## 1

#### Interpretation: Interpretation: If the affirmative delineates specific functions of its advocacy as normal means i.e. enforcement, actor, implementation, etc, then it must have a unified solvency advocate that agrees with all those specifications.

#### Violation: They don’t – 1AC Feldman advocates for the plan passing through FDA approval; Feldman also talks about data exclusivity which is not only about patents

#### 1] Limits – Not having a unified solvency advocate that agrees with all your “normal means” specifications allow you to choose any permutation of specifications which explodes neg prep burden. Not having a solvency advocate for it passing through the WTO at all should frame the limits debate. Unified solvency advocates grant sufficient aff flexibility while still ensuring a reasonable case list since specification all comes from one source.

#### 2] Ground – They can choose any permutation of best definition for “reduce” that suits them, the best enforcement mechanism, the best agent, all with any exceptions they want in conjunction with each other. Frame this standard through norm setting – best specifications make it extremely easy to delink out of core neg generics especially when it’s the fifth round on the topic. It also causes shiftiness since no 1AC solvency advocate for the WTO means that the 1ar can redefine normal means through their solvency advocate and delink out of all neg positions that don’t link to FDA approval

## 2

#### Interpretation: Affirmatives must defend a reduction in intellectual property for medicines.

#### Precluding a future increase is not a reduction

Melinda **Harmon 12**, Judge, United States District Court for the Southern District of Texas, Houston Division, 3/6/12, Zieche v. Burlington Res., Inc., 2012 U.S. Dist. LEXIS 30134, p. lexis

Zieche contends that the Court erred when it concluded that "there was no reduction in Zieche's salary or bonus percentage" that would constitute "good reason" for his resignation. Doc. 70 at 8, 9. The Court relied on the fact that Zieche received "his full 2006 performance bonus" after he began working at ConocoPhillips and that the bonus percentage increased from 30% in 2005 to 40% in 2006 as proof that Zieche did not suffer a reduction in salary.

Zieche contends that an increase in his bonus is irrelevant to a determination of whether his salary was reduced because a "bonus is not part of the salary," but is instead [\*12] "something in addition to what is expected or strictly due." Doc. 72 at 4. Additionally, Zieche alleges that "the [C]ourt's analysis ignores the specific provisions of the retention agreement," which defines "good reason" to include "any reduction from your annual rate of base salary." Id.

Initially, although Zieche alleges that ConocoPhillips reduced his salary, he introduced no summary judgment **ev**idence to support this contention. In his Response to ConocoPhillip's Motion for Summary Judgment, Zeiche repeatedly asserts that, in his new position at ConocoPhillips, he would "**not be eligible for annual merit salary *increases***" as he had previously received at Burlington. Doc. 54 at 4 (emph. added). The summary judgment evidence before the Court included Zieche's deposition, in which he admitted that his salary "remained the same . . . up to the time [he] resigned from ConocoPhillips." Doc. 48-1 at 50 (emph. added). Nevertheless, Zieche argues that the Court unnaturally should read the word "reduce" in the retention agreement to mean "**not increase**," rather than interpreting the word according to its plain meaning. **The Court does not agree with this reasoning**, and Zieche has introduced [\*13] no evidence to convince the Court otherwise.

#### Violation:

#### Vote neg:

#### 1] Limits and ground– they can read infinite affs precluding future increases that is unpredictable and we can’t have offense i.e. not getting a patent 100 years in the future or something so they will always win on specificity

#### 2] 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.

#### 3] TVA – defend the advantage to with the whole rez. We don’t prevent new FWs, mechanisms, or advantages. Evergreening already answers core neg ground like innovation – no reason why you need to delink out of it. PICs don’t solve – our model allows you to specify countries and medicines.

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation. Outweighs because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### Drop the debater – a] deter future abuse and b] set better norms for debate.

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices

## 3

#### Bipartisan antitrust bills passing now but continued PC needed to pacify republicans.

Perlman 9/3 [Matthew; 9/3/21; “*Interest Groups Back Big Tech Antitrust Bills In House,*” LAW360, <https://www.law360.com/competition/articles/1418789/interest-groups-back-big-tech-antitrust-bills-in-house>] Justin

Law360 (September 3, 2021, 7:25 PM EDT) -- A contingent of public interest groups are urging leaders of the U.S. House of Representatives to advance a package of legislation aimed at reining in Big Tech companies through updates and changes to antitrust law, though free market advocates have been jeering many of the bills. A total of 58 public interest and consumer advocacy groups signed on to a letter Thursday asking House leaders to swiftly pass the package of six antitrust bills that the Judiciary Committee approved in late June after a marathon markup session. The proposals include legislation prohibiting large platform companies from acquiring competitive threats, preferencing their own services and using their control of multiple business lines to disadvantage competitors in other ways. The proposals would also impose interoperability and data portability requirements on large tech platforms, increase merger filing fees and boost enforcement by state attorneys general. Charlotte Slaiman, competition policy director for Public Knowledge, which signed on to the letter, said in a statement Thursday that the package charts a path toward putting "people back in control of the digital economy." "The broad range of groups supporting this package shows just how widespread the problem of Big Tech dominance is, and that these bills deserve a full vote in the House imminently," Slaiman said. The letter contends that America has a monopoly problem that is resulting in lower wages, reduced innovation and increased inequality, while also undermining the free press and perpetuating "racial, gender and class dominance." "Big Tech monopolies are at the center of many of these problems," the letter said. "Reining in these companies is an essential first step to reverse the damage of concentrated corporate power throughout our economy." The proposals followed a 16-month investigation by the House antitrust subcommittee into Amazon, Apple, Facebook and Google that resulted in a sprawling report from Democratic members calling for a range of reform measures to rein in the dominance of the companies. While consumer advocacy groups have largely supported the measures, the tech companies themselves and other interest groups have been highly critical, including a coalition of more than 25 right-leaning groups that sent a letter to Congress ahead of the markup hearing. The letter called the bills a "Trojan horse package" aimed at cynically using conservative anger over Big Tech, particularly at perceived censorship by social media platforms, to seek bipartisan support for "European-style over-regulation." For its part, Facebook has called the proposals a "poison pill for America's tech industry at a time our economy can least afford it" and said the bills underestimate the fierce competition the U.S. companies face from abroad. Apple and Google also raised concerns about the impact the bills would have on innovation, as well as on privacy and security. And Amazon has warned about the potential consequences of the proposals for both small businesses that sell on its platform and the consumers who use it to shop. Ending Platform Monopolies Act Thursday's letter said that the Ending Platform Monopolies Act would address "the most problematic aspects of the Big Tech companies" by allowing enforcers to break-up or separate pieces of the businesses when they create conflicts of interest that give the platforms an advantage over potential competitors and business users. A fact sheet from Public Knowledge accompanying the letter said that the bill is an important tool to help the antitrust agencies "protect consumers from mammoth platforms and to ensure compliance with other parts of the package." But during the markup hearing, ranking Republican committee member Rep. Jim Jordan of Ohio blasted the bill as a regulatory overreach, calling it "quite literally central planning" and arguing that it has significant ambiguities, which is bad for business. The Competitive Enterprise Institute argued in a June statement that the bill "kills the goose that lays the golden egg," and would actually result in small businesses being unable to access the large platforms, which in turn would focus on their own offerings instead. The Chamber of Progress has warned that the proposal could bar Amazon from offering its Prime services and its Amazon Basics private label products, since they would compete against other sellers on the platform. Other groups have also warned it could also force tech companies to divest popular apps, including Google's Maps and YouTube, Facebook's WhatsApp and Instagram and Apple's iMessage and FaceTime. American Innovation and Choice Online Act The American Innovation and Choice Online Act is aimed at barring the platform companies from preferencing their own products and services over those of rival businesses and from excluding or discriminating against rivals. Thursday's letter said this proposal would "promote innovation and competition" by preventing the platforms from protecting their monopolies. The right-leaning think tank American Enterprise Institute and others have argued that the bill could prevent Apple from pre-installing certain apps on its mobile phones, since that would advantage it over competing app developers. It could also prevent Google from integrating maps or customer reviews into search results, among other things. "At a minimum, the act would significantly disrupt these platforms' business models in ways that undermine consumer value," Daniel Lyons, a senior fellow for the group wrote in a blog post in June. Platform Competition and Opportunity Act The Platform Competition and Opportunity Act is aimed at preventing platform companies from acquiring potential or nascent competitors and its supporters argued in Thursday's letter that it would prevent the tech giants from enhancing or maintaining their market power. The bill would presumably have blocked Facebook's purchases of WhatsApp, Instagram and other services it has acquired, as well as a slew of deals by Google over the past two decades. Detractors have contended that this bill would limit investments in startups because it restricts their ability to be acquired by the larger technology firms, which they say is a key way for founders to benefit from their success. An American Enterprise Institute blog post from June argues that "opportunities for acquisition have been important drivers of innovation in tech" and also said the bill would prevent the tech companies from entering new areas of business to compete with each other. ACCESS Act The Augmenting Compatibility and Competition by Enabling Service Switching, or ACCESS Act, imposes requirements for the tech companies to make user data portable and able to be used by competing services. The bill's supporters argued in Thursday's letter that this prevents the tech giants from locking users into their services, since users can take their data with them and use it on other networks. Privacy and security implications have been flagged as potential problems for the proposal, with the Competitive Enterprise Institute saying in a statement in June that it's an "anti-privacy bill" that forces companies to turn over private user information to others. The group also said the bill would try to micromanage "complex, dynamic, and highly competitive markets" that are beyond understanding for most politicians and regulators. The American Enterprise Institute has also contended that the requirements would actually make rivals even more dependent on the incumbent platforms. Filing fees and state enforcement Of the antitrust bills approved by the House Judiciary Committee, the ones with the most bipartisan support appear to be the Merger Filing Fee Modernization Act and the State Antitrust Enforcement Venue Act, though it took a day of debate before the committee passed them. A Senate version of the filing fee bill passed that chamber in June as part of the U.S. Innovation and Competition Act. It would raise the fees merging parties pay when reporting large transactions, while lowering fees for smaller deals, in order to raise more resources for the antitrust agencies. Information Technology & Innovation Foundation argued in an August blog post that the legislation does not give Congress enough oversight over how the agencies will use the funds that it raises and called for the bill to include provisions requiring the money be used to hire more staff dedicated to antitrust enforcement. The Competitive Enterprise Institute also raised concerns about congressional oversight and contended that the bill would increase the cost of doing business at a time when the economy is sputtering. "U.S. consumers need innovative services and affordable products, not higher prices passed onto them by businesses avoiding new, unnecessary regulatory compliance costs," the group said in a June blog post. The state enforcement bill would prevent antitrust cases brought by state attorneys general from being transferred to a different venue by the Judicial Panel on Multidistrict Litigation, similar to protections afforded to federal enforcers. The bill is intended to prevent companies targeted by state-led enforcement actions from trying to move the cases to more favorable venues, and it also has an analog in the Senate. Information Technology & Innovation Foundation acknowledged in their August post that having cases included in multidistrict litigation can handicap state enforcers, but contended the changes should only apply to criminal matters and that the current version is wrong to block transfers of civil cases too. Thursday's letter from supporters of the bills said the proposals were carefully crafted to address the abusive practices of Big Tech, informed by the House antitrust subcommitee's sprawling investigation and "historic" 450-page report. "We believe that these bills will bring urgently needed change and accountability to these companies and an industry that most Americans agree is already doing great harm to our democracy," the letter said.

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

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

The Biden administration recently announced its support for a proposal before the World Trade Organization that would suspend the intellectual property protections on Covid-19 vaccines as guaranteed by the landmark TRIPS Agreement, a global trade pact that took effect in 1995.

The decision has sparked furious debate, with supporters arguing that the decision will speed the vaccine rollout in developing countries. The reality, however, is that even if enacted, the IP waiver will have zero short-term impact—but could inflict serious, long-term harm on global economic growth. The myopic nature of the Biden administration’s announcement cannot be overstated.

Even if WTO officials decide to waive IP protections at their June meeting, it’ll simply kickstart months of legal negotiations over precisely which drug formulas and technical know-how are undeserving of IP protections. And it’s unthinkable that the Biden administration, or Congress for that matter, would actually force American companies to hand over their most cutting-edge—and closely guarded—secrets.

As a result, the inevitable foot-dragging will cause enormous resentment in developing countries. And that’s the real threat of the waiver—precisely because it won’t accomplish either of its short-term goals of improving vaccine access and facilitating tech transfers from rich countries to developing ones. It’ll strengthen calls for more extreme, anti-IP measures down the road.

Experts overwhelmingly agree that waiving IP protections alone won’t increase vaccine production. That’s because making a shot is far more complicated than just following a recipe, and two of the most effective vaccines are based on cutting-edge discoveries using messenger RNA.

As Moderna Chief Executive Stephane Bancel said on a recent earnings call, “This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist. And then even if all those things were available, whoever wants to do mRNA vaccines will have to, you know, buy the machine, invent the manufacturing process, invent creation processes and ethical processes, and then they will have to go run a clinical trial, get the data, get the product approved and scale manufacturing. This doesn’t happen in six or 12 or 18 months.”

Anthony Fauci, the president’s chief medical adviser, has echoed that sentiment and emphasized the need for immediate solutions. “Going back and forth, consuming time and lawyers in a legal argument about waivers—that is not the endgame,” he said. “People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible.”

Those claiming the waiver poses an immediate, rather than long-term, threat to IP rights also misunderstand what the waiver will—and won’t—do.

The waiver petition itself is more akin to a statement of principle than an actual legal document. In fact, it’s only a few pages long.

As the Office of the United States Trade Representative has said, “Text-based negotiations at the WTO will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The WTO director-general predicts negotiations will last until early December.

That’s a lot of wasted time and effort. The U.S. Trade Representative would be far better off spending the next six months breaking down real trade barriers and helping export our surplus vaccine doses and vaccine ingredients to countries in need.

#### Antitrust is key to the DIB – brink is now.

Sitaraman 20 [Ganesh; Vanderbilt University Law School; “The National Security Case for Breaking Up Big Tech,” Knight First Amendment Institute at Columbia; 3/12/20; <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3537870>] brett // Re-Cut Justin

Concentration in the tech sector also threatens the defense industrial base due to higher costs, lower quality, less innovation, and even corruption and fraud.71 Each of these dynamics has already been a problem for America’s over-consolidated defense industrial base. As technology becomes more and more central to defense and national security, it is likely that these same dynamics will replicate themselves with big tech companies. This will become a national security threat, both directly, in terms of the quality and speed of procurement, and indirectly, by reducing innovation and functionally redirecting defense budgets from research spending to higher monopoly profits.72 Conventional economic theory suggests that monopolists have the ability to increase prices and reduce quality because consumers are captive.73 When it comes to defense spending, the Government Accountability Office commented in 2019 that “competition is the cornerstone of a sound acquisition process and a critical tool for achieving the best return on investment for taxpayers.”74 At the same time, the GAO observed that “portfolio-wide cost growth has occurred in an environment where awards are often made without full and open competition.”75 Indeed, it found that 67 percent of 183 major weapons systems contracts had no competition and almost half of contracts went to a handful of firms. Of course, consolidation also means that the Defense Department is in a symbiotic relationship with these big contractors. Some startup executives wanting to sell to the government thus see the Pentagon as “a bad customer, one that is heavily skewed in favor of larger, traditional players,” and they don’t feel like they can break into the sector.76 Standard stories about political economy and capture also suggest that these firms will have outsized power over government.77 As Frank Kendall, the former head of acquisitions at the Pentagon, has said, “With size comes power, and the department’s experience with large defense contractors is that they are not hesitant to use this power for corporate advantage.”78 In the defense context, that means monopolists retain power (and profits), even if they overcharge taxpayers and risk the safety of military personnel in the field. In an important article in The American Conservative on concentration in the defense sector, researchers Matt Stoller and Lucas Kunce argue that contractors with de facto monopoly at the heart of their business models threaten national security. They write that one such contractor, TransDigm, buys up companies that supply the government with rare but essential airline parts and then hike up the prices, effectively holding the government “hostage.”79 They also point to L3, a defense contractor that had ambitions to be a “Home Depot” for the Pentagon, as its former CEO put it. L3’s de facto monopoly over certain products, according to Stoller and Kunce, means that it continues to receive lucrative government contracts, even after admitting in 2015 that it knowingly supplied defective weapons sights to U.S. forces.80 Consolidation also threatens U.S. defense capacity. The decline of competition, according to a 2019 Pentagon report, leaves the military vulnerable to “sole source suppliers, capacity shortfalls, a lack of competition, a lack of workforce skills, and unstable demand.”81 With a limited number of producers, there is less talent and knowhow available in the country if there is a need to build capacity rapidly.82 In 2018, the Defense Department released a report on vulnerable items in the military supply chain, including numerous items in which only one or two domestic companies (and, in some cases, zero domestic companies) produced the essential goods.83 How did the United States lose so much of its industrial base? The combination of consolidation and global integration is part of the story. As Stoller and Kunce argue, companies consolidated in the 1980s and 1990s while shifting emphasis from production and R&D to Wall Street-demanded profits. Globalization then allowed them to shift production overseas at a lower cost. The result was to gut America’s domestic industrial base—and, in many cases, to shift it to China, which engaged in a decades-long strategic plan to develop its own industrial base. The result, in the words of the 2018 Defense Department report, is that “China is the single or sole supplier for a number of specialty chemicals used in munitions and missiles.” In other areas too, the risks of losing access to critical resources are real. Describing the problem of limited carbon fiber sources, the same Pentagon report notes, “[a] sudden and catastrophic loss of supply would disrupt DoD missile, satellite, space launch, and other defense manufacturing programs. In many cases, there are no substitutes readily available.”84 As technology becomes more integral to the future of national security, it is hard to see how big tech will not simply go the way of the big defense contractors. Corporate mottos not to “be evil” are long gone,85 and big tech companies spend millions on conventional Washington, D.C., lobbying efforts.86 Over time, as contracts move to tech behemoths, there will no longer be competitive alternatives, and the Pentagon will likely be locked into relationships with big tech companies—just as they currently are with big defense contractors.87 Some commentators suggest that robust antitrust policies are a problem because only a small number of tech companies can contract for defense projects.88 But there is another way to look at it: The goal should be to encourage competition in the tech sector so that there are multiple contractors available. As former secretary of homeland security Michael Chertoff has said, defending the antitrust case against Qualcomm, “a single-source national champion creates an unacceptable risk to American security—artificially concentrating vulnerability in a single point. ... We need competition and multiple providers, not a potentially vulnerable technological monoculture.”89 The consequence of consolidation in tech is that taxpayers will likely see higher bills even as innovation slows due to reduced competition. Worse still, every taxpayer dollar that goes to monopoly profits—whether in the form of higher prices or fraud and corruption—is a dollar that is not going toward innovation for the future. A concentrated defense sector means not only less innovation due to the lack of competition in the sector; it means that funding that could have been available for innovation instead gets redirected via monopoly profits to the pockets of big tech executives and shareholders.

#### That solves extinction through great power war.

Marks 19 [Michael; Former Senior Policy Advisor to the Under Secretary for Security Assistance, Science and Technology at the U.S. Department of State; "Strengthen US Industry To Counter National Security Challenges," American Military News; 10/10/19; <https://americanmilitarynews.com/2019/10/strengthen-us-industry-to-counter-national-security-challenges/>] Justin

While U.S. defense budgets have recently been on the rise, it is likely that we will see a spending decline in the coming years as competition for non-defense federal budget dollars increases and deficits grow. The United States, therefore, must take action to ensure that we maintain our technological edge against our adversaries by empowering the private sector to provide cost-effective innovation for America’s defense. Since the end of the Second World War the U.S. has relied on qualitative superiority over its potential adversaries, especially those like the Soviet Union/Russia and China, who enjoyed comparative quantitative advantages. These qualitative advantages were vital to maintaining global stability and helped enable our nation to become the preeminent global economy, but they have been eroded over the last few decades. In 1960, the U.S. share of global research and development (R&D) spending stood at 69%. U.S. defense-related R&D alone accounted for 36% of total global expenditures. Soon thereafter other nations recognized the need to increase their R&D expenditures and build their own defense industrial bases to compete with the United States. From 2000-2016, China’s share of global R&D rose from 4.9% to 25.1% while the U.S. share of global R&D dropped to 28%. U.S. defense-related R&D meanwhile now makes up a mere 4% of global R&D spending. There can be no doubt that Russia and China are determined to challenge America’s qualitative advantage. From the rebirth of Russian military power under Vladimir Putin to the ever-growing Chinese military prowess across the board, their efforts show no sign of slowing down. Russia has been and continues to undergo a major modernization of its armed forces. For example, they are in the midst of a ten-year program to build hundreds of new nuclear missiles and have set a goal of modernizing 70% of the Russian Ground Force’s equipment by 2020. One of the most frightening examples of Russia’s resurgence is its development of a hypersonic missile that could be ready for combat as early as 2020. Worryingly, the US is currently unable to defend against this type of missile. To accompany these developments came the emergence in 2017 of Russia as the world’s second-largest arms producer, ready and able to support nations hostile to US interests. China, on the other hand, used to be a country that only manufactured cheap products and knockoffs, but that is no longer true. Technology development and innovation figure prominently in all of China’s national planning goals, with plans to make the country the global leader in science and innovation and the preeminent technological and manufacturing power by 2049, the 100th anniversary of the Chinese communist revolution. This, of course, has huge implications for China’s military capability. The country now has the second-largest national defense budget behind the U.S. and wants to be Asia’s preeminent military power. Beijing is developing next-generation fighter jets, ICBMs and shorter-range ballistic missiles, as well as advanced naval vessels. The People’s Liberation Army has reached a critical point of confidence and now feel they can match competitors like the United States in combat. This has implications for the security of Taiwan, Japan, other US allies in the region as well as to America itself. To make matters worse, there are a growing number of experts that see China developing asymmetric technologies, combined with conventional and nuclear systems that could create an existential threat to the U.S. pacific based assets. It is in the wake of these growing threats to our national security American industry will likely be expected to shoulder an even larger responsibility concerning investment in defense-related R&D. One of the ways we can empower companies to make these additional investments and lead next-generation defense innovation is to allow commonsense mergers between important defense and aerospace companies. Horizontal consolidation eliminates the redundancy of enormous fixed costs, leading to savings passed down to customers. Mergers can also create economies of scale and existing synergies that help the combined company realize access to larger numbers of engineers and innovators, while keeping costs low and improving the timeline for taking a product from concept to development. FA recent example of how this can work is the proposed Raytheon and United Technologies merger. The two parties project that the new combined company will employ more than 60,000 engineers, hold over 38,000 patents and invest approximately $8 billion per year in research and development. This will allow the development of new, critical technologies more quickly and efficiently than either company could on its own. Such private sector investments in innovation will be critical in the face of the growing challenges to American military dominance. America’s R&D advantage, crucial to maintaining military superiority, is increasingly at risk. As China and Russia continue to challenge America’s military dominance and pressures on the defense budget continue to mount, the federal government will likely turn more and more to contractors and commercial companies to develop next-generation defense capabilities. Strengthening U.S. industry, therefore, will be critical to countering our national security challenges.

## 4

#### The member nations of the World Trade Organization except for the United States ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection.

#### The United States ought to [reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection through a supreme court decision by petitioning the PTAB and getting a formal ruling from APJs.

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

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

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

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

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

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