lawmakers last month opposing the bill. Pharma’s **list of** policy **victories** goes on: Drug companies and allied patient groups forced the Trump administration to back off a proposal to make relatively minor changes to Medicare’s so-called protected classes policy. Currently, Medicare is required to cover all drugs for certain conditions, including depression and HIV. The Trump administration proposed in November that private Medicare plans should be able to remove certain drugs in those classes from their formularies, if the drugs were just new formulations of a cheaper, older version of the same drug, or when a drug spiked in price. But drug industry opposition helped convince the administration to spike that effort. A week ago, the industry struck its biggest blow yet. Three of the country’s largest pharmaceutical companies —Amgen, Eli Lilly, and Merck — prevailed in a lawsuit to strike down a Trump administration requirement that they disclose list prices in television advertisements. The lack of congressional action — despite the Democratic enthusiasm and bipartisan appetite — is still further evidence of industry’s ability to **stave off defeat**. As the dozens of Democrats running for president ramp up their anti-pharma rhetoric, both Trump and progressives have begun to fret that Washington’s efforts have proven to be **all bark and no bite**. With two weeks remaining before the August recess and an escalating 2020 campaign, some advocates fear that the window for bold action is closing quickly. “It’s appalling that we are six months into this Congress and we haven’t seen meaningful legislation passed on American’s number one issue for this congress,” said Peter Maybarduk, who leads drug-pricing initiatives for the advocacy group Public Citizen. “Congress needs to get its act together.”

#### A major country operating outside WTO consensus wrecks global trade norms

**Bacchus 20** [James Bacchus, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida, 12-16-2020, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, [https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines]/Kankee](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines%5d/Kankee)

In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the **last thing** the WTO needs is another debate over perceived trade obstacles to public health. Unless WTO members reach a **consensus**, the multilateral trading system may be further **complicated** by a delay like that in resolving the **two‐​decades‐​old dispute** between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North‐​South” **political struggle** definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19. Background In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 … until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”1 India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic. In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”2 Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.3 One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”4 A spokesperson for the European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID‐​19‐​related medicines and technologies.”5 In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021. Balancing IP Rights and Access to Medicines Not New to WTO This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all **damaged** by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease. Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”6 It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”7 But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.8

#### US withdrawal from the WTO collapses global trade and causes WWIII

**Hopewell and Horton 08-03** [Kristen Hopewell Associate Professor and Canada Research Chair in Global Policy at the University of British Columbia, and Ben Horton, Communications Manager; Project Lead, Common Futures Conversations, 08-03-2021, "Lessons from Trump’s assault on the World Trade Organization," Chatham House – International Affairs Think Tank, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization]/Kankee

What has this episode revealed about the strength of multilateral institutions such as the WTO, in the face of spoiling tactics from major powers? The WTO is unique amongst international institutions because it has a powerful enforcement mechanism – the dispute settlement system. However, the fundamental vulnerability is that if powerful states like the US and others won’t participate in the system and be bound by its rules, they quickly **risk** becoming **irrelevant**. And that’s the situation we’re in right now with the appellate body crisis, where, without a functioning mechanism to ensure that WTO rules are enforced, the **entire** system of global trade rules risk **collaps**ing. Ironically, the United States has been the leader of the liberal trading order for the past 70 years, but since Trump, it has become its leading saboteur. What are the implications of a **permanent collapse** of the international trading system? The very real danger from such a breakdown is a return to what we saw in the 1930s. In response to the outbreak of the Great Depression, you had countries imposing trade barriers, blocking imports from other state, and a general escalation of **tit-for-tat protectionism**. This response wound up not only exacerbating the effects of the depression itself but has also been credited by some as paving the way for the outbreak of the second **world war**. The reason why institutions like the WTO were created in the first place was to prevent a recurrence of the 1930s

protectionist trade spiral. The danger now – if those rules become meaningless and unenforceable – is the institutional foundations of postwar economic prosperity could **unravel**, throwing us back into economic chaos and potentially **political disorder**. What does the WTO’s future look like under new director-general Dr Okonjo-Iweala?

**Extinction**

**Sapiro 14** (Miriam, Visiting Fellow in the Global Economy and Development program at Brookings, former Deputy US Trade Representative, former Director of European Affairs at the National Security Council, “Why Trade Matters,” September 2014, http://www.brookings.edu/~/media/research/files/papers/2014/09/why%20trade%20matters/trade%20global%20views\_final.pdf

This policy brief explores the economic rationale and strategic imperative of an ambitious domestic and global trade agenda from the perspective of the United States. International trade is often viewed through the relatively narrow prism of trade-offs that might be made among domestic sectors or between trading partners, but it is important to consider also the impact that increased trade has on global growth, development and security. With that context in mind, this paper assesses the implications of the Asia-Pacific and European trade negotiations underway, including for countries that are not participating but aspire to join. It outlines some of the challenges that stand in the way of completion and ways in which they can be addressed. It examines whether the focus on “mega-regional” trade agreements comes at the expense of broader liberalization or acts as a catalyst to develop higher standards than might otherwise be possible. It concludes with policy recommendations for action by governments, legislators and stakeholders to address concerns that have been raised and create greater domestic support. It is fair to ask whether we should be concerned about the future of international trade policy when **dire developments are threatening** the security interests of the United States and its partners in the Middle East, Asia, Africa and Europe. In the Middle East, significant areas of Iraq have been overrun by a toxic offshoot of Al-Qaeda, civil war in Syria rages with no end in sight, and the Israeli-Palestinian peace process is in tatters. **Nuclear negotiations** with Iran have run into trouble, while Libya and Egypt face continuing instability and domestic challenges. In Asia, historic rivalries and disputes over territory have **heightened tensions** across the region, most acutely by China’s aggressive moves in the South China Sea towards Vietnam, Japan and the Philippines. **Nuclear-armed North Korea** remains isolated, reckless and unpredictable. In Africa, countries are struggling with rising terrorism, violence and corruption. In Europe, Russia continues to foment instability and destruction in eastern Ukraine. And within the European Union, lagging economic recovery and the surge in support for extremist parties have left people fearful of increasing violence against immigrants and minority groups and skeptical of further integration. It is tempting to focus solely on these pressing problems and defer less urgent issues – such as forging new disciplines for international trade – to another day, especially when such issues pose challenges of their own. But that would be a mistake. A key motivation in building greater domestic and international consensus for **advancing trade liberalization** now is precisely the role that greater economic integration can play in opening up new avenues of opportunity for promoting development and increasing economic prosperity. Such initiatives can help **stabilize key regions** and **strengthen** the **security** of the United States and its partners. The last century provides a powerful example of how expanding trade relations can help **reduce global tensions** and raise living standards. Following World War II, building stronger economic cooperation was a centerpiece of allied efforts to erase battle scars and embrace former enemies. In defeat, the economies of Germany, Italy and Japan faced ruin and people were on the verge of starvation. The United States led efforts to rebuild Europe and to repair Japan’s economy. **A key element** of the Marshall Plan, which established the foundation for unprecedented growth and the level of European integration that exists today, was to revive trade by reducing tariffs.1 Russia, and the eastern part of Europe that it controlled, refused to participate or receive such assistance. Decades later, as the Cold War ended, the United States and Western Europe sought to make up for lost time by providing significant technical and financial assistance to help integrate central and eastern European countries with the rest of Europe and the global economy. There have been subsequent calls for a “Marshall Plan” for other parts of the world,2 although the confluence of dedicated resources, coordinated support and existing capacity has been difficult to replicate. Nonetheless, important lessons have been learned about the valuable role economic development can play in **defusing tensions**, and how opening markets can hasten growth. There is again a growing recognition that economic security and national security are two sides of the same coin. General Carter Ham, who stepped down as head of U.S. Africa Command last year, observed the close connection between increasing prosperity and bolstering stability. During his time in Africa he had seen that “security and stability in many ways depends a lot more on economic growth and opportunity than it does on military strength.”3 Where people have opportunities for themselves and their children, he found, the result was better governance, increased respect for human rights and lower levels of conflict. During his confirmation hearing last year, Secretary John Kerry stressed the link between economic and national security in the context of the competitiveness of the United States but the point also has broader application. Our nation cannot be strong abroad, he argued, if it is not strong at home, including by putting its own fiscal house in order. He asserted – rightly so – that “more than ever foreign policy is economic policy,” particularly in light of increasing competition for global resources and markets. Every day, he said, “that goes by where America is uncertain about engaging in that arena, or unwilling to put our best foot forward and win, **unwilling to demonstrate our resolve to lead**, is a day in which we weaken our nation itself.”4 Strengthening America’s economic security by **cementing** its **economic alliances** is not simply an option, but an **imperative.** A strong nation needs a strong economy that can generate growth, spur innovation and create jobs. This is true, of course, not only for the United States but also for its key partners and the rest of the global trading system. Much as the United States led the way in forging strong military alliances after World War II to discourage a resurgence of militant nationalism in Europe or Asia, now is the time to place equal emphasis on shoring up our collective economic security. A failure to act now could **undermine** international security and place **stability in key regions** in further jeopardy.