# 1NC

## Off

### 1NC – Court Politics DA

#### The court has taken up a challenge to EPA climate authority under the non-delegation doctrine, but will refrain from a broad decision because of fear of public backlash

Smith 21 – Lexi Smith, former advisor to the Mayor of Boston on climate policy, currently JD candidate at Yale Law School, “Supreme Court to weigh EPA authority to regulate greenhouse pollutants,” 11/7/21, https://yaleclimateconnections.org/2021/11/supreme-court-to-weigh-epa-authority-to-regulate-greenhouse-pollutants/

The Supreme Court agreed to hear a case, West Virginia v. EPA, challenging the Environmental Protection Agency’s authority to regulate greenhouse gases as pollutants.

The case presents an opportunity for the Court to overturn key climate precedents and potentially change the relationship between federal agencies and Congress. The decision could have far-reaching consequences for federal climate policy and perhaps even for federal agencies more broadly.

How did we get here, how far might the Court go, and what consequences might the case have for climate change regulation and executive branch authority?

EPA’s authority to regulate greenhouse gases: Massachusetts v. EPA

In a groundbreaking decision in 2007, the Supreme Court held 5-4 that EPA has authority to regulate greenhouse gases under the Clean Air Act. During the Bush administration, environmentalists petitioned the agency to issue a rule on the regulation of greenhouse gases. The Bush EPA denied the petition, and environmental groups, states, and local governments challenged that decision in court. The Supreme Court’s decision turned on whether greenhouse gases like carbon dioxide fall under the definition of “air pollutants,” which the Clean Air Act authorizes EPA to regulate.

The Court concluded that carbon dioxide and other greenhouse gases are air pollutants under the Clean Air Act’s definition, and also noted that the EPA cannot refuse to regulate greenhouse gases for policy reasons outside the Clean Air Act itself, as the Bush administration had done. The Court ordered EPA to either issue a finding that greenhouse gases are dangerous to the public health and welfare, the first step toward regulation, or to give a reasoned explanation for why greenhouse gases do not meet the threshold of endangerment outlined in the Clean Air Act. The agency ultimately found that greenhouse gases are dangerous to the public health and welfare, which formed the foundation for EPA’s regulation of greenhouse gases.

That Supreme Court’s ruling in Massachusetts v. EPA was a 5-4 decision, and environmental advocates leading up to it were not at all certain that they would win the case. In fact, the case was controversial at the time because many environmentalists worried that it would result in a harmful adverse ruling. The four liberals on the Court in 2007, Justices Souter, Ginsburg, Breyer, and Stevens, were joined by Justice Kennedy to form a majority. But Chief Justice Roberts and Justices Thomas, Scalia, and Alito dissented.

Chief Justice Roberts’s dissent (joined by Justices Scalia, Thomas, and Alito) argued that the states, local governments, and environmental groups challenging the EPA should not have been allowed to sue in the first place because they lacked standing: One requirement of standing is a “concrete and particularized” injury. Chief Justice Roberts argued that harms from climate change affect everyone, so the injury in question was not sufficiently individualized and personal to support a lawsuit.

Justice Scalia’s dissent (joined by Chief Justice Roberts and Justices Thomas and Alito) focused on the Clean Air Act and argued that the Act is meant to address conventional air pollutants that harm human health directly through exposure, such as inhalation. He maintained that the Act was not meant to address the broader issue of climate change, and that greenhouse gases therefore did not fall under the definition of “air pollutants.”

Of course, the Supreme Court’s composition has changed significantly since 2007. With a 6-3 conservative-liberal divide, the conservative dissenters’ objections to Massachusetts v. EPA may now represent the majority view.

The ‘worst case scenario’: What could West Virginia v. EPA bring?

There are reasons to expect that the Court will show restraint when it hears the upcoming challenge to EPA’s authority in the West Virginia v. EPA case. But first, let’s walk through the worst potential outcomes from the perspective of climate advocates.

As suggested above, the Court could overturn its decision in Massachusetts v. EPA and effectively take away EPA’s authority to regulate greenhouse gases. With such a ruling, EPA could no longer issue rules directly regulating greenhouse gas emissions, and past greenhouse gas rules issued under its Clean Air Act authority would be invalid.

Richard Lazarus, a Harvard Law School professor who recently wrote a book about Massachusetts v. EPA, called the Court’s decision to hear West Virginia v. EPA “the equivalent of an earthquake around the country for those who care deeply about the climate issue.”

The consequences of the case could even reach far beyond climate regulation. The case presents an opportunity for the Court to revive the “nondelegation doctrine,” a mostly defunct principle that purported to limit Congress’s authority to delegate legislative power to executive branch agencies. The doctrine comes from Article I of the Constitution, which says that “[a]ll legislative powers herein granted shall be vested in a Congress of the United States.” The Supreme Court has not used the nondelegation doctrine to strike down agency action in more than 80 years.

Implications of enforcing nondelegation doctrine

The practical consequences of enforcing the nondelegation doctrine would debilitate the current system of executive branch rulemaking and regulation, subject to judicial review and congressional oversight. If Congress were to do all the rulemaking currently done by EPA, for instance, environmental regulation would become virtually impossible to enact. Congress in that case would have to make thousands of granular and technical decisions about environmental policy, even though we know it can barely pass major legislation as it is.

More broadly, nondelegation could mean that much of the work done by all federal agencies would have to be done instead by a clearly ill-equipped Congress. Even without current gridlock on Capitol Hill, the sheer volume of policy decisions Congress would have to make would be completely unworkable.

While this outcome sounds unlikely and illogical to those who support federal agency regulation, several of the current Justices at various times have expressed interest in weakening the administrative state and deregulating industry. For them, the nondelegation doctrine may be an attractive principle.

Notably, for instance, in a case called Gundy v. United States in 2019, four of the conservatives (Chief Justice Roberts and Justices Gorsuch, Thomas, and Alito) showed a willingness to revisit the nondelegation doctrine. At that time, Justice Kennedy had retired, and Justice Kavanaugh had not yet been confirmed, so the case was 4-4. With Justices Kavanaugh and Barrett now on the court, there appears to be some chance that reviving the nondelegation doctrine would garner the support of five or even six Justices.

The petitioners – West Virginia and North American Coal Corporation – that brought the appeal in West Virginia v. EPA explicitly suggested that this case could be an opportunity for the Court to reconsider nondelegation: “Nothing in the statute [the Clean Air Act] approaches the clear language Congress must use to assign such vast policymaking authority – assuming, of course, it can delegate enormous powers like these in the first place.”

In short, the worst-case scenario from the perspective of climate action advocates is that the Supreme Court takes away the EPA’s authority to regulate greenhouse gases and also revives the nondelegation doctrine, which would strip most federal agencies of much of their regulatory power.

Reasons for a less sweeping outcome

Let’s now consider some reasons the Court may be unlikely to completely overturn Massachusetts v. EPA or fully embrace the nondelegation doctrine.

First, Chief Justice Roberts, and increasingly Justices Kavanaugh and Gorsuch, appear keenly mindful and protective of the Court’s reputation and legacy. They have tended to look out for the public perception of the Court and avoid decisions that would have provoked especially strong public backlash. Recent examples include upholding the Affordable Care Act and civil rights protections for the LGBT community.

These cautious impulses may be heightened by the looming threat of court reform, which could gain more momentum if a particularly controversial conservative decision were issued. Given the strong public backlash likely to result from a decision taking away EPA authority to regulate greenhouse gases and/or reviving the nondelegation doctrine, the Court may proceed with caution.

#### The plan’s liberal ruling provides breathing room for a conservative decision on non-delegation

Bazelon 15 – Emily Bazelon, staff writer for the New York Times Magazine, Truman Capote Fellow at Yale Law School, “Marriage of Convenience,” 1/27/2015, https://www.nytimes.com/2015/02/01/magazine/marriage-of-convenience.html

More significant, if the court is seen as transcending partisan politics, Roberts will probably have more chances, over time, to accomplish what appears to be his primary long-term goal: to move the court in a more conservative direction on a range of issues. In particular, Roberts's brand of conservatism has manifested itself in two main areas. The first is in decisions that are sympathetic to corporations. A 2013 study found that he had been more likely to side with businesses than any justice in the previous 65 years, except for Samuel Alito. The second is in decisions that are antagonistic toward the idea of taking race into account in shaping law or policy. Roberts has voted repeatedly against affirmative action, writing last year that it was not hard to conclude that racial preferences may ''do more harm than good.'

When Roberts was nominated to be chief justice 10 years ago by President George W. Bush, he exuded calm neutrality at his confirmation hearing, comparing judges to umpires who call balls and strikes. At the end of his first term, he emphasized the importance of the court's ''credibility and legitimacy as an institution,'' in an interview with the George Washington University law professor Jeffrey Rosen.

But in 2010, Roberts supplied the fifth vote for the court's remarkably unpopular ruling in Citizens United. By striking limits that Congress set on campaign spending by corporations, the court was perceived as favoring the interests of the wealthy. The court's approval rating fell 10 percentage points, to barely break even, from 61 percent.

Since then, the court has fared better with the public when it pairs conservative decisions with progressive ones. And same-sex marriage is part of that equation. In 2013, the term ended with a splashy ruling in which five justices -- Roberts not among them -- struck down part of the Defense of Marriage Act, which restricted federal benefits for spouses to male-female couples. This decision came one day after the court gutted a central component of the Voting Rights Act, in a 5-to-4 decision written by Roberts.

#### Domestic U.S. climate regulations are key to avoiding dangerous climate change globally – extinction

Friedman 21 – Lisa Friedman, climate and energy reporter for the New York Times, “At Climate Talks, Biden Will Try to Sell American Leadership to Skeptics,” 10/31/21, https://www.nytimes.com/2021/10/31/climate/climate-change-biden-cop26.html

If Mr. Biden lacks a reliable plan for the United States to significantly cut its emissions this decade, it would “send a signal” to other major emitters that America is still not serious, she said. And it would be difficult for Mr. Biden to urge other countries to take more meaningful steps away from fossil fuels, others said.

“Some of these countries are saying, ‘Oh yeah, but look at what you did guys, and now you’re coming back and demanding after you were away for the past four years?’” said Andrea Meza, the environment and energy minister of Costa Rica.

Tensions were already running high ahead of the summit. China, currently the world’s top emitter, announced a new target on Thursday that was supposed to be a more ambitious plan to curb its pollution but is virtually indistinguishable from what it promised six years ago. President Xi Jinping has indicated he will not attend the summit in person, as have presidents of two other top polluting nations, Vladimir V. Putin of Russia and Jair Bolsonaro of Brazil.

Democrats close to President Biden said he is painfully aware that the credibility of the United States is on the line in Glasgow, particularly after a botched withdrawal from Afghanistan this summer and a dust-up with France over a military submarine contract.

Representative Ro Khanna, Democrat of California, met with the president recently to discuss how to salvage Mr. Biden’s legislative climate agenda.

“He indicated that many world leaders like Putin and Xi are questioning the capability of American democracy to deliver, so we need to show them that we can govern,” Mr. Khanna said.

Mr. Biden, who is accompanied in Glasgow by 13 Cabinet members, insists they have a story of success to tell, starting with his decision on his first day on the job to rejoin the 2015 Paris Agreement, an accord of nearly 200 countries to fight climate change, from which Mr. Trump had withdrawn the United States.

Since then, Mr. Biden has taken several steps to cut emissions, including restoring and slightly strengthening auto pollution regulations to levels that existed under President Barack Obama but were weakened by Mr. Trump. He has taken initial steps to allow the development of large-scale wind farms along nearly the entire coastline of the United States, and last month finalized regulations to curb the production and use of potent planet-warming chemicals called hydrofluorocarbons, which are used in air-conditioners and refrigerators.

But Mr. Biden is likely to emphasize the $555 billion that he wants Congress to approve as part of a huge spending bill. The climate provisions would promote wind and solar power, electric vehicles, climate-friendly agriculture and forestry programs, and a host of other clean energy programs. Together, those programs could cut the United States’ emissions up to a quarter from 2005 levels by 2030, analysts say.

That’s about halfway to Mr. Biden’s goal of cutting the country’s emissions 50 to 52 percent below 2005 levels. “We go in with a fact pattern that is pretty remarkable, as well as real momentum,” Ali Zaidi, the deputy White House national climate adviser, told reporters.

Mr. Biden plans to release tough new auto pollution rules designed to compel American automakers to ramp up sales of electric vehicles so that half of all new cars sold in the United States are electric by 2030, up from just 2 percent this year. His top appointees have also promised new restrictions on carbon dioxide emissions from coal and gas-fired power plants. And earlier this year, Biden administration officials said they would roll out a draft rule by September to regulate emissions of methane, a powerful planet-warming gas that leaks from existing oil and natural gas wells.

So far, the administration has not offered drafts of any of those rules. Several administration sources said that delay has been due in part to staff shortages, as well as an effort not to upset any lawmakers before they vote on Mr. Biden’s legislative agenda.

But time is running out. It can take years to complete work on such complex and controversial government policies, and several are likely to face legal challenges. On Friday, the U.S. Supreme Court, which has a conservative majority, said it would review the E.P.A.’s authority to regulate greenhouse gas emissions, potentially complicating Mr. Biden’s plans.

The U.S. track record

For three decades, American politics have complicated global climate efforts.

Former President Bill Clinton, a Democrat, joined the first global effort to tackle climate change, the 1997 Kyoto Protocol. His Republican successor, President George W. Bush, renounced the treaty. Mr. Obama, another Democrat, joined the 2015 Paris Agreement and rolled out dozens of executive orders to help meet his promises to cut emissions. His Republican successor, Mr. Trump, abandoned the accord, repealed more than 100 of Mr. Obama’s regulations and took steps to expand fossil fuel drilling and mining.

Mr. Biden is facing similar resistance. No Republicans in Congress back his current climate effort. Representative Frank Lucas of Oklahoma, the top Republican on the House science committee, said the international community should be skeptical of the Biden administration’s promises. “I think they’ll roll their eyes just as people will continue to do in the United States,” Mr. Lucas said.

The president has also struggled to win over two pivotal players within his own party. Senator Joe Manchin III, Democrat of West Virginia, has been steadfastly opposed to a central feature of Mr. Biden’s climate plan: a program that would have rapidly compelled power plants to switch from burning coal, oil and gas, to using wind, solar and other clean energy. Mr. Manchin’s state is a top coal and gas producer, and he has personal financial ties to the coal industry. He was able to kill the provision. Senator Kyrsten Sinema, Democrat of Arizona, has also withheld her support, saying she wants a more modest spending bill.

Environmental leaders said America’s past inconsistency on climate action makes it more important for Mr. Biden to succeed now.

“The U.S. has had to be dragged kicking and screaming to the climate table and has slowed down action that was needed to tackle the climate crisis,” said Mohamed Adow, director of Power Shift Africa, a Nairobi-based environmental think tank. “That is the legacy Biden has to deal with.”

What’s at stake

Average global temperatures have already risen about 1.1 degrees Celsius (2.7 degrees Fahrenheit), compared with preindustrial levels, locking in an immediate future of rising seas, destructive storms and floods, ferocious fires and more severe drought and heat.

At least 85 percent of the planet’s population has already begun to experience the effects of climate change, according to research published in the journal Nature Climate Change. This summer alone, more than 150 people died in violent flooding in Germany and Belgium. In central China, the worst flooding on record displaced 250,000 people. In Siberia, summer temperatures reached as high as 100 degrees, feeding enormous blazes that thawed what was once permanently frozen ground.

“Clearly, we are in a climate emergency. Clearly, we need to address it,” Patricia Espinosa, head of the U.N. climate agency, said Sunday as she welcomed delegates to Glasgow. “Clearly, we need to support the most vulnerable to cope. To do so successfully, greater ambition is now critical.”

If the planet heats even a half-degree more, it could lead to water and food shortages, mass extinctions of plants and animals, and more deadly heat and storms, scientists say.

### 1NC – Advantage CP

#### The United States federal government, including the Patent and Trademark Office and International Trade Commission, should:

#### Establish that a finding of objective baselessness is not sufficient to trigger a finding of subjective intent to exclude competitors under the sham exception to Noerr-Pennington antitrust immunity and that serial litigation is not sufficient to trigger antitrust liability without a finding of objective baselessness.

#### Apply the doctrine of patent law to restrict unfair methods of competition by Patent Assertion Entities and patent thickets by pharmaceutical companies and establish that the First Amendment right to petition the government does not immunize patent infringement assertions by Patent Assertion Entities and pharmaceutical companies from patent law penalties.

#### Limit citizen petitioning of the Food and Drug Administration via parallel review, defined time frames for submission and review of petitions by brand-name manufacturers, required disclosures of conflicts of interest, and automatic dismissal of petitions based on fraud and misrepresentation.

#### Overturn *Citizens United v. FEC* and increase funding for Congressional staffing.

#### The first plank has the court codify the status quo – that provides certainty and resolves circuit splits – solves advantage three.

#### The patent plank allows the ITC to restrict unfair complaints by patent trolls – solves the advantage

Donahey ’16 [Teague; intellectual property litigator in the Boise, Idaho office of Holland & Hart; July/August 2016; “Expanding horizon of Section 337 jurisdiction”; <https://www.hollandhart.com/files/36919_IPM_July_Aug_2016-Feat.pdf>; accessed 10/28/21; TV]

Under 19 USC § 1337 (“Section 337”), the US International Trade Commission (ITC) is authorised to investigate and adjudicate international trade disputes involving imported products. For many years, the ITC has been one of the most popular venues in the US for patent litigation, and contentious patent infringement disputes have consumed the vast majority of the ITC’s § 337 bandwidth over the years. Parties involved in cross-border business disputes, however, should recognise that the scope of the ITC’s § 337 jurisdiction is much broader than just patents. Indeed, under the express language of § 337, the statute operates to address any number of “unfair methods of competition” and “unfair acts” related to products imported into the US, and the precise contours of this ambiguous language have never been determined.

The ITC’s popularity as a forum for patent infringement disputes

The ITC’s popularity as a patent infringement forum derives from several key factors. First, the ITC is statutory mandated to complete its investigations in an expeditious fashion – approximately 18 months, which is much faster than the typical case in the federal court system – placing enormous practical and financial pressures on defendants, who are termed respondents in ITC parlance. Such pressures are often sufficient to drive early settlement, thereby avoiding what can seem like endless litigation in federal court.

Secondly, § 337 offers US complainants powerful statutory remedies: exclusion orders barring infringing products from being imported into the US, which are enforced by US Customs and Border Protection (CBP), as well as cease-and-desist orders prohibiting related conduct (eg, product-marketing activities) within the US. These remedial orders are effectively injunctive relief, which has become more difficult to obtain in US courts given developments in patent infringement case law.

Thirdly, although proper notice must be given to all respondents, § 337 proceedings are ultimately adjudicated on an in rem basis against the imported products. This is significant, given that US complainants often face enforcement challenges when required to proceed on an in personam basis in US courts against overseas infringers.

Fourthly, in contrast to US courts, the ITC is unlikely to stay its § 337 proceedings during co-pending inter partes review (IPR) proceedings before the US Patent & Trademark Office involving the same patent or patents. Thus, an ITC respondent is typically unable to block the enforcement proceeding by filing an IPR petition – a typical defence tactic.

ITC § 337 proceedings apply to essentially all IP disputes involving imported goods

The ITC’s historical focus on patents, however, has obscured the fact that § 337 is, at heart, a trade provision covering a much broader range of unfair trade practices. In addition to patent infringement, § 337 expressly reaches disputes involving trademark or copyright infringement, as well as infringement of statutory rights with respect to semiconductor mask works and vessel hull designs. Section 337 also covers other “unfair methods of competition and unfair acts”, which language has been understood to include such practices as trade secret misappropriation, unfair competition and passing off, false advertising and false designation of origin, trademark dilution, trade dress infringement and antitrust violations.1

One recent and prominent example of a non-patent § 337 adjudication was Converse’s 2014 complaint2 against 31 different respondent entities alleging trademark infringement related to Converse’s All Star/Chuck Taylor shoe line, along with claims for false designation of origin, unfair competition under the Lanham Act and trademark dilution. The ITC Administrative Law Judge ruled in Converse’s favour and recommended an exclusion order. Several years earlier, in a landmark 2012 case, Louis Vuitton was similarly successful in obtaining an ITC exclusion order against counterfeit handbags and luggage.3

In another highly publicised § 337 investigation,4 the ITC issued an exclusion order in 2009 barring the importation of cast steel railway wheels from China. The ITC’s determination was based on its finding that a misappropriation of trade secrets had occurred and an exclusion order was issued against the implicated products on an in rem basis even though the misappropriation had occurred abroad, in China.

The full breadth of the ITC’s § 337 jurisdiction remains untested

Notwithstanding the diverse nature of such decisions, § 337’s disjunctive reference to both unfair methods of competition and, separately, unfair acts indicates that the ITC’s § 337 jurisdiction is likely even broader. Indeed, it has long been recognised that the statutory unfair acts language provides a distinct basis for jurisdiction over and above the statute’s reference to unfair methods of competition.5

When § 337’s predecessor statute – the Tariff Act of 1922 – was originally enacted, the Senate Finance Committee reported that the provision was “broad enough to prevent every type and form of unfair practice”.6 Similarly, an early appellate decision explained that the provision’s language “is broad and inclusive and should not be held to be limited to acts coming within the technical definition of unfair methods of competition as applied in some decisions… Congress intended to allow wide discretion in determining what practices are to be regarded as unfair.”7

Although the concept of unfairness is inherently vague, the ITC has attempted to define the scope of unfair acts under § 337 as being “within the general range of practices ‘heretofore regarded as opposed to good morals because characterised by deception, bad faith, fraud or oppression, or as against public policy because of their dangerous tendency unduly to hinder competition or create monopoly’.”8 The ITC has further indicated that “the concept of an unfair act involves some sense of an intentional tort which constitutes an offence not merely against the immediate victim, but against the values of society as well”– in summary: “intentionally tortious behaviour contrary to public morals”.9

The ITC and the courts have also occasionally sought guidance from § 5 of the Federal Trade Commission Act (15 USC § 45), which, using language almost identical to § 337, empowers the Federal Trade Commission (FTC) to prohibit “unfair methods of competition” and “unfair or deceptive acts or practices”. In this regard, the FTC, somewhat cryptically, has interpreted the FTC Act’s reference to unfair methods of competition as including “not only those acts and practices that violate the Sherman or Clayton Act but also those that contravene the spirit of the antitrust laws and those that, if allowed to mature or complete, could violate the Sherman or Clayton Act.”10 The FTC Act’s separate reference to unfair acts is currently understood to be directed to consumer unfairness, with ‘unfairness’ being evaluated in light of the following factors: whether the practice injures consumers; whether it violates established public policy; and whether it is unethical or unscrupulous.11 Courts have emphasised that § 5 is intended to be flexible and that unfairness should be determined on case-by-case basis in light of the facts.

Going forward, it remains to be seen how far the ITC will permit the unfairness envelope to be pushed. Section 337 litigants have raised claims such as breach of contract and tortious interference, for example, although the jurisdictional viability of such claims has not been conclusively resolved. Could such claims ever constitute the required “intentionally tortious behaviour contrary to public morals”, or do they constitute merely private offences directed at the immediate victim alone – offences less likely to give rise to § 337 jurisdiction? Recent observers have gone further and proposed that § 337 could cover circumstances rarely conceived as being relevant to the statute. For example, it has been surmised that § 337 could be invoked to prevent the importation of products manufactured overseas in circumstances involving: human rights violations; child labour; violations of environmental norms; food and drug safety violations; endangered plant or animal species; and/or conflict minerals.12 All of these types of conduct could arguably provide the foreign manufacturer of imported goods an unfair cost advantage over US competitors and, as such, constitute unfair methods of competition and unfair acts within the spirit of § 337. But any such claims would move § 337 well beyond its traditional frame of reference.

Regardless, it is clear that the ITC’s § 337 jurisdiction is not limited to patent infringement disputes, despite past practice before the Commission. Indeed, essentially any intellectual property dispute involving products imported into the US would be a strong candidate for § 337 enforcement before the ITC.

#### The counterplan distinguishes patent law from Noerr-Pennington immunity, meaning that it restricts patent trolls without touching antitrust law

Gugliuzza 16 – Paul Gugliuzza, Professor of Law, Temple University Beasley School of Law, “Regulating Patent Assertions,” 2016, https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=1173&context=faculty\_scholarship

Although it is difficult for a plaintiff to prove that an allegation of patent infringement was objectively baseless, it is not a foregone conclusion that patent holders’ claims of immunity will always succeed. To the extent that challenges to patent enforcement conduct proceed in state court, such as the Vermont attorney general’s suit against MPHJ, those courts could develop a narrower immunity rule than the Federal Circuit, for state courts are not bound to follow Federal Circuit law.

Moreover, the Federal Circuit could – and should – reconsider its case law, as there is a strong argument that the court has erred in granting patent holders broad immunity for their enforcement conduct. As noted, the Federal Circuit derived its immunity test from antitrust law’s Noerr-Pennington doctrine, which protects defendants from antitrust liability based on their litigation conduct in order to preserve the First Amendment right “to petition the government for a redress of grievances.” But the Federal Circuit’s reliance on Noerr-Pennington and the First Amendment’s Petition Clause is a mistake. Most fundamentally, letters sent from one private party to another, such as letters threatening patent infringement litigation, are simply not “petition[s]” to “the government” within the meaning of the First Amendment. Moreover, the holding in Noerr was “a construction of the Sherman Act” informed by the Act’s purpose to regulate “business activity,” not political activity or litigation conduct (Noerr 1961, 137– 138; see also California Motor Transport 1972 (extending Noerr immunity to litigation conduct)). But this statutory rationale for immunity from antitrust liability is absent in the context of patent enforcement. In contrast to the antitrust laws, the regulation of litigation conduct or misleading assertions of legal rights is a core purpose of laws used to challenge patent enforcement, such as consumer protection laws and the new state patent-assertion statutes.

By looking to history, the Federal Circuit could better balance the goals of protecting patent holders from liability when they make legitimate allegations of infringement and punishing patent holders when they employ unfair or deceptive tactics. At the time the Federal Circuit was created in 1982, the lower federal courts had, for nearly a century, been addressing the precise question of when a patent holder could be held liable for its enforcement conduct. Those courts enjoined patent holders from making infringement assertions “in bad faith” (see, e.g., Emack 1888) – precisely the behavior many of the new state statutes condemn. But the Federal Circuit has largely ignored that long line of decisions, instead demanding that anyone challenging patent enforcement conduct prove that the infringement allegations were objectively baseless (Gugliuzza 2015, 1624–27).

Historically, the courts treated bad faith as a flexible standard with both subjective and objective components (Bicks 1977, 303–304). Under this equity-based immunity standard – as opposed to the rigid “objective baselessness” test mandated by the Federal Circuit – the government could impose reasonable restrictions on patent enforcement, enjoining enforcement campaigns when, for instance, the patent holder conducted no investigation into the alleged acts of infringement (e.g., Besser Manufacturing 1951), failed to follow its threats with actual lawsuits (e.g., Adriance, Platt 1903), or falsely claimed that a patent’s validity had previously been confirmed in court or in reexamination (e.g., A.B. Farquhar Co. 1900). At the same time, cases in which courts enjoined enforcement conduct under the bad faith standard were usually egregious and often involved claims that were objectively weak on the merits (e.g., Emack 1888). Accordingly, a bad faith immunity standard, as opposed to the Federal Circuit’s “objective baselessness” rule, would protect patent holders’ ability to provide legitimate notice of their patent rights while also offering the government some leeway to punish unfair or deceptive behavior.

If the cases brought against Innovatio by the router manufacturers and against MPHJ by the Nebraska attorney general had been decided under a bad faith standard, the courts could have held the patent holders’ enforcement tactics to be unlawful. In both cases, the claims challenging those tactics failed because they did not allege that the infringement allegations were objectively baseless. Under a more flexible bad faith standard, however, the courts likely could have condemned the patent holders’ enforcement activities. For instance, it is extremely unlikely that Innovatio and MPHJ investigated the alleged acts of infringement, given that they sent out thousands of demand letters at one time. Moreover, Innovatio made allegedly false statements that its patents’ validity had been upheld in court and in reexamination, and MPHJ never sued the targets of its enforcement campaign. Historically, this is the type of enforcement conduct that courts held to be in bad faith. Thus, a change of course by the Federal Circuit could make a real difference to private plaintiffs and government officials who seek to challenge unfair or deceptive patent enforcement campaigns.

### 1NC – Pharma DA

#### Restricting Noerr-Pennington immunity causes a chilling effect on pharma innovation

Gidley 21 – J. Mark Gidley, White & Case LLP, “BRIEF OF AMICI CURIAE LAW PROFESSORS IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176016/20210419113917235\_2021-04-19%20AbbVie%20v.%20FTC%20No.%2020-1293%20Law%20Professors%20Amicus%20Brief.pdf

This Court should grant the petition for a writ of certiorari and reverse the Third Circuit’s decision because it conflicts with this Court’s sham-litigation test articulated in PRE by effectively eliminating the second step of the sham litigation test: the inquiry into whether a patent owner had a subjective belief that his patent infringement suit lacked merit or was indifferent to the outcome of the suit. The Third Circuit’s novel approach—inferring subjective bad faith from a finding of objective baselessness—is at odds with PRE itself and sham-litigation jurisprudence in the other circuit courts. The petitioners address the relevant facts of this case, as well as this Court’s applicable jurisprudence. Therefore, Amici offer additional insights concerning how the Third Circuit’s decision threatens innovators’ property rights, as well as the Congressionally created incentives in the Hatch- Waxman Act, and poses a real and serious threat to pharmaceutical innovation, a key pillar of the U.S. innovation economy.

The FTC’s urging of the Third Circuit to adopt a truncated approach to the sham-litigation test is simply another attempt by the FTC to dictate that so-called “reverse-payment” settlement agreements in the pharmaceutical industry are necessarily anticompetitive. After failing to convince this Court in Actavis to adopt a “quick-look” approach to evaluating reverse- payment settlement agreements, the FTC is now seeking to avoid having to develop actual proof of subjective bad faith on the part of a patent owner. Instead of marshalling any such evidence, the FTC seeks to rely on an inference that a finding that a patent suit was objectively baseless given a complicated patent validity issue necessarily means that the patent owner harbored a subjective belief that the suit was without merit or was indifferent to whether the suit succeeded.

This truncated inquiry into subjective intent undoes the safeguard that the bad-faith inquiry serves— namely, ensuring that litigants whose suits are ultimately found to be meritless but who sincerely sought a favorable outcome are immune from antitrust liability under the Noerr-Pennington doctrine. Moreover, the Third Circuit’s novel approach to the subjective prong of the PRE test is particularly ill suited in the context of the Hatch-Waxman Act. The Third Circuit’s subjective-motivation analysis conflicts with the incentives inherent in the Hatch-Waxman regime by subjecting an innovator to antitrust liability—and accompanying treble damages—when an innovator files a patent infringement suit against an alleged infringer and automatically activates the thirty-month-stay provision designed by Congress to encourage quick resolution of patent challenges.

If this Court allows the Third Circuit’s new interpretation of the subjective-motivation prong of the sham-litigation test to stand, it will have detrimental chilling effects on Hatch-Waxman lawsuits and settlements, both of which are encouraged by Hatch-Waxman. In turn, the Third Circuit’s truncated version of the sham-litigation test will discourage pharmaceutical innovation and harm our innovation economy—an acutely undesirable result in an era where the need for rapid pharmaceutical innovation is paramount. This Court should reverse the Third Circuit’s erroneous decision.

#### Pharma innovation stops extinction.

Millett ’17 [Dr. Piers, PhD, Senior Research Fellow at the University of Oxford, Future of Humanity Institute, and Andrew Snyder-Beattie, MS, Director of Research at the University of Oxford, Future of Humanity Institute, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Volume 15, Number 4, 8/1/2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5576214/]

Abstract

In the decades to come, advanced bioweapons could threaten human existence. Although the probability of human extinction from bioweapons may be low, the expected value of reducing the risk could still be large, since such risks jeopardize the existence of all future generations. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios.

Keywords: : Biothreat, Catastrophic risk, Existential risk, Cost-effectiveness, Cost-benefit analysis

How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives.

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21

Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that “we can ensure Gaia's survival only through the extinction of the Humans as a species … we now have the specific technology for doing the job … several different [genetically engineered] viruses could be released”(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32

What is the appropriate response to these speculative extinction threats? A balanced biosecurity portfolio might include investments that reduce a mix of proven and speculative risks, but striking this balance is still difficult given the massive uncertainties around the low-probability, high-consequence risks. In this article, we examine the traditional spectrum of biosecurity risks (ie, biocrimes, bioterrorism, and biowarfare) to categorize biothreats by likelihood and impact, expanding the historical analysis to consider even lower-probability, higher-consequence events (catastrophic risks and existential risks). In order to produce reasoned estimates of the likelihood of different categories of biothreats, we bring together relevant data and theory and produce some first-guess estimates of the likelihood of different categories of biothreat, and we use these initial estimates to compare the cost-effectiveness of reducing existential risks with more traditional biosecurity measures. We emphasize that these models are highly uncertain, and their utility lies more in enabling order-of-magnitude comparisons rather than as a precise measure of the true risk. However, even with the most conservative models, we find that reduction of low-probability, high-consequence risks can be more cost-effective, as measured by quality-adjusted life year per dollar, especially when we account for the lives of future generations. This suggests that despite the low probability of such events, society still ought to invest more in preventing the most extreme possible biosecurity catastrophes.

Here, we use historical data to analyze the probability and severity of biothreats. We place biothreats in 6 loose categories: incidents, events, disasters, crises, global catastrophic risk, and existential risk. Together they form an overlapping spectrum of increasing impact and decreasing likelihood (Figure 1).\*

A spectrum of differing impacts and likelihoods from biothreats. Below each category of risk is the number of human fatalities. We loosely define global catastrophic risk as being 100 million fatalities, and existential risk as being the total extinction of humanity. Alternative definitions can be found in previous reports,33 as well as within this journal issue.34

The historical use of bioweapons provides useful examples of some categories of biothreats. Biocrimes and bioterrorism provide examples of incidents.† Biological warfare provides examples of events and disasters. These historical examples provide indicative data on likelihood and impact that we can then feed into a cost-effectiveness analysis. We should note that these data are both sparse and sometimes controversial. Where possible, we use multiple datasets to corroborate our numbers, but ultimately the “true rate” of bioweapon attacks is highly uncertain.

Biocrimes and Bioterrorism

Historically, risks of biocrime‡ and bioterrorism§ have been limited. A 2015 Risk and Benefit Analysis for Gain of Function Research detailed 24 biocrimes between 1990 and 2015 (0.96 per year) and an additional 42 bioterrorism incidents between 1972 and 2014 (1 per year).36 This is consistent with other estimates of biocrimes and bioterrorism frequency, which range from 0.35 to 3.5 per year (see supplementary material, part 1, at http://online.liebertpub.com/doi/suppl/10.1089/hs.2017.0028).

Most attacks typically result in no more than a handful of casualties (and many of these events include hoaxes, threats, and attacks that had no casualties at all). For example, the anthrax letter attacks in the United States in 2001, perhaps the most high-profile case in recent years, resulted in only 17 infections with 5 fatalities.37 The 2015 Risk and Benefit Analysis for Gain of Function Research detailed only a single death from the recorded biocrimes.\*\* Only 1 of the bioterrorism incidents in the report had associated deaths (the 2001 anthrax letter attacks).36 Based on this data, for the purposes of this article, we assume that we could expect 1 incident per year resulting in up to tens of deaths.

Biological Warfare

Academic overviews of biological warfare†† detail 7 programs prior to 1945.38 A further 9 programs are recorded between 1945 and 1994.39 For most of the last century, at least 1 program was active in any given year (Table 1).

The actual use of bioweapons by states is less common: Over the 85 years covered by these histories (1915 to 2000), 18 cases of use (or possible use) were recorded, including outbreaks connected to biological warfare (see supplementary material, part 2, at http://online.liebertpub.com/doi/suppl/10.1089/hs.2017.0028). Extrapolating this out (dividing 18 by 85), we would have about a 20% chance per year of biowarfare. It is worth noting the limitations of these data. Most of these events occurred before the introduction of the Biological Weapons Convention and were conducted by countries that no longer have biological weapons programs. Since many of these incidents occurred during infrequent great power wars, we revise our best guess to around 10% chance per year of biowarfare.

We use 2 sets of data to estimate the magnitude of such events. The first dataset was Japanese biological warfare in China,40 where records indicate a series of attacks on towns resulted in a mean of 330 casualties per event and 1 case in which an attack resulted in a regional outbreak causing an estimated 30,000 deaths (see supplementary material, part 3, at http://online.liebertpub.com/doi/suppl/10.1089/hs.2017.0028). The second data set came from disease events that were alleged to have an unnatural origin.41 In one case study, a point source release of anthrax resulted in at least 66 deaths. In a second case study, a regional epidemic of the same disease resulted in more than 17,000 human cases. While these events were not confirmed as having been caused by biological warfare, contemporary or subsequent analysis has suggested that such an origin was at least feasible. Combined, these figures provide an estimated impact of between 66 to 330 and 17,000 to 30,000.

For the purposes of this analysis, we are assuming the lower boundary figures from biological warfare are indicative of events, with a likelihood of 10% per year and an impact ranging between tens and thousands of fatalities. The upper boundary figures from biological warfare are indicative of disasters, with a likelihood of 1% per year and an impact range of thousands to tens of thousands of fatalities.‡‡

Unlike standard biothreats, there is no historical record on which to draw when considering global catastrophic or existential risks. Alternative approaches are required to estimate the likelihood of such an event. Given the high degree of uncertainty, we adopt 3 different approaches to approximate the risk of extinction from bioweapons: utilizing surveys of experts, previous major risk assessments, and simple toy models. These should be taken as initial guesses or rough order-of-magnitude approximations, and not a reliable or precise measure.

An informal survey at the 2008 Oxford Global Catastrophic Risk Conference asked participants to estimate the chance that disasters of different types would occur before 2100. Participants had a median risk estimate of 0.05% that a natural pandemic would lead to human extinction by 2100, and a median risk estimate of 2% that an “engineered” pandemic would lead to extinction by 2100.42

The advantage of the survey is that it directly measures the quantity that we are interested in: probability of extinction from bioweapons. The disadvantage is that the estimates were likely highly subjective and unreliable, especially as the survey did not account for response bias, and the respondents were not calibrated beforehand. We therefore also turn to other models that, while indirect, provide more objective measures of risk.§§

Recent controversial experiments on H5N1 influenza prompted discussions as to the risks of deliberately creating potentially pandemic pathogens. These agents are those that are highly transmissible, capable of uncontrollable spread in human populations, highly virulent, and also possibly able to overcome medical countermeasures.44 Previous work in a comprehensive report done by Gryphon Scientific, Risk and Benefit Analysis of Gain of Function Research,36 has laid out very detailed risk assessments of potentially pandemic pathogen research, suggesting that the annual probability of a global pandemic resulting from an accident with this type of research in the United States is 0.002% to 0.1%. The report also concluded that risks of deliberate misuse were about as serious as the risks of an accidental outbreak, suggesting a 2-fold increase in risk. Assuming that 25% of relevant research is done in the United States as opposed to elsewhere in the world, this gives us a further 4-fold increase in risk. In total, this 8-fold increase in risk gives us a 0.016% to 0.8% chance of a pandemic in the future each year (see supplementary material, part 4, at http://online.liebertpub.com/doi/suppl/10.1089/hs.2017.0028).

The analysis in Risk and Benefit Analysis of Gain of Function Research suggested that lab outbreaks from wild-type influenza viruses could result in between 4 million and 80 million deaths,36 but others have suggested that if some of the modified pathogens were to escape from a laboratory, they could cause up to 1 billion fatalities.45 For the purposes of this model, we assume that for any global pandemic arising from this kind of research, each has only a 1 in 10,000\*\*\* chance of causing an existential risk. This figure is somewhat arbitrary but serves as an excessively conservative guess that would include worst-case situations in which scientists intentionally cause harm, where civilization permanently collapses following a particularly bad outbreak, or other worst-case scenarios that would result in existential risk. Multiplying the probability of an outbreak with the probability of an existential risk gives us an annual risk probability between 1.6 × 10–8 and 8 × 10–7.†††

Model 3: Naive Power Law Extrapolation

Previous literature has found that casualty numbers from terrorism and warfare follow a power law distribution, including terrorism from WMDs.46 Power laws have the property of being scale invariant, meaning that the ratio in likelihood between events that cause the deaths of 10 people and 10,000 people will be the same as that between 10,000 people and 10,000,000 people.‡‡‡ This property results in a distribution with an exceptionally heavy tail, so that the vast majority of events will have very low casualty rates, with a couple of extreme outliers.

Past studies have estimated this ratio for terrorism using biological and chemical weapons to be about 0.5 for 1 order of magnitude,47 meaning that an attack that kills 10x people is about 3 times less likely (100.5) than an attack that kills 10x–1 people (a concrete example is that attacks with more than 1,000 casualties, such as the Aum Shinrikyo attacks, will be about 30 times less probable than an attack that kills a single individual). Extrapolating the power law out, we find that the probability that an attack kills more than 5 billion will be (5 billion)–0.5 or 0.000014. Assuming 1 attack per year (extrapolated on the current rate of bio-attacks) and assuming that only 10% of such attacks that kill more than 5 billion eventually lead to extinction (due to the breakdown of society, or other knock-on effects), we get an annual existential risk of 0.0000014 (or 1.4 × 10–6).

We can also use similar reasoning for warfare, where we have more reliable data (97 wars between 1820 and 1997, although the data are less specific to biological warfare). The parameter for warfare is 0.41,47 suggesting that wars that result in more than 5 billion casualties will comprise (5 billion)–0.41 = 0.0001 of all wars. Our estimate assumes that wars will occur with the same frequency as in 1820 to 1997, with 1 new war arising roughly every 2 years. It also assumes that in these extreme outlier scenarios, nuclear or contagious biological weapons would be the cause of such high casualty numbers, and that bioweapons specifically would be responsible for these enormous casualties about 10% of the time (historically bioweapons were deployed in WWI, WWII, and developed but not deployed in the Cold War—constituting a bioweapons threat in every great power war since 1900). Assuming that 10% of biowarfare escalations resulting in more than 5 billion deaths eventually lead to extinction, we get an annual existential risk from biowarfare of 0.0000005 (or 5 × 10–7).

Perhaps the most interesting implication of the fatalities following a power law with a small exponent is that the majority of the expected casualties come from rare, catastrophic events. The data also bear this out for warfare and terrorism. The vast majority of US terrorism deaths occurred during 9/11, and the vast majority of terrorism injuries in Japan over the past decades came from a single Aum Shinrikyo attack. Warfare casualties are dominated by the great power wars. This suggests that a typical individual is far more likely to die from a rare, catastrophic attack as opposed to a smaller scale and more common one. If our goal is to reduce the greatest expected number of fatalities, we may be better off devoting resources to preventing the worst possible attacks.

Why Uncertainty Is Not Cause for Reassurance

Each of our estimates rely to some extent on guesswork and remain highly uncertain. Technological breakthroughs in areas such as diagnostics, vaccines, and therapeutics, as well as vastly improved surveillance, or even eventual space colonization, could reduce the chance of disease-related extinction by many orders of magnitude. Other breakthroughs such as highly distributed DNA synthesis or improved understanding of how to construct and modify diseases could increase or decrease the risks. Destabilizing political forces, the breakdown of the Biological Weapons Convention, or warfare between major world powers could vastly increase the amount of investment in bioweapons and create the incentives to actively use knowledge and biotechnology in destructive ways. Each of these factors suggests that our wide estimates could still be many orders of magnitude off from the true risk in this century. But uncertainty is not cause for reassurance. In instances where the probability of a catastrophe is thought to be extremely low (eg, human extinction from bioweapons), greater uncertainty around the estimates will typically imply greater risk of the catastrophe, as we have reduced confidence that the risk is actually at a low level.48 §§§

Given that our conservative models are based on historical data, they fail to account for the primary source of future risk: technological development that could radically democratize the ability to build advanced bioweapons. If the cost and required expertise of developing bioweapons falls far enough, the world might enter a phase where offensive capabilities dominate defensive ones. Some scholars, such as Martin Rees, think that humanity has about a 50% chance of going extinct due in large part to such technologies.49 However, incorporating these intuitions and technological conjectures would mean relying on qualitative arguments that would be far more contentious than our conservative estimates. We therefore proceed to assess the cost-effectiveness on the basis of our conservative models, until superior models of the risk emerge.

### 1NC – States CP

#### The fifty states and relevant subnational entities should narrow the scope of Noerr-Pennington antitrust immunity by applying a profit sacrifice test to adjudicate sham exceptions.

#### States solve.

Arteaga ’21 [Juan; 1/28/21; Partner @ Crowell & Moring LLP, JD @ Columbia; and Jordan Ludwig; Partner @ Crowell & Moring LLP, JD @ Loyola Law School, Los Angeles; “The Role of US State Antitrust Enforcement,” *Global Competition Review*; https://globalcompetitionreview.com/guide/private-litigation-guide/second-edition/article/the-role-of-us-state-antitrust-enforcement; AS]

During the 1980s, for example, state attorneys general once again emerged as vigorous antitrust enforcers, especially with respect to the prosecution of resale price maintenance practices and other vertical restraints. The rise in the level and prominence of state antitrust enforcement during this period was largely due to a perceived enforcement void at the federal level, where the DOJ and FTC had mostly limited their focus to ‘prohibiting cartels and large horizontal mergers’. No longer content with ceding antitrust enforcement to federal enforcers, state attorneys general expanded their antitrust dockets from prosecuting purely ‘local matters, such as bid-rigging on state contracts’, to actively investigating and litigating matters with multistate and national implications. To help ensure that they had a larger seat at the antitrust enforcement table, state attorneys general also increased the coordination of their enforcement efforts and competition advocacy through organisations such as the National Association of Attorneys General (NAAG), which created a Multistate Antitrust Task Force and issued state Vertical Restraints and Horizontal Merger Guidelines during this period.

Since the reawakening of state antitrust enforcement nearly 30 years ago, state attorneys general have continued to play an important role in the enforcement of both state and federal antitrust laws. During periods of lax federal antitrust enforcement, state attorneys general have often ramped up their enforcement activity in order to protect consumers from anticompetitive transactions and business practices. During periods of vigorous federal antitrust enforcement, they have often served as strong partners for the DOJ and FTC by, among other things, offering valuable insights about competitive dynamics in local markets, assisting with obtaining information from key market participants (including state governmental entities that are direct purchasers of goods and services), and helping develop and implement litigation strategies for cases being tried before federal judges presiding in their states.

Since January 2017, state attorneys general have increasingly played a leading and independent antitrust enforcement role. State antitrust enforcers have significantly increased their enforcement activity and willingness to act separately from their federal counterparts because many of them believe that there has been ‘under-enforcement’ by the DOJ and FTC. State antitrust enforcers have also been able to enhance their influence over key competition policy issues and the antitrust enforcement agenda within the United States because there appears to have been a significant decline in the coordination and relationship between the DOJ and FTC.

### 1NC – CSR DA

#### Noerr Pennington is necessary to corporate social responsibility [CSR]

Miazad 21 – Founding Director and Senior Research Fellow of the Business in Society Institute at Berkeley Law. (Amelia, Prosocial Antitrust (March 11, 2021). Available at SSRN: <https://ssrn.com/abstract=3802194>)//gcd

The first critique comes from proponents of the current articulation of the consumer welfare standard, who point to regulation as a better avenue for competitors to advocate for various policy goals.338 After all, that is why the Noerr Pennington exception immunizes private entities from liability under the antitrust laws for collaborating to influence new laws or regulation, or the enforcement of existing ones.339 Importantly, the exception applies even if the intent or actual impact of the legislation is anti-competitive.340 Competitors are free to lobby for lower emissions standards, a ban on single use plastic, stricter human rights due diligence, or a generous federal minimum wage. This Article does not disagree that the Noerr-Pennington doctrine offers businesses a powerful tool that they should and do utilize, nor does it dispute or discount the value of regulation. But there is a complimentary and unique role for competition policy that should not be overlooked. As this Article has argued throughout, the claim that regulation is better at addressing “environmental” or “social” issues relies on the false presumption that actions to address these issues are not procompetitive and welfare-enhancing. This Article emphatically agrees that antitrust law should remain firmly tethered to economic considerations. To honor this devotion, though, courts and enforcement agencies must honestly account for the economic impacts of climate change and other systematic risks.

#### Corporate sustainability solves extinction from environmental collapse but antitrust deters it

Folke et al 19 – member of the Royal Swedish Academy of Sciences. He is a specialist in economics, resilience, and social-ecological systems. ([Carl Folke](https://www.nature.com/articles/s41559-019-0978-z#auth-Carl-Folke), [Henrik Österblom](https://www.nature.com/articles/s41559-019-0978-z#auth-Henrik-_sterblom), [Jean-Baptiste Jouffray](https://www.nature.com/articles/s41559-019-0978-z#auth-Jean_Baptiste-Jouffray), [Eric F. Lambin](https://www.nature.com/articles/s41559-019-0978-z#auth-Eric_F_-Lambin), [W. Neil Adger](https://www.nature.com/articles/s41559-019-0978-z#auth-W__Neil-Adger), [Marten Scheffer](https://www.nature.com/articles/s41559-019-0978-z#auth-Marten-Scheffer), [Beatrice I. Crona](https://www.nature.com/articles/s41559-019-0978-z#auth-Beatrice_I_-Crona), [Magnus Nyström](https://www.nature.com/articles/s41559-019-0978-z#auth-Magnus-Nystr_m), [Simon A. Levin](https://www.nature.com/articles/s41559-019-0978-z#auth-Simon_A_-Levin), [Stephen R. Carpenter](https://www.nature.com/articles/s41559-019-0978-z#auth-Stephen_R_-Carpenter), [John M. Anderies](https://www.nature.com/articles/s41559-019-0978-z#auth-John_M_-Anderies), [Stuart Chapin III](https://www.nature.com/articles/s41559-019-0978-z#auth-Stuart-Chapin), [Anne-Sophie Crépin](https://www.nature.com/articles/s41559-019-0978-z#auth-Anne_Sophie-Cr_pin), [Alice Dauriach](https://www.nature.com/articles/s41559-019-0978-z#auth-Alice-Dauriach), [Victor Galaz](https://www.nature.com/articles/s41559-019-0978-z#auth-Victor-Galaz), [Line J. Gordon](https://www.nature.com/articles/s41559-019-0978-z#auth-Line_J_-Gordon), [Nils Kautsky](https://www.nature.com/articles/s41559-019-0978-z#auth-Nils-Kautsky), [Brian H. Walker](https://www.nature.com/articles/s41559-019-0978-z#auth-Brian_H_-Walker), [James R. Watson](https://www.nature.com/articles/s41559-019-0978-z#auth-James_R_-Watson), [James Wilen](https://www.nature.com/articles/s41559-019-0978-z#auth-James-Wilen) & [Aart de Zeeuw](https://www.nature.com/articles/s41559-019-0978-z#auth-Aart-Zeeuw) Transnational corporations and the challenge of biosphere stewardship. Nat Ecol Evol 3, 1396–1403 (2019). <https://doi.org/10.1038/s41559-019-0978-z)//gcd>

* TNC – transnational corporation

A handful of TNCs have a major direct or indirect influence on the world’s ocean, the global atmosphere and terrestrial biomes, system components that serve critical functions in Earth’s dynamics (Fig. 1 and Table 1). TNCs dominate harvesting of the largest and most valuable fish stocks, including species with important functions in ocean ecosystems31. The same is true for the world’s forest capacity to regulate Earth’s climate 32. About 70% of greenhouse gas emissions are attributed to 100 companies, including both TNCs and stateowned monopolies producing coal, oil and gas33. These companies disproportionally influence climate change and ocean acidification. Sectors that generate contaminated effluents, with impact on ecosystems and biodiversity, show similar dominance (Table 1). TNCs have also become central in the development of the global food system, a major driver of environmental change, through simplification of landscapes, loss of biodiversity, release of greenhouse gas emissions, and alteration of biogeochemical and freshwater cycles34,35 (Table 1). Following recent mergers and acquisitions, the fertilizers market, the global agrochemical industry and the commercial crop seed market are dominated by ten, four and three TNCs, respectively. The same is true for ten corporations engaged in animal pharmaceuticals (Fig. 1). The observed levels of consolidation in the food system are also striking for individual commodities such as coffee, banana, cocoa, soy, palm oil or farmed salmon (Fig. 1 and Table 2). Mega-merger trends continue to drive consolidation vertically and horizontally within and across sectors, borders, systems and the land–ocean interface36,37, with dominant companies being often interlinked and interdependent. Clearly, TNCs are central actors in the human-dominated world and possess the ability to influence critical functions of the biosphere. This global keystone actor dimension of TNCs 31, whether producers, suppliers or financial actors, should be recognized, accounted for and governed in efforts towards sustainability within planetary boundaries. TNCs and sustainability Reality presents us with dominance40 and the environmental time window for transforming human actions towards sustainability is shrinking28. In this context, could the power of dominant TNCs help leverage large-scale systemic chang e41, accelerate positive transformations towards sustainability42 and contribute to a safe operating environmental space for humanity 30? In the face of insufficient environmental agreements and regulations, dominance poses a threat to sustainability. For instance, companies able to set barriers to entry in a sector can stifle sustainable practices and technological innovation in general. They can also impose low prices on suppliers, which reduces suppliers’ capacity to diversify and can force them into monocultural practices (particularly in the agricultural sector). Finally, TNCs often lobby regulators to weaken environmental and social standards to the benefit of their own businesses43–45. More generally, there exists scepticism towards businesses as sustainability leaders given two decades of relative ineffectiveness of voluntary corporate social responsibility25,46. Market concentration and corporate power are often regarded as roadblocks to social progress given the business priority of economic profit over nonmarket values24. Concerns have also been raised about viewing business as the solution to the problems they themselves took part in creating24. Also, emerging TNC sustainability initiatives have been questioned as they do not challenge the underlying imperative of business growth47. On the other hand, should dominant TNCs impose effective sustainability standards throughout their supply chain, this could influence both upstream and downstream market actors, including small and medium enterprises. This was the case when the world’s largest retailer committed to certified seafood, which is thought to have catalysed other retailers and triggered a rapid increase in certification48. Hence, as dominant actors impose sustainability measures, behavioural changes may propagate throughout global markets. Over the past two decades, 250 to 300 pioneering companies have actively invested for sustainable development, followed by several thousand other companies integrating sustainability considerations in their business49. Reputational risk management represents an important part of corporate strategy, particularly for large household-facing brands that are vulnerable to naming-and-shaming campaigns16,50. Such exposure helped realize the corporate sector soy moratorium, which contributed to reduced deforestation in the Brazilian Amazon 51. The World Wildlife Fund has consequently worked to influence companies with the greatest impacts on commodity demand, with the aim of shifting entire markets towards corporate stewardship of biodiversity, water and climate, and reducing the impact from commodity production on key areas of importance for global conservation52. However, TNC leadership is unlikely to be sufficient unless governments also provide a regulatory context that safeguards nonmarket ecological and social values. Antitrust law and institutions have a central role to play in regulating dominance and keeping markets competitive, but they are ill suited to address concerns associated with public governance of goals like environmental sustainability or with the political power of large corporations53,54. Importantly, the delineation between public governance and large corporations is increasingly blurred55. Private governance is rapidly emerging in a range of biosphere-related sectors56,57, where TNCs play a big role in shaping their own regulatory space58 including how sustainability is defined and enacted. Concerns have been raised over such increasing influence, particularly with respect to accountability, fair representation and global equity16. In this context, major changes in the strategy and practice of TNCs are needed to help shift power away from being exercised to the detriment of sustainable use of the biosphere24. Towards corporate biosphere stewardship Are we starting to observe the beginnings of such a shift? Action is urgently needed to stabilize the Earth system within conditions favourable for humanity28 and rising awareness of the dependence of the global economy on the biosphere foundation59 is creating incentives for rapid innovation in business strategy and practice60. Although the primary goal of TNCs is not to produce for the common good, different incentives have led some progressive companies to increasingly engage in substantive sustainability efforts.

### 1NC – Spec

#### Interpretation – in addition to prohibited practices, the aff should specify the agent of antitrust authority and sanctions.

William **KOVACIC** Global Competition Professor of Law and Policy @ George Washington University Law School **’12** “The Institutions of Antitrust Law: How Structure Shapes Substance Substance” 110 MICH. L. REV. 1019 p. 1026

A more complete framework of the institutional elements of antitrust law enforcement might organize the examination of the system around the following questions:

What is the purpose of the statutes? What do the statutes prohibit?

By what means are infringements detected and evidence gathered? Which entities have authority to prosecute violations?

Which body decides guilt or innocence?

What sanctions are imposed for wrongdoers?

A classification scheme cast along these lines would help identify more clearly the volume's examination of the U.S. antitrust system and assist in illuminating connections among its elements.

#### Violation – the plan text does not specify agent, authority, or sanctions.

#### Standard:

#### Negative ground. Institutional structure and agent of implementation key to antitrust outcomes. Any debate over only the preferred outcomes is hopelessly incomplete.

William **KOVACIC** Global Competition Professor of Law and Policy @ George Washington University Law School **’12** “The Institutions of Antitrust Law: How Structure Shapes Substance Substance” 110 MICH. L. REV. 1019 p. 1019-1020

Forty years ago, Graham Allison wrote the Essence of Decision' and transformed the study of foreign policy and public administration.2 Allison's analysis of the Cuban Missile Crisis appeared amid profound concerns about the competence of U.S. government institutions. "Few issues about the American government," he wrote, "are more critical today than the matter of whether the federal government is capable of governing."3 To Allison, better performance required greater insight into how the structure and operations of public institutions shaped policy results. "[B]ureaucracy is indeed the least understood source of unhappy outcomes produced by the U.S. government,"4 Allison wrote. "If analysts and operators are to increase their ability to achieve desired policy outcomes, . . . we shall have to find ways of thinking harder about the problem of 'implementation,' that is, the path between preferred solution and actual performance of the government."5 Essence of Decision quickly appeared on reading lists in political science departments and schools of public administration, and its analytical orientation and vocabulary have become enduring elements of academic discourse.

Daniel Crane's The Institutional Structure of Antitrust Enforcement ("InstitutionalStructure")7 may do for antitrust law what Essence of Decision did for public administration. Unlike most literature on antitrust law, this superb volume does not address pressing issues of substantive analysis (e.g., when can dominant firms offer loyalty discounts?).8 Instead, Institutional Structure studies the design and operation of the institutions of U.S. antitrust enforcement. Professor Crane skillfully advances a basic and powerful proposition: to master analytical principles without deep knowledge of the policy implementation mechanism is dangerously incomplete preparation for understanding the U.S. antitrust system, or any body of competition law. "Institutions," Professor Crane observes, "are a critical and underappreciated driver of an antitrust policy that interacts in many subtle ways with substantive antitrust rules and decisions" (p. xi). Institutional Structure demonstrates that the causes of observed policy outcomes, good and bad, often reside in the institutional framework. Seemingly potent conceptual insights may fizzle, or create mischief, if the institutions that must apply them are deformed. Good policy results depend on the strength of what Allison called "the path between preferred solution and actual performance." In the language of modem technology, one cannot deliver broadband-quality policy outcomes through dial-up institutions.

#### Voting issue – cross-ex is too late for counterplan competition. 2AC clarification destroys 1NC strategic coherence. Every branch is topical. Rule-making and common law don’t link to any of the same positions and reading both requires contradiction.

#### It crushes solvency – the plan’s vagueness gets re-interpreted to mean its opposite

Hanley 21 – policy analyst at Open Markets Institute (Daniel, "How Antitrust Lost Its Bite," Slate Magazine, <https://slate.com/technology/2021/04/antitrust-hearings-congress-legislation-bright-line-rules.html> APRIL 06, 2021)//gcd

As Congress considers enacting new legislation, it must start by reclaiming control over antitrust by enacting laws with clear rules that could deter exclusionary conduct and greatly simplify the litigation process for plaintiffs. Moreover, instead of just restoring many of the historical bright-line rules that the judiciary has eroded over the last 60 years, new laws should go further to ensure that markets remain deconcentrated and to promote economic fairness. For example, Congress could enact strict prohibitions on firms entering certain lines of business, such as AT&T being prohibited from entering the computer industry [in 1956](https://www.cybertelecom.org/notes/att1949.htm), or ban the use of specific competitive practices outright, such as noncompetes that restrict the mobility of workers. Rules like these ensure the markets are structured by publicly accountable institutions to incentivize socially beneficial corporate conduct, such as investments in research and development and product quality. Importantly, rules-based laws would also ensure the judiciary is adhering to Congress’ directive to keep markets deconcentrated and acknowledge that the judiciary is not a reliable safeguard for smaller independent firms and workers who often do not have access to significant amounts of capital to litigate an antitrust lawsuit. In fact, in commonly applied rules for [how judges interpret Congress’ laws](https://www.jstor.org/stable/1070047?seq=1), the judiciary views ambiguity as an opportunity to fill any legal gaps with its interpretation and ideology. History has consistently shown that only bright-line rules will lead to an effective and vigorous enforcement environment, as they do in other areas of law, and prevent the judiciary from favoring dominant economic enterprises and distorting the antitrust laws to preference increased concentration. The Supreme Court’s original development of the rule of reason and its subsequent gutting of the enforcement of the Clayton Act in the 1930s is particularly illustrative of why bright-line rules are necessary. A critical weakness of the Sherman Act when it was passed in 1890 was that it did not incorporate bright-line rules and left the interpretation of the act almost entirely to the judiciary. Despite its broad moral intentions, the first 15 years of its enforcement were anemic against concentrated private power and even [hostile to organized labor](https://escholarship.org/uc/item/8cj0z1tq). Eventually the federal government would obtain its first significant victory [in 1904](https://en.wikipedia.org/wiki/Northern_Securities_Co._v._United_States), but the legal standard that the court would use to determine the legality of antitrust violations was not fully decided until the 1911 Standard Oil case, in which the Supreme Court codified the rule of reason. [Standard Oil v. United States](https://en.wikipedia.org/wiki/Standard_Oil_Co._of_New_Jersey_v._United_States) is widely known for breaking up the company. However, the case was actually a pyrrhic victory for antitrust enforcers. In the case, the court created the foundation for the rule of reason by declaring that only “unreasonable” trade practices (known as restraints of trade) were illegal under the Sherman Act. In other words, the judiciary in Standard Oil anointed itself with unilateral discretionary power to manage and organize the economy and neutered the Sherman Act’s application. Outrage from Congress and the public over the judiciary’s seizure of power resulted in swift action. Less than three years later, Congress would try to reassert its position to ensure a deconcentrated marketplace with the Clayton Act. When Congress enacted the Clayton Act in 1914, its primary goal was to supplement the Sherman Act by bolstering a plaintiff’s ability to arrest certain enumerated conduct in its incipiency—to nip monopolistic behavior in the bud. The Clayton Act explicitly lessened the litigation burden on plaintiffs for certain exclusionary practices, including certain forms of tying (conditioning the purchase of a product on the purchase of another product), price discrimination, and exclusive dealing (contracts or coercive behavior that prevents suppliers or distributors from engaging with a firm’s rivals). Most importantly, Congress included in the Clayton Act a highly deferential and plaintiff-friendly legal standard meant to prohibit mergers (although only limited to acquisitions of assets and not for stock) that only “may be to substantially lessen competition” or “tend to create a monopoly.” The Clayton Act made clear that Congress was trying to arrest certain antitrust violations such as mergers as a means to grow corporate operations, and to reverse the Supreme Court’s declaration in [Standard Oil](https://en.wikipedia.org/wiki/Standard_Oil_Co._of_New_Jersey_v._United_States). However, the Supreme Court would instead successfully hijack this antitrust law too, in order to favor its own prescription for managing the economy. In a 1930 case known as [International Shoe](https://supreme.justia.com/cases/federal/us/280/291/), the Supreme Court decided to interpret the Clayton Act’s directive on mergers, despite its explicit purpose and statutory language, in an equivalent way to the Sherman Act. The court said the Clayton Act also deemed the indicator of an illegal merger to be whether it “injuriously affect[ed] the public”—yet again, a gutting of Congress’ intentions for a robust antitrust law. After the court’s holding in International Shoe, [almost no merger cases](https://heinonline.org/HOL/LandingPage?handle=hein.journals/antlervi3&div=6&id=&page=) were brought either by the Federal Trade Commission or the Department of Justice between 1930 and 1950. Even though the New Deal during the 1930s invigorated antitrust enforcement for violations of the Sherman Act targeting cartels and monopolies, it still took decades of advocacy for the Clayton Act to be significantly amended in 1950 to undo the Supreme Court’s damage. Even then, however, Congress did not impose a bright-line rule for mergers. And although the 1950 amendments to the Clayton Act did lead to vigorous enforcement, it would last only for another decade until the Supreme Court would, in a series of decisions, invent two doctrines, known as [antitrust injury](https://supreme.justia.com/cases/federal/us/479/104/) and [antitrust standing](https://supreme.justia.com/cases/federal/us/429/477/). These doctrines would again erode significant aspects of antitrust enforcement of both the Sherman Act and Clayton Act to the present day. The implementation of the consumer welfare framework since the 1970s is additional evidence from more than a century of consistent judicial mismanagement and hostility toward Congress’ desire to stop corporate concentration. Simply put, the courts cannot be trusted to adequately enforce antitrust laws without bright-line rules. If Congress is going to amend the antitrust laws to ensure they are effectively administered, rules that ban big mergers and the monopolization of markets, prohibit coercive contracts against small suppliers and distributors, and protect workers from dominant corporations must be imposed. Anything less leaves the door open for the judiciary to continue subverting Congress’ economic agenda, as dictated by the voting public, and instead substitute its own. Without bright-line rules, the current reform efforts will be in vain.

## AT: Sham Litigation

### 1NC – AT: Sham Litigation

#### Innovation high now.

Accenture, global professional services company, 2-2-2022, "Global Industrial Companies Ramp Up R&D Spending Following Covid Shock, Accenture Study Finds," automation, https://www.automation.com/en-us/articles/february-2022/global-industrial-companies-r-d-spending-covid

Growth in R&D spending by over 200 of the world’s largest electrical, machinery and medical equipment companies has been on the rise since mid-2020, according to new research conducted by Capital Economics and Accenture. As a whole, industrial company spend on R&D grew by 17.5% in the third quarter of 2021 compared with the same period a year earlier. The rebound is particularly evident in the electrical sector, where spending grew by over 25% in Q3.

The findings confirm a trend of growing R&D investment. The report “R&D and Innovation across Industry”, also looks at the spending of a larger sample of industrial companies across 12 countries. This shows that R&D spend increased by over 35% in real terms between 2012-2019. On average global R&D investment has been growing at an annual pace of 3.6% in the 5 years up to 2019, outpacing growth in the wider economy of 2.1%. Across a sample of the largest industrial firms, 1.6-11% of revenue was invested in R&D.

Austria claimed the number one spot in the ranking, thanks to its high absolute R&D spend as a share of industry output. France, Sweden and the US trailed closely behind. At the end of the ranking table was the UK and Norway, whose R&D efforts are weaker in both absolute spending terms and research intensity.

Digitisation was identified as the key focus of R&D efforts, particularly given the Covid-19 pandemic wreaking havoc in working arrangements, supply chains and demand patterns. Software and data skills remain in high demand, with google searches for “software engineer jobs” rising fourfold since 2005. For reference, this is a much faster pace than hardware engineers or even solicitors or accountants, where searches have not even doubled over this time period.

Commenting on the findings, Thomas Rinn, Accenture’s Global Lead for Industrials, said: “Far from derailing investment in R&D, the pandemic has accelerated it. More firms across the industrial sector are recognising its direct correlation with higher production efficiency and elevated business agility. AI, cloud computing, digital twins and automation has skyrocketed across the sector, allowing businesses to respond quickly to disruption and changing demand to generate sustainable returns. As Covid-19 continues to accelerate new social and economic trends, as well as radically impacting supply chains, it is vital that industrial firms continue to invest in R&D to stay ahead of the curve. Those that fail to do so risk being left behind.”

#### The plan can’t solve patent trolls

Sipe ’17 [Matthew G; J.D., Yale Law School; B.A., University of Virginia; 2017; “Patents v. Antitrust: Preempting Conflict”; <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1958&context=aulr>; American University Law Review, Vol. 66, Issue 2; accessed 10/12/21; TV]

The analysis in Part IV examines the extent that conflicting guidance and requirements are likely to emerge if antitrust law and patent law are permitted to overlap. That analysis focused primarily on the damage that overlap would do to patent law: from disrupting the “fine, complex, detailed line[s]” of patent doctrines to improperly interpreting patents due to a lack of requisite “expertise.”298 But as antitrust law increasingly attempts to supervise patent activity, antitrust law itself is at risk of warping as well.

For example, antitrust courts have attempted in recent years to police patent trolls: entities that acquire and enforce patents without actually practicing them.299 The troll business model—acquiring licensing fees from entities that actually do create goods and services— has led many academics and policymakers to characterize them as a pure anticompetitive nuisance worthy of antitrust intervention.300 But there are “clear doctrinal . . . roadblocks to leveraging antitrust law” to police much of patent troll behavior, ranging from “quasiconstitutional” protections to textual limitations.301

In terms of constitutional protections, the Supreme Court has established that the First Amendment’s protection of the right to petition grants presumptive immunity from liability under the antitrust laws for “attempts to influence the passage or enforcement of laws,” such as patent infringement suits.302 This immunity applies even when a suit is brought with anticompetitive intent:

Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act. The jury should have been so instructed and, given the obviously telling nature of this evidence, we cannot hold this lapse to be mere harmless error.303

The only exception to this immunity is where a lawsuit is a “sham,” determined by a two-prong test: (1) the suit “must be objectively baseless,” such that “no reasonable litigant could realistically expect success on the merits,” and (2) the suit must be brought with the “subjective motivation” to interfere with a competitor through “governmental process—as opposed to the outcome of that process.”304

However, neither prong is likely to be met in many troll cases. With regard to the first prong, the patent quality of troll portfolios is generally at least as high as portfolios owned by non-trolls,305 and patents owned by trolls tend to fare no better or worse on average in reexamination proceedings.306 With regards to the second prong, troll plaintiffs genuinely hope to succeed on the merits. Trolls, by definition, do not participate in the actual product market—and hence are not in competition with the product sellers—so merely hurting producers through nuisance litigation does them no good. A successful infringement suit, on the other hand, grants them damages. As a result, for antitrust law to reach patent trolls, arguably the most important carve-out from antitrust liability307 would need to be eroded.

In terms of textual limitations, in the types of patent troll cases where immunity does not apply, commentators have frequently suggested using section 5 of the Federal Trade Commission Act as the doctrinal hook for antitrust enforcement.308 The scope of section 5— prohibiting any “unfair or deceptive acts or practices in or affecting commerce”309—is quite broad. This breadth makes it a seemingly natural tool against a novel threat like patent trolls, who do not appear to implicate other antitrust laws.310 But the use of section 5 as a catchall to expand antitrust law’s reach has significant drawbacks. Critics rightly point out the “apparent absence of limiting principles” in both section 5’s language311 and interpretation,312 and the commensurate risk of uncertainty and rent-seeking generated by its application in novel contexts.313 Attempts to police patent trolls only exacerbate this increasingly atextual approach to antitrust enforcement.

Hence, if antitrust law is to play a role in policing patent troll activity, it would first have to “distort” antitrust law in order to do so,314 whether by overriding key doctrinal carve-outs or by permitting atextual expansion. Either way, the existing risk of false antitrust positives and chilling effects associated with antitrust intervention is increased significantly. In comparison, patent law may already have the tools to curtail troll behavior.315 Where, as in the context of patent trolls, antitrust law must be stretched or distorted in order to reach patent activity, the benefits of preemption as an alternative are therefore substantial.

#### Status quo solves – patent trolls will already lose under Noerr-Pennington

* PAE – Patent Assertion Entities

Wegner 20 – University of California, Hastings College of the Law, Juris Doctor Candidate, 2020; California Polytechnic State University, San Luis Obispo, Bachelor of Arts in Political Science, Concentration in Pre-Law, 2011 (Wenger, You Don’t Have to Pay the Troll Toll: Antitrust Violations of Patent Assertion Entities and the Noerr-Pennington Doctrine “Sham Litigation” Exception, 47 HASTINGS CONST. L.Q. 557 (2020). Available at: https://repository.uchastings.edu/hastings\_constitutional\_law\_quaterly/vol47/iss4/5)//gcd

1. PAE Claims are so Objectively Baseless No Reasonable Litigant Could Realistically Expect Success on the Merits Even if the PREI standard was the appropriate standard, PAE’s conduct would still qualify as “sham litigation” and, thus, should not be afforded Noerr-Pennington doctrine immunity. The Court held that “[non-serial] litigation cannot be deprived of immunity as a sham unless the litigation is objectively baseless” and affirmed the Ninth Circuit’s refusal to characterize a lawsuit as a sham that the antitrust defendant “admittedly had probable cause to institute.”206 The PREI Court resolved whether litigation may be sham merely because a subjective expectation of success does not motivate the litigant, holding that “an objectively reasonable effort to litigate cannot be sham regardless of intent.”207 In sum, for a non-serial lawsuit to qualify as a sham litigation, the suit: (1) “must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits”; and (2) must be subjectively baseless and an attempt to interest with competitors.”208 Under the first prong of the two-prong sham litigation exception test, a claimant must prove that the lawsuit is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.”209 Additionally, if the suit contains objective merit, the claimant cannot proceed to the subjective purposes prong and the action does not constitute sham litigation .210 Thus, this prong is determined by whether “no reasonable litigant could realistically expect success on the merits” by filing the lawsuit in question.211 PAE enforcement claims are objectively baseless and, thus, fail the first prong of the PREI standard. In re Cardizem CD Antitrust Litigation concerns plaintiff indirect purchasers of a brand name heart medication manufactured by the defendants. The defendants asserted that plaintiffs failed to sufficiently show that the suit was not objectively baseless and brought for anticompetitive purposes.212 Plaintiffs argued but for the patent infringement litigation the Hatch-Waxman 30-month period would not have gone into effect, resulting in generic versions entering the market sooner.213 The plaintiffs supported their objectively baseless allegations with damning communications.214 The court found that the plaintiffs alleged sufficient facts to satisfy the objective prong because allegations in the plaintiffs’ complaint are construed in light most favorable to the plaintiffs.215 Similar to In re Cardizem CD Antitrust Litigation, when viewed in the light most favorable to the party alleging counterclaims, facts alleged by Capital One reasonably showed that IV initiated its suits asserting only five patents out of the demanded 3,500-patent portfolio, many of which are invalid or expired, and only two of the five remained viable, for objectively baseless purposes.216 IV cofounder Edward Jung even described how IV acquires patents only for the enforcement of market power once aggregated and not the merits of the patent themselves. Jung stated, “[IV] buy[s] a bunch of low-cost asset[s], which gives us market power” and “[i]t just feels like we are on a diet of filler . . . . [W]e already have two funds with plenty of fluff . . . . We didn’t kill as many deals [as] we should have, we just tried to get them cheap and in most cases it was clear there was no future bet, the patents just weren’t monetizeable or practiced.”217 Moreover, one of IV’s outside inventors, hired to evaluate its patents, described the portfolio as “poor quality financial-services related patents.”218 Furthermore, the Virginia district court determined that the remaining asserted patents were ineligible subject matter under Alice Corp. v. CLS Bank International. 219 In Maryland, Capital One successfully sought a declaratory judgment that the asserted patents were invalid, with one patent invalid due to inequitable conduct.220 IV thus filed these suits against Capital One in retaliation for Capital One’s refusal to expensively license. Through IV’s own testimony and the asserted patents invalidation, no reasonable litigant could have expected to win on the merits, making these suits objectively baseless.221 The FTC also advises that “should the [asserted] patent be invalidated in one case . . . it would make further litigation in the other cases unnecessary.”222 And, the FTC since observed that PAEs may avoid asserting patents, such as those in the Capital One cases, “if they expect that: (1) the patents likely would be found invalid under Alice analysis, or (2) that courts may dispose of the case in the early stages of litigation, under Alice analysis.”223 Therefore, it follows that any PAE suits that are likely to be invalid under Alice, and projected to settle in the early stages of litigation, are objectively baseless under the PREI standard.

#### No impact to patent trolling

Giudici 17 – Emiliano Giudici, Associate Professor of Finance, Rusche College of Business, Stephen F. Austin State University, “Evaluating Market Reactions to Non-Practicing Entity Litigation,” 2017, <https://scholarship.law.vanderbilt.edu/cgi/viewcontent.cgi?article=1083&context=jetlaw>

[NPEs = non-practicting entities = patent trolls]

An ongoing and important debate in patent law concerns the actions of "non-practicing entities" or "patent assertion entities," which are sometimes pejoratively referred to as "patent trolls" (hereinafter collectively referred to as "NPEs").1 Generally, NPEs are individuals or entities that own a patent, either through invention or acquisition, but do not use it to produce or manufacture anything. 2 Most NPEs referred to as patent trolls do not invent-their typical business model is to license or purchase patent rights and assert them through litigation against entities that make products that allegedly infringe upon their patent rights. 3 Depending upon whom you ask, NPEs are either valid, useful actors in the market for innovation or leeches that feed off the innovation of others.4

This Article seeks to add to the literature on this debate by analyzing what the market has to say about NPE litigation through an event study.5 Many of the targets of NPE litigation are publicly traded companies. If the market exhibits at least some level of efficiency, and if NPE litigation in fact stifles innovation and creates costs for product-producing companies, one would expect to see some effect on the market when new patent litigation is filed. 6 Using the RPX Corporation patent litigation database,7 this study analyzes the effect that NPE patent litigation brought by the ten largest NPEs had on the stock price of the eight largest targets of NPE patent litigation claims to determine whether and to what extent the market reacts to the filing of these claims.8 Based upon this analysis, it appears the market largely ignores the filing of NPE patent claims against large companies, calling into question the damaging effect on innovation and the economy claimed by the opponents of NPEs.

#### Their internal links are pure hype with terrible methodologies

Katznelson 16 – Ron D. Katznelson, president of Bi-Level Technologies, a signal and image processing technology firm, “The $83 Billion Patent Litigation Fallacy,” Spring 2016, https://www.cato.org/sites/cato.org/files/serials/files/regulation/2016/4/regulation-v39n1-3.pdf

These patent owners (e.g., universities, research and development consortia, patent intermediaries, individual inventors, etc.) are variously called non-practicing Entities (NPEs) or patent Assertion Entities (PAEs), but most pejoratively, “patent trolls.” The apparent purpose of this last, mythological name is to evoke the specter of dangerous, subhuman creatures that live in the dark and exact tribute on all who pass by. it’s clever spin, but it’s grotesquely false. The Wright Company was not a patent troll; it held a pioneer aviation patent and sought to expand, not restrict, the domain in which the Wright brothers’ inventions could improve American society and its economy. The same goes for many of today’s NPEs.

in 2013, the White House Office of Science and Technology policy (OSTP) published a report entitled, “Patent Assertion and U.S. innovation,” and more commonly called the PAE report. it purportedly shows that when NPEs seek to protect their legally acquired intellectual property rights, they “act to significantly retard innovation in the United States.” The PAE report further asserts that this results “in economic ‘dead weight loss’ in the form of reduced innovation, income, and jobs for the American economy.”

This follows the same false narrative spun by the navy a century ago, complete with factual claims that lack legitimate foundation. (Indeed, I have submitted a petition for correction of the PAE report to the OSTP under the Information Quality Act [IQA], arguing that the report fails to meet all applicable federal standards for transparency, reproducibility, and perhaps most importantly, objectivity. Unlike a century ago, U.S. government agencies like the OSTP are statutorily precluded from disseminating influential information that is demonstrably false, yet, in contravention of the IQA guidelines issued by the Office of Management and Budget, the PAE report relies on studies that have undergone no peer review, relied on opaque or erroneous methods and surveys, lack objectivity, and contain demonstrable bias.

A central claim of the report is that patent lawsuits by NPEs recently caused lost wealth of over $300 billion over four years. For this, the report relies on estimates by James Bessen, Jennifer Ford, and Michael Meurer, published in their Regulation article, “The private and Social Costs of patent Trolls” (Winter 2011–2012). Their paper was the issue’s cover story, promoted with an illustration portraying—as the hoary myth requires—oversized humanoids with visibly malign intent, armed with clubs, holding-up innocent travelers for payment at a toll bridge. The unmistakable message: patent owners who license their intellectual property are evil.

Bessen, Ford, and Meurer’s article examines the economic effects of patent lawsuits by NPEs, which they define as firms that do not produce goods but rather acquire patents in order to license them to others. Their conclusions are startling. They claim losses to defendants in NPE patent suits during a period of four years “average over $83 billion per year in 2010 dollars, which equals over a quarter of U.S. industrial R&D spending per annum.” This, the article says, proves that NPE patent litigation constitutes a “very large disincentive to innovation.” In other words, NPEs destroy the incentive to innovate when they protect innovation from the various high-tech highwaymen who otherwise would misappropriate it.

However, Bessen, Ford, and Meurer’s article suffers from fundamental analytical and inferential shortcomings. As I explain below, its cost estimates and inferences should be dismissed, along with their indictment of NPEs and similar patent holders.

#### No emerging tech impact.

Sechser 19 – Todd S. Sechser, Public Policy Professor at the University of Virginia. Neil Narang, Political Science Professor at the University of California, Santa Barbara. Caitlin Talmadge, Security Studies Professor at Georgetown University. [Emerging technologies and strategic stability in peacetime, crisis, and war, Journal of Strategic Studies, 42(6), Taylor and Francis]

Yet the history of technological revolutions counsels against alarmism. Extrapolating from current technological trends is problematic, both because technologies often do not live up to their promise, and because technologies often have countervailing or conditional effects that can temper their negative consequences. Thus, the fear that emerging technologies will necessarily cause sudden and spectacular changes to international politics should be treated with caution. There are at least two reasons to be circumspect.

First, very few technologies fundamentally reshape the dynamics of international conflict. Historically, most technological innovations have amounted to incremental advancements, and some have disappeared into irrelevance despite widespread hype about their promise. For example, the introduction of chemical weapons was widely expected to immediately change the nature of warfare and deterrence after the British army first used poison gas on the battlefield during World War I. Yet chemical weapons quickly turned out to be less practical, easier to counter, and less effective than conventional high-explosives in inflicting damage and disrupting enemy operations.6 Other technologies have become important only after advancements in other areas allowed them to reach their full potential: until armies developed tactics for effectively employing firearms, for instance, these weapons had little effect on the balance of power. And even when technologies do have significant strategic consequences, they often take decades to emerge, as the invention of airplanes and tanks illustrates. In short, it is easy to exaggerate the strategic effects of nascent technologies.7

Second, even if today’s emerging technologies are poised to drive important changes in the international system, they are likely to have variegated and even contradictory effects. Technologies may be destabilising under some conditions, but stabilising in others. Furthermore, other factors are likely to mediate the effects of new technologies on the international system, including geography, the distribution of material power, military strategy, domestic and organisational politics, and social and cultural variables, to name only a few.8 Consequently, the strategic effects of new technologies often defy simple classification. Indeed, more than 70 years after nuclear weapons emerged as a new technology, their consequences for stability continue to be debated.9

#### Asteroids won’t hit earth, and even if they do they won’t kill us.

**Britt ‘5** – science writer for LiveScience

[Robert Roy Britt, science writer for LiveScience; “The Odds of Dying;” published 1/6/2005; http://www.livescience.com/3780-odds-dying.html ; Jay]

Perceptions of risk factors can change over time simply because more is learned. The chances of an Earth-impacting asteroid killing you have dropped dramatically, for example, from about 1-in-20,000 in 1994 to something like 1-in-200,000 or 1-in-500,000 today. The new numbers -- their range reflecting the need for further research -- were offered up last week by Clark Chapman of the Southwest Research Institute and David Morrison at NASA's Ames Research Center. Why such a dramatic downgrade? Active intervention. "A significant part of it is that we have now discovered, in the last dozen years, a good fraction of the largest, most deadly asteroids and found that they won't hit the Earth," Chapman told LiveScience. Also, projections of the destruction a large space rock would cause have been revised downward a bit. Finally, since Earth is two-thirds water, asteroid risks include the possibility of an impact-induced tsunami. And Chapman says asteroid-generated tsunamis may not be as deadly as once presumed.

#### Asteroid calculations are bad science

**BENNETT 2010** (James, Prof of Economics at George Mason, *The Doomsday Lobby: Hype and Panic from Sputniks, Martians, and Marauding Meteors*, p. 157-158

We should here acknowledge, without necessarily casting aspersions on any of the papers discussed in this chapter, the tendency of scientific journals to publish sexy articles. (Sexy, at least, by the decidedly unsexy standards of scientific journals.) Writing in the Public Library of Science, Neal S. Young of the National Institutes of Health, John P.A. Ioannidis of the Biomedical Research Institute in Greece, and Omar Al-Ubaydli of George Mason University applied what economists call the “winner’s curse” of auction theory to scientific publishing. Just as the winner in, say, an auction of oil drilling rights is the firm that has made the highest estimation — often overestimation — of a reserve’s size and capacity, so those papers that are selected for publication in the elite journals of science are often those with the most “extreme, spectacular results.”63 These papers may make headlines in the mainstream press, which leads to greater political pressure to fund projects and programs congruent with these extreme findings. As The Economist put it in an article presenting the argument of Young, Ioannidis, and Al-Ubaydli, “Hundreds of thousands of scientific researchers are hired, promoted and funded according not only to how much work they produce, but also where it gets published.” Column inches in journals such as Nature and Science are coveted; authors understand full well that studies with spectacular results are more likely to be published than are those that will not lead to a wire story. The problem, though, is that these flashy papers with dramatic results often “turn out to be false.”64 In a 2005 paper in the Journal of the American Medical Association, Dr. Ioannidis found that “of the 49 most-cited papers on the effectiveness of medical interventions, published in highly visible journals in 1990–2004… a quarter of the randomised trials and five of six nonrandomised studies had already been contradicted or found to have been exaggerated by 2005.” Thus, those who pay the price of the winner’s curse in scientific research are those, whether sick patients or beggared taxpayers, who are forced to either submit to or fund specious science, medical or otherwise. The trio of authors call the implications of this finding “dire,” pointing to a 2008 paper in the New England Journal of Medicine showing that “almost all trials” of anti-depressant medicines that had had positive results had been published, while almost all trials of anti-depressants that had come up with negative results “remained either unpublished or were published with the results presented so that they would appear ‘positive.’” Young, Ioannidis, and Al-Ubaydli conclude that “science is hard work with limited rewards and only occasional successes. Its interest and importance should speak for themselves, without hyperbole.” Elite journals, conscious of the need to attract attention and stay relevant, cutting edge, and avoid the curse of stodginess, are prone to publish gross exaggeration and findings of dubious merit. When lawmakers and grant-givers take their cues from these journals, as they do, those tax dollars ostensibly devoted to the pursuit of pure science and the application of scientific research are diverted down unprofitable, even impossible channels. The charlatans make names for themselves, projects of questionable merit grow fat on the public purse, and the disconnect between what is real and what subsidy-seekers tell us is real gets ever wider.65 The matter, or manipulation, of odds in regards to a collision between a space rock and Earth would do Jimmy the Greek proud. As Michael B. Gerrard writes in Risk Analysis in an article assessing the relative allocation of public funds to hazardous waste site cleanup and protection against killer comets and asteroids, “Asteroids and comets are… the ultimate example of a low-probability/high-consequence event: no one in recorded human history is confirmed to have ever died from one.” Gerrard writes that “several billion people” will die as the result of an impact “at some time in the coming half million years,” although that half-million year time-frame is considerably shorter than the generally accepted extinction-event period.66 The expected deaths from a collision with an asteroid of, say, one kilometer or more in diameter are so huge that by jacking up the tiny possibility of such an event even a little bit the annual death rate of this never-beforeexperienced disaster exceeds deaths in plane crashes, earthquakes, and other actual real live dangers. Death rates from outlandish or unusual causes are fairly steady across the years. About 120 Americans die in airplane crashes annually, and about 90 more die of lightning strikes. Perhaps five might die in garage-door opener accidents. The total number of deaths in any given year by asteroid or meteor impact is zero — holding constant since the dawn of recorded time.

## AT: Patent Thickets

### 1NC – AT: Patent Thickets

#### Best data proves – patent trolls don’t affect pharma companies

Kramer 14 – Thomas H. Kramer, intellectual property lawyer, “Proposed Legislative Solutions to the Non-Practicing Entity Patent Assertion Problem: The Risks for Biotechnology and Pharmaceuticals,” 2014, 39 DEL. J. CORP. L. 467

[NPEs = non-practicing entities = patent trolls]

The telecommunications, computer technology, and software industries appear prominently in most analyses of the patent assertion issue. 5 Recently published empirical studies of patent suits brought by NPEs identify telecommunications, computer technology, and software as the patent subject matter most often in controversy." In addressing the question of an increase in the incidence of suits and whether the increase affects all industry segments, it is important to recognize the increasing number of patents in these industry segments.

The rate of issuance of patents in these fields has exploded: the annual number of patents granted by the USPTO in the telecommunications segment has risen from 7,865 in 1999 to 26,391 in 2012; the total number of such patents granted in that period was 215,384.67 Likewise, in electrical computers, digital processing systems, information security, and error/fault handling, the number of patents granted in 1999 was 14,166 and rose to 50,277 in 2012; the total number of patents granted in this period was 404,236.68 By contrast, the total number of chemical classes patents granted-750,398-was greater than the previous two segments combined, but the rate of growth in chemical classes was minimal in comparison: 43,071 patents were granted in 1999 and 49,325 in 2012.' By these measures, patent issuance in the telecommunications and computer area has increased three-to-four-fold since 1999, whereas issuance of chemical patents has scarcely changed."

Patents asserted by NPEs are disproportionately concentrated in the areas of information technology, telecommunications, and software.7' Several authors have recently published analyses of patent litigation, which highlight this subject-matter concentration.72 Brian Love conducted an empirical analysis of the relative ages of patents litigated by practicing and non-practicing entities.3 Love found that NPEs "overwhelmingly assert high-tech patents."74 Specifically, Love found that "about 65% of NPE-asserted patents cover computer- or electronics-related inventions, and almost 40% cover the narrower category of software-related inventions," whereas the comparable figures for non-NPE (or "product company") assertions were 40% and 25%, respectively.75 When expressed in terms of the number of suits or assertions brought, the data were even more striking: "The share of high-tech litigation by product companies is roughly the same whether measured by patent, by suit, or by assertion. However, for NPEs, high-tech litigation accounts for a substantially higher 82% of suits and 80% of assertions."76 Other research corroborates this finding, in the sense that NPEs often sue repeatedly on the same patent, creating multiple suits or assertions on a per-patent basis.77

John Allison and his colleagues conducted a study of the frequency of litigation of individual patents." Using the Stanford IP Litigation Clearinghouse database,79 the authors "identified every patent that has been litigated eight or more times between 2000 and 2007" and compared them to a randomly selected control group of patents that had been litigated only once. The patents were classified with respect to technology area, relevant industry, and the type of plaintiff asserting the patent, in order to measure the association between frequent litigation and these factors.' The authors' findings relevant to this Note are as follows: (1) the most-litigated patents by technology area are software patents; 2 (2) the most-litigated patents by industry area are computer and communications-related (information technology) patents;"3 and (3) "more than 80% of the most-litigated-patent suits are filed by NPEs.""4

Sannu Shrestha published an analysis of NPE litigation data, also relying on the Stanford IP Litigation Clearinghouse database." The definition of NPE used for this study" was narrower than that employed by Allison's study and therefore probably identified fewer NPEs."7 The data set encompassed 287 patents owned by 51 NPEs, most of which were granted in the 1990s." Despite these limitations, Shrestha's findings largely anticipated those of the Allison and Love studies: "Most of the NPE patents are in high technology areas such as consumer electronics, computing, and telecommunications."89

The pharmaceutical industry, it is now routinely asserted, does not incur the NPE assertions now suffered by the technology industries.9" The three empirical studies of NPE litigation cited above support this argument.' In Love's study of patent litigation timing, out of 421 patents examined, no patents on pharmaceuticals or biotechnology were asserted by NPEs.92 Allison's study found that biotechnology was only negligibly present among frequently litigated patents."3 Shrestha's study does not even separately identify pharmaceutical or biotechnology patents as present in the NPE litigation group." It is suggested that the nature of pharmaceutical research and products are so distinctly different from those in information technology that NPEs would have great difficulty profitably asserting pharmaceutical patents." Moreover, it appears that the pharmaceutical industry, unlike the communications technology and software industries, remains largely opposed to reform efforts.'

#### Generics don’t solve drug prices and they don’t solve other anticompetitive behavior

Sarpatwari 15 – Ameet Sarpatwari, Instructor in Medicine at Harvard Medical School and Associate Epidemiologist at Brigham and Women’s Hospital, “Why many generic drugs are becoming so expensive,” 10/22/15, https://www.health.harvard.edu/blog/why-many-generic-drugs-are-becoming-so-expensive-201510228480

The high cost of prescription drugs is big news. You hear about it on television, in your doctor’s office, and even on the campaign trail. When you think about expensive drugs, you may think about novel therapies for lung cancer or hepatitis C. But in fact, prices are also skyrocketing for the generic versions of some commonly prescribed drugs.

An article published last year in The New England Journal of Medicine reported that between 2012 and 2013, captopril — a generic drug used to treat high blood pressure and heart failure — increased in price from 1 cent to 40 cents per pill. During this same period, the cost of doxycycline, an older antibiotic, increased from 6 cents to $3.36 per pill. Connecture, a health insurance information technology company, reports that while the price of most generic drugs remained constant between 2008 and 2015, almost 400 generics saw price increases of more than 1,000%. At a time when 18% of prescription drug costs are paid for out-of-pocket and 8% of Americans report not taking their medications in order to save money, such dramatic increases in generic drug prices place a heavy burden on public health.

Why are generics going up in price?

Most of us think of generics as the less expensive alternative to the brand-name version of a prescription drug — and that’s often the case. The pharmaceutical companies that make generics can sell them for lower prices because they didn’t have to pay for the research and development that brought the drug to market in the first place. However, this cost advantage can take a back seat in situations such as the following, in which competition is reduced or delayed, enabling generic manufacturers to increase their prices:

The market for some generic drugs is so small that it does not attract multiple producers, as with pyrimethamine (Daraprim), a very old drug used to treat a parasitic infection called toxoplasmosis. GlaxoSmithKline had long been the only producer of pyrimethamine, but priced it modestly. This August, however, Turing Pharmaceuticals acquired rights to the drug and exploited its monopoly, raising the price 5,000% (from $13.50 to $750 a pill).

In some cases, the number of producers of a generic drug decreases because of an ongoing wave of market consolidation within the pharmaceutical industry.

Unanticipated safety issues can limit the supply of a generic drug. Hikma Pharmaceuticals, for example, was forced to stop production of doxycycline in 2011 due to quality concerns at its New Jersey plant. The shortage resulted in a 6,000% increase in the price of the drug.

It can be difficult and expensive for a manufacturer to get a generic drug to market in the first place. The average time for the Food and Drug Administration (FDA) to process a generic drug application was 42 months in 2014, compared with an average of 8 months for a standard new drug application.

A generic manufacturer must demonstrate that its version of a drug is equivalent to an existing “reference” product already on the market. When only one company produces a drug and tightly controls its distribution, it can be extremely difficult for other companies to secure samples of this reference product.

#### Pharma innovation and generic drugs are both high now, but the aff goes too far – it crushes innovation and causes a shift to more expensive drug development which turns prices

Branstetter 14 – Lee Branstetter, professor of economics and public policy at Carnegie Mellon University, “Starving (or Fattening) the Golden Goose? Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation,” September 2014, https://www.nber.org/system/files/working\_papers/w20532/w20532.pdf

In his provocative paper, “The Health of Nations,” Yale University economist William Nordhaus (1999) argues that the advances in human welfare generated by better medical science over the past half century have been equal in value to the consumption increases from all other sources put together. Victor Fuchs (1982) has suggested that most of the real improvement in human health generated over this period stems from modern medicine’s expanding arsenal of pharmaceutical products. While documenting these claims in a way that meets modern evidentiary standards is challenging, the work of scholars such as Frank Lichtenberg (2001, 2004, 2007) has provided evidence suggesting that the gains from pharmaceutical innovation have been very large. In the long run, global investments in pharmaceutical research have proven to be very good ones.

These benefits have come with significant costs; pharmaceutical innovation is risky and expensive. These costs are passed on to consumers in the form of higher prices for branded pharmaceuticals. In recent years, prescription drug spending in the U.S. has exceeded $300 billion, an increase of $135 billion since 2001. Consumption of prescription drugs now accounts for approximately 12 percent of total health care spending (GAO, 2012). However, over this time period, generic products have accounted for an increasing share of prescription drug expenditures, saving consumers an estimated $1 trillion (GAO, 2012). Current regulation attempts to strike a balance between access to lower cost generics on the one hand and adequate incentives to promote pharmaceutical innovation on the other. While the rise in generic penetration has brought substantial benefits to consumers (Branstetter et al., 2013), some have argued that the regulatory "balance" has shifted so far in the direction of access to inexpensive drugs that it has undermined the incentives for new drug development (Higgins and Graham, 2009; Knowles, 2010). Such a shift could have strong implications, even for drug companies outside the United States, because the global industry relies disproportionately on the U.S. market as a source of its profits. Has the increase in generic entry affected pharmaceutical innovation? Our study attempts to address this question and quantify, for the first time, the impact of generic entry on early-stage drug development.

We start by constructing a novel and unique dataset that allows us to analyze this issue at the level of narrowly defined therapeutic areas. Instead of relying on patents as measures of innovation, we focus on early-stage drug development. While patenting is certainly important in the pharmaceutical industry, it can occur anytime throughout the drug development process, and it often occurs long before the actual therapeutic value of a compound has been demonstrated. Our outcome variable, on the other hand, allows us to measure what is actually happening in the early stages of the clinical development process. We also utilize comprehensive data on branded and generic drug sales across all therapeutic categories in the U.S. market1 , obtained at the firm-product-year level, such that we can measure the differential exposure of individual firms to generic competition across these different therapeutic markets. Finally, we seek to control for changes in scientific opportunity by building a comprehensive database of citation-weighted scientific journal articles in the medical sciences and mapping them to our pharmaceutical product market categories.

Using these data, we find that the aggregate level of new drug development has not declined as generic penetration in the U.S. market has risen; the total number of new compounds (including both small and large molecules) in early stage development has risen over our sample period (Figure 1). However, rising generic competition has had a statistically and economically significant impact on how pharmaceutical product development is undertaken and where those efforts are focused. We show this by using an empirical framework that models the flow of early-stage pharmaceutical innovations as a function of generic entry and penetration, as well as scientific opportunity and challenges, firm innovative capability and a vector of additional controls. Using this framework, we document a negative and significant relationship between generic entry (penetration) and early-stage innovation at the ATC 2-digit therapeutic category level. The elasticity from our specification implies that a 10% increase in generic penetration in a particular market will lower early-stage innovations, in that same market, by 7.9%.

The interpretation that an increase in generic penetration within a market lowers early-stage innovation is strengthened by a series of alternative specifications and robustness checks. First, we limit our sample to a set of therapeutic categories where substitution between generics and branded products is limited for clinical reasons, and we find that our measured effect attenuates to the point of insignificance, as expected. Second, we show that our estimated effect is strongly negative for early-stage innovation, where it is possible to redirect R&D in response to market shifts, but much weaker for late-stage innovation, where firms have stronger incentives to deploy products that have survived the clinical trials process, even if generic competition is limiting the addressable market. Third, we show that our baseline effect is robust to inclusion of (therapeutic market \* year) interaction terms that effectively remove all the unobserved market-specific effects that change in a common way across firms.

Finally, we consider the possibility that, within therapeutic markets, a shift is occurring out of chemical-based (small molecule) products and into biologic-based (large molecule) products. The regulatory mechanisms that have accelerated generic entry in chemical-based drugs do not extend to biologics. Additionally, the pathways by which biologic-based generics (known in the industry as ‘biosimilars’) could enter the U.S. market have yet to be finalized.2 Exploiting this regulatory difference between chemical-and biologic-based innovations, we find a positive relationship between generic entry and a shift towards biologic-based products within therapeutic categories. As conjectured by Golec et al. (2010), this movement suggests that the nature of innovation taking place in the pharmaceutical industry is changing.

Is this shift in the direction and nature of drug development socially beneficial or socially harmful? At this stage in the research process, it is not yet possible to produce a definitive answer to this question. On the one hand, one could argue that current regulation is ‘pushing’ innovation toward therapeutic markets for which significant numbers of viable generics do not exist. In other words, R&D efforts and expenditures could be flowing to therapeutic areas that are relatively underserved, thereby generating welfare gains. On the other hand, our evidence of a significant movement in the data from development of chemical-based to biologic-based products may have important implications for the future, especially since biologics tend to be more expensive, on average, than chemical-based products. Until current regulatory challenges are resolved, these higher prices may persist for long periods of time. As the regulatory playing field tilts sharply in the direction of biologics, and firms respond rationally to the incentives they confront, we cannot rule out the possibility that recent efforts to balance access with incentives for innovation will give us cheaper drugs today, but more expensive drugs tomorrow.

#### Generic drugs undermine quality control – turns every health care access impact

Eban 19 – Katherine Eban, investigative journalist and the author of the New York Times bestseller Bottle of Lies: The Inside Story of the Generic Drug Boom, “How Some Generic Drugs Could Do More Harm Than Good,” 5/17/19, https://time.com/5590602/generic-drugs-quality-risk/

For the 16 years that Dr. Brian Westerberg, a Canadian surgeon, worked volunteer missions at the Mulago National Referral Hospital in Kampala, Uganda, scarcity was the norm. The patients usually exceeded the 1,500 allotted beds. Running water was once cut off when the debt-ridden hospital was unable to pay its bills. On some of his early trips, Westerberg even brought over drugs from Canada in order to treat patients. But as low-cost generics made in India and China became widely available through Uganda’s government and international aid agencies in the early 2000s, it seemed at first like the supply issue had been solved.

Then on February 7, 2013, Westerberg examined a feverish 13-year-old boy who had fluid oozing from an ear infection. He suspected bacterial meningitis, though he couldn’t confirm his diagnosis because the CT scanner had broken down. The boy was given intravenous ceftriaxone, a broad-spectrum antibiotic that Westerberg believed would cure him. But after four days of treatment, the ear had only gotten worse. As Westerberg prepared to operate, the boy had a seizure. With the CT scanner working again, Westerberg ordered an urgent scan, which revealed small abscesses in the boy’s skull, likely caused by the infection.

When a hospital neurosurgeon looked at the images and confidently declared that surgery was unnecessary and the swelling and abscesses would abate with effective antibiotic treatment, Westerberg was confused. They had already treated the boy with intravenous ceftriaxone, which hadn’t worked. His confusion deepened when his colleague suggested that they switch the boy to a more expensive version of the drug. Why swap one ceftriaxone for another?

Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it’s made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished.

But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large.

These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review.

The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” In swaths of Africa, Southeast Asia and other areas with developing markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught.

In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive. But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,” he told me.

## AT: Circuit Split

### 1NC – AT: Circuit Split

#### Cannot solve the predictability of the entire antitrust regime – they affect only exemption.

#### No internal link to impact

#### CEO surveys prove – business planning strong now.

Mourgelas 1/10 – Isabella Mourgelas, research analyst with Chief Executive Group, “CEO Confidence Jumps At Start Of 2022,” 1/10/22, https://chiefexecutive.net/ceo-confidence-jumps-at-start-of-2022/

At the start of 2022, America’s business leaders are hopeful that persistent issues in the supply chain and growing inflation—and maybe even Covid-19—will wind down this year. Their rating of future business conditions reached its highest level since July of 2021, when vaccinations became widely available across the country. Many CEOs we polled point to persistent demand, even during a large spike in Covid-19 cases, as the source of their growing confidence.

Those are the key findings from Chief Executive’s latest poll of 210 U.S. CEOs, fielded January 4 through 6, which asks America’s business chiefs to rate the environment today and 12 months out based on their assessment of business conditions—and forecast the impact on their company’s growth.

Their 7 out of 10 rating of future business conditions was a stunning 7 percent increase over last month—matching their forecast at the beginning of 2021. Their rating of the current business environment, however, dropped by 1.5 percent to 6.7 out of 10, from 6.8/10 in December. Nevertheless, CEOs’ current rating of today’s business environment is 8 percent higher than their rating of conditions in January of 2021.

“The worst is here. Now it’s the beginning of the end for Covid,” says Andrew Ly, CEO of Sugar Bowl Bakery, summing up the hope of many CEOs across the nation.

“I’ve been keeping a watchful eye on inflation and interest rates and I anticipate increased business as COVID-19 and supply chain conditions improve over the next year,” says Arthur James, President at Mills James Productions, a video production company. He expects that conditions will improve from a 6 to a 7 one year from now.

Andrew Featherman, Esq., President at Intergroup, a real estate company, agrees with James, saying, “Supply shocks and inflation are one-offs and will stabilize by 4th quarter.” He expects conditions to remain at the 8 he rates them now.

#### Business investment rising – generates longer-term growth

Ro 21 – Sam Ro, Markets Correspondent for Axios, “The "remarkable" business investment recovery,” 7/28/21, <https://www.axios.com/business-investment-recovery-0f7e7080-269e-4838-976a-fc91debb8d4f.html>

[Capex = capital expenditure]

Businesses are investing in themselves.

Why it matters: Core capital goods orders, or those for durable goods that aren’t aircraft or defense-related, are a proxy for business investment.

These equipment orders will get fulfilled in the months ahead, so they reflect businesses’ expectations for the future.

Continued growth in this measure suggests the economic growth we’re experiencing today may not be the peak.

By the numbers: Core capital goods orders increased by 0.5% in June to $76.1 billion, up from an upwardly revised $75.7 billion in May. Year-over-year, this measure is up 16.7%.

What they’re saying: Pantheon Macroeconomics’ Ian Shepherdson says the elevated levels of these orders is “remarkable.”

“A combination of rebounding earnings and support from the federal government, coupled recently with clear evidence of acute labor shortages, is pushing companies into raising capex in order to expand capacity and remain competitive,” he writes.

“If you aren't spending but your competitors are, you'll lose market share," Shepherdson adds.

The big picture: “These data points provide insight into businesses’ plans for investment in the third quarter,” Grant Thornton chief economist Diane Swonk writes.

“Continued strength in computers and electronics offset a small drop in orders in the vehicle sector, which has suffered some of the biggest supply-chain problems due to a shortage of computer chips,” Swonk says.

What to watch: These mounting orders for new capital equipment should translate to higher growth expectations from businesses.

Meanwhile, the monthly durable goods reports bear watching to see if these core capital goods orders continue to rise.

“Companies in aggregate are cash-rich, but they remain asset-constrained after a decade of under-investment following the financial crisis,” Shepherdson said. “Accordingly, we expect capex to continue rising at a rapid pace for the foreseeable future.”

The bottom line: Orders for business equipment represent companies putting their money where their mouths are. Whether or not you believe economic activity has peaked, it is the case that businesses are positioning themselves for more growth.

#### The consumer welfare standard ensures the antitrust regime is predictable now.

Auer 18 – Dick Auer, Senior Fellow, International Center for Law & Economics, “Comments of the International Center for Law & Economics: Topic 4: Antitrust law and the consumer welfare standard,” FTC Hearings on Competition & Consumer Protection in the 21st Century, https://www.ftc.gov/system/files/documents/public\_comments/2018/10/ftc-2018-0074-d-0071-155999.pdf

The adoption of the consumer welfare standard was an enormous improvement over what came before it. Yet no one would assert that every aspect of antitrust policy in furtherance of the consumer welfare standard is perfect and should remain unchanged. There will always be grounds for critique and improvement of specific policy decisions and processes. But none of these arguments undercuts the basic merits of the standard and its supremacy over alternatives.

Antitrust enforcers and courts have a difficult time as it is ensuring that their decisions actually benefit consumers. As Robert Pitofsky once said, “antitrust enforcement along economic lines al-ready incorporates large doses of hunch, faith, and intuition.”40 But the existence of imperfections does not justify intervention that would move us further away from economic objectives. Indeed, such intervention would more than likely make the imperfections worse.

When antitrust policy is unmoored from economic analysis, it exhibits fundamental and highly problematic contradictions, as Herbert Hovenkamp highlighted in a recent paper:

As a movement, antitrust often succeeds at capturing political attention and engaging at least some voters, but it fails at making effective or even coherent policy. The result is goals that are unmeasurable and fundamentally inconsistent, although with their contra-dictions rarely exposed. Among the most problematic contradictions is the one between small business protection and consumer welfare. In a nutshell, consumers benefit from low prices, high output and high quality and variety of products and services. But when a firm or a technology is able to offer these things they invariably injure rivals, typically those who are smaller or heavily invested in older technologies. Although movement antitrust rhetoric is often opaque about specifics, its general effect is invariably to encourage higher prices or reduced output or innovation, mainly for the protection of small business or those whose technology or other investments have become obsolete.41

Even with careful economic analysis, it will not always be clear how to resolve the inevitable tensions between consumer welfare and other policy preferences. In 1978, then-FTC-Chairman Michael Pertschuk laid out his vision for a “new competition policy” at the FTC. In it, he asserted that anti-trust policy must consider

the social and environmental harms produced as unwelcome by-products of the market-place: resource depletion, energy waste, environmental contamination, worker alienation, the psychological and social consequences of market-stimulated demands.”42

It is not clear what it would mean to take account of these things in the context of anything approaching a rigorous policy framework. But even more troublingly, many, if not all of them call for a rejection of the core, competition-focused objective of antitrust.

For instance, Jonathan Adler has described the collision between antitrust and environmental protection in cases where, precisely because of reduced output, collusion might lead to better environ-mental outcomes, such as improved conservation of wild fish and other common pool resources.43 How would a court or enforcer conceivably evaluate that trade-off? It is difficult enough to evaluate the procompetitive justifications for certain conduct already — including in somewhat similar circumstances where intrabrand price or distribution constraints, for example, may be aimed at pre-serving the “common pool resource” of brand value or consumer goodwill. But that difficulty is only magnified where the trade-off is between incommensurate benefits, distributed over entirely different populations, and without any operational connection between them within the firm undertaking the conduct in question.

Whatever benefits might conceivably come from giving weight to non-economic values, even just at the margin, they would inevitably come at the expense of the core, competitive values of modern antitrust. As Ernest Gellhorn noted in his masterful critique of Pertschuk’s “socially conscious” vision for the FTC:

Competitive values must be sacrificed if social values are to be given primacy — or else the new policy is nothing more than rhetoric and official deception. The second and equally important point is that the new chairman’s “humanistic model” for antitrust is formless, shapeless, and unpredictable. There simply are no generally accepted “democratic and social norms” for applying the antitrust laws — and some of the new chairman’s announced values are worrisome, at least to the extent they are offered as the basis for determining the shape and operation of much of our economy.

The problem is that unless antitrust law has an objective and principled foundation, antitrust enforcement can become the personal plaything of enforcement personnel, or the stock in trade of lobbyists and influence-peddlers.44

While it is perfectly reasonable to care about political corruption, worker welfare, and income ine-quality, it is not at all reasonable to try to shoehorn goals based on these political concerns into antitrust — a body of legal doctrine whose tools are wholly inappropriate for achieving those ends. As Carl Shapiro has noted, “The fundamental danger that 21st century populism poses to antitrust is that populism will cause us to abandon this core principle and thereby undermine economic growth and deprive consumers of many of the benefits of vigorous but fair competition.”45

#### FTC losses in court ensure predictability for businesses and make the FTC look weak

McLaughlin 21 – David McLaughlin, economics and antitrust reporter for Bloomberg, “Antitrust Crusader Lina Khan Faces a Big Obstacle: The Courts,” 6/23/21, https://www.bloomberg.com/news/articles/2021-06-23/tech-antitrust-lina-khan-faces-courts-as-challenge-to-ftc-s-progressive-agenda?sref=iKB6XOvf

Instead, hours after the Senate confirmed her, Biden put the 32-year-old Khan—one of the most prominent antagonists of big business—in charge of the agency, where she’ll be responsible for challenging mergers and taking on companies when they use their market muscle to snuff out competition.

Now comes the hard part: putting her agenda into action. The biggest hurdle, say antitrust experts, is a judiciary that has made it very difficult for competition watchdogs to win ambitious cases. And to make any change of consequence, whether breaking up a monopoly or stopping a takeover, enforcers must prevail in court.

“None of that is easy, and it’s particularly not easy when courts are very conservative, as they are today,” says Stephen Calkins, a law professor at Wayne State University and a former general counsel at the FTC. “She’s certainly talked about breaking up companies but, my golly, that’s incredibly hard to do.”

Khan made her mark in 2017, with a law review article she wrote while still a student at Yale Law School. Titled “Amazon’s Antitrust Paradox,” it traced how the online retailer came to control key infrastructure of the digital economy and how traditional antitrust analysis fails to consider the danger to competition the company poses. The paper was widely talked about in antitrust circles and was read by senior enforcement officials.

U.S. tech titans are at the center of the antitrust debate in Washington. They are ever more powerful, with Apple Inc., Amazon.com Inc., Alphabet Inc., and Facebook Inc. among the top 10 largest companies in the world, by market value. A House of Representatives investigation last year accused the companies of abusing their dominance to thwart competition, and lawmakers are considering a raft of bills to impose new rules on how the companies operate. Federal antitrust enforcers and state attorneys general have sued Google and Facebook for what authorities say are monopoly abuses.

Khan, who was counsel to the House antitrust committee during its probe, was one of the main authors of the House report. It recommended a series of reforms to antitrust laws that she and anti-monopoly activists have long championed, like restricting which markets the companies can operate in and requiring them to treat other businesses on their platforms fairly and without favoritism.

Khan’s work helped revolutionize competition-policy debates and shift support for a more forceful approach that abandoned the playbook inspired decades ago by Robert Bork, the conservative legal scholar and judge. That framework came to be known as the consumer welfare standard and relies on price effects as the measure of competitive harm. Khan argued in her paper for a new approach, focused on the competitive process and the structure of markets, that she said would more fully capture harms that the consumer welfare standard misses.

Once considered on the fringes of antitrust thinking, Khan and her acolytes—often dubbed the New Brandeis School, after Supreme Court Justice Louis Brandeis—are now firmly mainstream with Khan’s appointment as FTC chairwoman.

The FTC has suffered some stinging defeats recently. Last year, the agency lost a major monopoly case filed against chipmaker Qualcomm. In April, a unanimous Supreme Court eliminated a tool used by the FTC to recover money for defrauded consumers. Later this month, a federal judge in Washington is expected to rule on whether the agency’s monopoly lawsuit against Facebook can proceed.

Still, there’s widespread agreement that the status quo is no longer tenable. Over the last two decades, concentration has risen in industries across the economy. Some economists say dominant companies can use their market power to suppress wages, for example, exacerbating inequality. The worries are bipartisan. Republicans and Democrats alike are pushing for antitrust reforms to rein in the biggest tech platforms, and Khan was confirmed by the Senate with significant Republican support.

Big losses in the courts would eventually hurt Khan’s authority and demoralize her staff, says William Kovacic, a former FTC chairman who now teaches at George Washington University Law School. “You become like a sports team that is known to its opponents as unable to win,” he says. But defeats also could provide the foundation for the kind of sweeping antitrust legislation that Khan and her supporters want.

“If you want to change the world, at some point it goes to the courts or it goes to the legislature,” Kovacic says. “But you can’t do it by yourself.”

#### Supply bottlenecks are easing and confidence is rising

Mutikani 1/11 – Lucia Mutikani, macroeconomics editor for Reuters, “U.S. small business sentiment rises modestly in December – NFIB,” 1/11/22, https://www.reuters.com/world/us/us-small-business-sentiment-rises-modestly-december-nfib-2022-01-11/

WASHINGTON, Jan 11 (Reuters) - U.S. small business confidence increased modestly in December amid growing concerns about inflation and worker shortages, a survey showed on Tuesday.

The National Federation of Independent Business said its Small Business Optimism Index rose 0.5 point to 98.9 last month. Twenty-two percent of owners said inflation was the single most important problem for operations, up from 18% in November.

The economy is experiencing a period of high inflation as the COVID-19 pandemic snarls supply chains.

But there are tentative signs that supply bottlenecks are starting to ease, with an Institute for Supply Management survey last week showing manufacturers reporting improved supplier deliveries in December. Economists and Federal Reserve officials expect inflation will start subsiding this year.

Even as inflation concerns mounted last month, the NFIB survey showed the share of owners raising average selling prices decreased two points to 57%. Price hikes were the most frequent in wholesale, construction and retail industries.

The proportion of businesses planing to raise prices fell five points to 49%.

#### Capital spending is up because of increased confidence

Ezrati 1/17 – Milton Ezrati, Senior Contributor to Forbes, “Capital Spending Points To Growth, At Least For The Time Being,” 1/17/22, https://www.forbes.com/sites/miltonezrati/2022/01/17/capital-spending-points-to-growth-at-least-for-the-time-being/?sh=48d13bea2369

Among other signs of economic recovery, the Commerce Department has added a positive report on capital spending. Orders for capital goods from business and industry surged in November. Growth was more pronounced in some areas than others, but the general strength was undeniable and offers economic encouragement on three fronts: First, the spending will directly buoy economic activity. Second, it will enlarge the economy’s capacity to produce over the longer term. Third, it speaks to business confidence, a necessary component of any economic expansion.

# 2NC

## CP

### AT: PDCP

#### 1. The counterplan PICS out of “core antitrust law” because it doesn’t expand the three federal “core antitrust laws” – prefer contextual evidence defining conjunctive phrases. Severance is a voting issue for neg ground.

Sonia Kuester Pfaffenroth et al, Justin Hedge and Monique N. Boyce Arnold & Porter, ‘21 “ A Comparison Of Proposed Antitrust Legislation In 2021: Federal And New York State”

At the federal level, there are three core antitrust laws: (1) the Sherman Act, in which Section 1 outlaws "every contract, combination, or conspiracy in [unreasonable] restraint of trade," and Section 2 outlaws any "monopolization, attempted monopolization, or conspiracy or combination to monopolize";1 (2) the Federal Trade Commission Act, which prohibits "unfair methods of competition" and "unfair or deceptive acts or practices";2 and (3) Section 7 of the Clayton Act, which prohibits mergers and acquisitions where the effect "may be substantially to lessen competition, or to tend to create a monopoly."3 Criminal violations of the Sherman Act carry a maximum penalty of a $100 million fine for corporations, and a maximum penalty of 10 years in prison and a $1 million fine for individuals. A prevailing plaintiff in a civil suit can recover treble damages and attorneys' fees. But federal law currently does not provide for civil penalties when the government brings an antitrust case, only injunctive relief.

#### 2. Their definition of “scope” is unlimiting and would allow affs to expand CFIUS, the 14th amendment, or any regulatory prohibition as a topical mechanism. A more limiting definition of scope refers only to the total number of prohibited business practices.

Keith N. Hylton, Professor of Law, Boston University, and Fei Deng, and Consultant, NERA Economic Consulting, ‘7, “ANTITRUST AROUND THE WORLD: AN EMPIRICAL ANALYSIS OF THE SCOPE OF COMPETITION LAWS AND THEIR EFFECTS” Antitrust Law Journal [Vol. 74 2007] https://www.jstor.org/stable/pdf/27897550.pdf?refreqid=excelsior%3A424f12ccaeba1aa8d4150377ebe7192d

We turn our attention now to dominance law – or, in the language of American antitrust specialists, monopolization law. The Dominance Score is an attempt to measure the number of types of conduct specified in a country's competition law as unlawful abuse of a dominant position. For those familiar with American law, the dominance measure is an attempt to measure the scope of laws equivalent to Section 2 of the Sherman Act. One can think of the Dominance Score as the size of the net specifically designed to capture dominant firms that engage in anticompetitive con duct.3

#### 3. Antitrust and patent law are conceptually and legally distinct.

Feldman 8 - Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation at UC Hastings. (Robin, "Patent and antitrust: Differing shades of meaning." Va. JL & Tech. 13 (2008): 1. <https://web.stanford.edu/dept/law/ipsc/pdf/feldman-robin.pdf>) //S.He

The relationship between patent law and antitrust law has challenged legal minds since the emergence of antitrust law in the late 19th century. In reductionist form, the two concepts pose a natural contradiction: One encourages monopoly while the other restricts it. The inherent tension can be framed in the following manner: Can a body of case law that grants monopoly opportunities be reconciled with a body of case law that curtails monopolization.2

To avoid uncomfortable dissonance, the trend across time has been to try to harmonize patent and antitrust law. Since the 1930s, for example, the Supreme Court has ruled that antitrust law operates only when patent holders reach beyond the boundaries inherent in the patent grant. 3

It is an inspired attempt at reconciling the two bodies of case law. Unfortunately, no one has been able to determine what boundaries are inherent in the patent grant, a confusion that has spawned almost a century of consternation and conflict over what exercise of power lies within the patent grant and what lies outside. In recent decades, harmonization efforts have led Congress and the courts to engage in a series of attempts, some aborted and some half-formed, to graft antitrust doctrines onto patent law. 4 In addition, many scholars have advocated various harmonization approaches. 5

These efforts, too, have failed to resolve the conflicts. This piece argues that the deviations between patent law and antitrust law run far deeper than courts and commentators recognize. The problem isn't just that one encourages monopoly while the other limits it. Rather, patent law and antitrust law often use the same concepts and terminology with differing meanings and contexts. In other words, it may appear that they are talking about the same things, and yet, they are not.

Our tendency to assume parallel meanings threatens any attempt to reconcile the two bodies of law. Most importantly, ignoring asymmetries can lead to both underprotection and overprotection of patent rights, as well as the improper application of antitrust laws. To highlight the problem, this piece explores a number of examples of differing meanings in hopes of promoting a more subtle understanding of the patent/antitrust terrain.

The relationship between patent and antitrust is particularly important at this moment in time. Patent law is experiencing a moment in the sun, both in the courts and in the public eye. In particular, after accepting relatively few patent cases over the last decade, the Supreme Court accepted a record number of patent cases last term and this term, including ones that touch on the boundaries of the exercise of power permitted to patent holders6 . The Supreme Court also has accepted an unusually large number of antitrust cases. As both patent and antitrust law enjoy the spotlight of focus, it is particularly important to develop a more nuanced understanding of the shades of meaning in patent law and how those differ from antitrust.

### 2NC – CP

**The United States federal government should provide incentives to relevant firms in the private sector to increase Corporate Social Responsibility.**

### AT: Links to DA – General

#### The counterplan’s bottom-up, property-based approach avoids devastating innovation through heavy-handed antitrust application.

Barnett ’18 [Jonathan M; Professor, University of Southern California, Gould School of Law; 2018; “The Patent System at a Crossroads”; <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3147181>; Regulation, Vol. 41, No. 1; accessed 10/26/21; TV]

The accumulated and growing body of contrarian evidence poses a stiff challenge to conventional assumptions that have undergirded government actions and statements targeting propertylike attributes of the patent system. Contrary to popular belief, there is no firm factual basis to confidently assert that patent litigants are typically bringing opportunistic suits, that the patent system is regularly issuing low-quality patents, that smartphone and other consumer electronics markets are threatened with onerous royalty burdens, or that technology markets are stuck in a morass of patent claims that will frustrate innovation. If these "problems" are far less significant than had been thought to be the case, then much of "patent reform" starts looking like a solution in search of a problem.

But that is not the only failing of the prevailing consensus. The conventional narrative not only overstates the vices of a strong property-like patent system, but largely neglects its virtues. Those virtues extend substantially beyond the standard incentive rationale behind intellectual property rights. That standard rationale focuses on the role of patents in motivating invention while overlooking the role of patents in facilitating and structuring the follow-on commercialization process leading to market release.

Patents play two key functions in that process. First, a strong patent system supplies a robust revenue mechanism for idea-rich but capital-poor innovators who would otherwise have difficulty protecting their innovations against second-movers. Business history shows that the large incumbent is often the second-mover, deploying its formidable financing, production, and distribution capacities to outmatch the entrepreneur-innovator who came up with the bright idea in the first place. Second, a strong patent system provides a reliable legal infrastructure for making markets in intellectual assets. Secure patents enable a scientist-founded biotech startup to attract capital from investors and negotiate partnerships with large pharmaceutical firms that can undertake the "heavy lifting" required to deliver new therapies to the medical marketplace. Secure patents enable a chip-design startup to negotiate relationships with independent chip manufacturers and bypass the capital requirements that would otherwise frustrate entry into a market once dominated by large, integrated firms. In these cases, patents are hardly a tax that stunts innovation and hurts consumers; rather, they are a tool that enables entrants to challenge incumbents.

The patent system stands at a historical crossroads between the weak system of the postwar economy and the strong system that emerged in the early 1980s. Both the head of the U.S. Justice Department's Antitrust Division, Assistant Attorney General Makan Delrahim, and the acting chairman of the Federal Trade Commission, Commissioner Maureen Ohlhausen, have separately called for revisiting recent patent-skeptical policies. These statements echo empirical work that has raised significant grounds to rethink conventional understandings of the realworld effects of the patent system.

At this important juncture, the issues raised by Oil States illustrate the fundamental choice between a bottom-up, propertybased or top-down, administratively oriented approach toward patent and innovation policy. That choice is embodied by Oil States but, whatever the Court's decision in this particular case, it will continue to drive debates over the direction of patent and innovation policy. In weighing that choice in different contexts, it will be worthwhile for policymakers and commentators to bear in mind the error committed by several decades of pre-Chicago antitrust jurisprudence, which repeatedly protected the interests of particular competitors at the expense of competition in general. Only the latter objective is consistent with consumer welfare from anything other than an extremely short-term perspective.

Eroding patent security delivers an immediate gain by reducing the input costs of integrated manufacturers, platform firms, and other "implementers" located at midstream and downstream points on the technology supply chain. Unsurprisingly, these stakeholders have mostly (and successfully) advocated for curtailing patent strength.

Depending on competitive pressures, heeding these constituencies' calls for "patent reform" may also deliver short-term price reductions for consumers. (If reducing patent strength only reduces input costs, then it engineers a difficult-to-justify wealth transfer from upstream innovators to downstream implementers.) But this runs the risk of making a myopic social choice that forfeits future "macro" growth for present "micro" cost-savings. Replacing the wired telephone with a smartphone is the social goal of patent law-not taking a few cents off the existing wired telephone.

Perhaps of greatest concern, substantially diluting the property-like attributes of patents endangers the viability of upstream R&D-intensive firms that often deliver the most dramatic innovations but require a secure intellectual property portfolio in order to monetize those innovations through commercialization relationships. As patent security falters, innovation is prone to turn inward as innovator-entrepreneurs retreat to the shelter of platform-based firms and other large integrated enterprises that can wield scale and scope to internalize returns from new technologies. That hardly seems like the recipe for an entrepreneurial innovation economy in the 21st century.

#### The key distinction is that the counterplan deals with suits more effectively, but doesn’t expose companies to liability for even filing them – the link is about the chilling effect of antitrust liability, not about whether the suits succeed or not

Mosier 21 – Mark Mosier, Partner at Covington & Burling LLP, “BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, <https://www.supremecourt.gov/DocketPDF/20/20-1293/176010/20210419114711882_Main%20Document.pdf>

[Modified for gendered language]

Hatch-Waxman litigation is fraught with uncertainty and is enormously costly to innovator pharmaceutical companies. See Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) (recognizing that “[n]o one can be certain that ~~he~~ [they] will prevail in a patent suit”) (emphasis in original). Given the technical complexities inherent in these lawsuits, the existing case law hardly provides a reliable guide for the likelihood that an innovator will ultimately succeed in enforcing its rights. See TM Patents, L.P. v. Int’l Bus. Machs. Corp., 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999) (noting that “nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit”); see also, e.g., Purdue Pharma L.P. v. Endo Pharm. Inc. 438 F.3d 1123, 1125-26 (Fed. Cir. 2006) (initially affirming a ruling in favor of a generic challenger, only to vacate and remand on reconsideration). Moreover, as discussed above, by design, the Hatch-Waxman Act incentivizes innovators to act quickly to enforce their rights in order to be eligible for a stay of up to 30 months. Consistent with this, a party bringing a patent infringement lawsuit before concluding that it is certain to win the case does not act in bad faith. See Asahi Glass Co., 289 F. Supp. 2d at 993 (“It is not bad faith . . . to assert patent rights that one is not certain will be upheld in a suit for infringement . . .”).

If allowed to stand, the decision below would penalize innovators for filing suit in the face of this uncertainty. The standard for subjective intent that the court of appeals applied would deter innovators faced with potential generic infringers from asserting their rights based on the prospect of treble-damage antitrust liability. While parties typically seek the advice of counsel to avoid taking any actions that could result in antitrust liability, the decision below discourages that approach by treating a patent holder’s decision to rely on advice from experienced attorneys to bring ultimately unsuccessful suits as a reason for treating the suit as a sham. Pet. App. 66a-70a. Even for patent holders who decide to bring suit to enforce their rights, the decision below will serve as a powerful deterrent to making reasonable arguments for the development or modification of patent law principles. That outcome is in sharp tension with PRE’s statement that an “objectively good faith argument for the extension, modification, or reversal of existing law” cannot render a lawsuit baseless. 508 U.S. at 65.

Penalizing patent owners for asserting uncertain but presumptively valid patent rights undermines a critical element of the patent protections on which innovators depend to protect their enormous investments in developing life-saving drugs. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1369 (Fed. Cir. 1998) (innovators “must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent’s validity or infringement not survive litigation”). Absent robust patent protections, biopharmaceutical innovators face diminished prospects of recouping the high costs of developing new treatments, and are consequently less likely to make the necessary R&D investments.15 As a former Acting Chairman of the FTC has observed, “innovation in the life sciences industry would suffer catastrophic decline without patent protection.”16

### AT: Antitrust Key to Deterrence

#### The counterplan’s reforms solve deterrence

Avery 13 – Matthew Avery, Associate at Baker Botts LLP, “The Antitrust Implications of Filing “Sham” Citizen Petitions with the FDA,” 2013, 65 Hastings L.J. 113

The FDA should implement a multi-level review process to screen out improper or unfounded petitions based on disclosed conflicts. For example, to help the FDA evaluate whether a petition’s main objective is to delay approval of an ANDA, the Agency could require submission of more information concerning the circumstances under which a petition is filed. Five requirements would be particularly useful to the FDA’s initial review: (1) an accurate statement of procedural history, (2) an indication of any pending ANDAs or NDAs the citizen petition would affect, (3) a statement of financial interest, including financial relationships of any kind to the stakeholders, (4) a statement of likely financial impact, and (5) a corporate disclosure statement indicating any corporate relationships between affected parties. With this screening information at the outset, the FDA could quickly identify “suspect” petitions—such as those having a main purpose of delay— for secondary screening. Petitions involving large sums of money or that are filed shortly before ANDA approval is expected on a blockbuster drug might be subject to additional review to weed out clearly improper petitions, or to designate pressing petitions for immediate review to avoid financial loss. Falsification of screening information could be subject to harsh fines and outright denial of the citizen petition.

In concert with the screening process, the FDA should require petitioners to provide full disclosure of conflicts of interest, such as financial interests as noted above, in the approval or submission of the petition.230 For example, petitioners could be required to certify that: (1) petitioners have submitted all information the petition relies on, (2) the petition is legally and factually well grounded, (3) it is submitted in good faith, and (4) the petition includes all available information that is unfavorable to the petition.231 Although these additional certifications would burden all petitioners, they may also deter improperly motivated citizen petitions. Further, the proposed certification requirement could be given teeth by imposing a bond or potential penalties where delay of ANDA approval is sought. As noted above, this process would allow the FDA to identify and potentially screen out the petitions that are likely to be improperly motivated.

2. Adopt More Efficient Methods of Review

The FDA should adopt more efficient methods of review to improve response rates under the new proposed rule, or other changes that would urge adherence to the timeframe for all petitions rather than most petitions. The FDA currently reviews a citizen petition’s legal and scientific issues consecutively.232 Instead, the petitions should be routed based on whether they raise legal issues, scientific issues, or both.233 If a petition raises both legal and scientific issues, both issues should be reviewed in parallel by appropriate personnel.234 The review process could also be improved by implementing a tracking system to monitor how the FDA handles citizen petitions, which would help to identify systemic deficiencies or potential improvements.235

3. Time Restrictions on Submitting Citizen Petitions

Imposing a deadline to submit citizen petitions prior to ANDA approval could further deter abuse of the process. For example, the FDA could refuse to consider, for purposes of ANDA approval, citizen petitions submitted less than nine months from the pioneer’s patent expiration date.236 Alternatively, the Agency could provide would-be petitioners with a comment period consisting of a predetermined number of days in which they could submit citizen petitions concerning a submitted ANDA, similar to the predefined comment period for citizens to respond to a proposed FDA rule.237 Limiting opportunities to interfere with the ANDA approval process through such restrictions would stop dubious eleventh-hour citizen petitions and require petitioners to put forth their best arguments in a timely manner. Under this system, the FDA could review citizen petitions with fewer delays and thus determine whether to approve generic entry more rapidly.238

Another option is for the FDA to implement some type of “abbreviated citizen petition” process that would put the FDA on notice about concerns without making formal requests for action. The Agency could respond to an abbreviated petition by determining whether the concerns are prima facie legitimate, prioritizing them based on legitimacy, and then requesting a more formal “non-abbreviated” citizen petition for the highest priority concerns. This would essentially make the filing of a citizen petition an organic process that would raise all concerns at the outset and allow the FDA to engage in a conversation with the filer. The FDA could then specify what further evidence would be required to warrant the relief requested, strictly control the review schedule, and eliminate the need to review evidence that cannot support such relief.

4. Prima Facie Review of Intent

The FDA should exercise its discretion to determine whether citizen petitions concerning ANDA review appear to be anticompetitive by determining whether such petitions are filed with an intent to delay ANDA approval. Under 505(q)(1)(E), if the Agency finds that a petition’s main purpose is to delay ANDA approval, then it may deny the petition at any time.239 However, the FDA has never actually denied a petition based on such a finding and has refused to issue guidance on how such an intent to delay might be determined.240 Consequently, it is not at all clear and when a citizen petition could be summarily denied based on the Agency’s finding of intent to delay.

In order to give 505(q)(1)(E) some teeth, the FDA should issue guidelines defining what it means for a petition to have a “main purpose of delay,” “intent to delay,” or when a petition is a “delaying petition,” then refer dubious petitions to the Federal Trade Commission or Department of Justice for antitrust analysis or criminal investigation.241 Because the FDA is capable of determining factual issues for agencies and judges, such a referral could create a presumption that the FDA’s determinations regarding delaying intent are correct. Such a presumption may be justified given the FDA’s experience in reviewing citizen petitions and its history of maintaining the dialogue between industry and the government. This would lead to deterrence in the courts as well because of the presumption against sham petitioners.

A consequence of the FDA’s free reign to deny citizen petitions is that brand-name manufacturers who petitioned to keep generics off the market may vigorously challenge such denials. However, the Agency is in a favorable position to deny petitions while simultaneously fending off any suits from aggrieved petitioners. It has long been established that a purely legal challenge to a “final agency action” may not be fit for judicial review.242 Denial of a petition that could affect the approval of a related ANDA submitted by a generic competitor constitutes “final agency action,” and a challenge to such denial may not be ripe until the Agency makes a concrete determination on the related generic application.243 Consequently, the FDA can indefinitely defend or dismiss suits by petitioners who are denied until it approves the generic drug that the petitioners opposed in the first place. This gives the Agency maneuvering room to issue clarifying guidance or exercise its discretion.

5. Lengthen and Enforce the Time Period for Response

The source of the problem with citizen petition misuse is the time it takes to approve or deny the petitions and the FDA’s failure to act on ANDAs in the interim. The FDA has increasingly failed to meet the statutory response time, which was previously 180 days and has now been reduced to 150 days. Now that the FDA has even less time to respond to citizen petitions, it seems even more likely that the Agency will fail to respond in a timely manner. Consequently, changes in regulations should first target this aspect of the citizen petition process.244

One option arises from the rule that requires the FDA to notify an ANDA applicant within thirty days if the FDA’s response to an ANDA will be delayed beyond 180 days.245 If the FDA imported a similar rule requiring the Agency to notify ANDA applicants of anticipated delays caused by citizen petitions in a timely manner, it may encourage the FDA to stop ignoring the time limit and increase the response rate.

A second solution would be to require a response to a citizen petition even if the FDA has not completed its review within the imposed response period or has not acted on related ANDAs. While this solution is supported by the recently amended law prohibiting the FDA from delaying ANDA approval in response to citizen petitions unless the delay is necessary to protect the public health, it carries the risk that the FDA will release superficial or incomplete responses.246

A third alternative would be to expand, rather than reduce, the time limit.247 However, petitions that did not receive a response within 180 days were typically delayed for more than a year.248 Expanding the time limit for the sake of the relatively few petitions that receive late responses could increase the average response time and create more delays in the otherwise-timely petition process.

A two-pronged approach—extending the period to make review more feasible and giving the requirement teeth to make it a hard deadline—could significantly improve the current system. Legitimate petitions would be less likely to get shortchanged, and improper petitions would have to be denied in a timely manner.

#### Raising the standard for Noerr-Pennington relies on the antitrust rule of reason – that’s inconsistent and contradictory, which undermines deterrence signaling – the counterplan’s expert patent law approach is better

Sipe ’17 [Matthew G; J.D., Yale Law School; B.A., University of Virginia; 2017; “Patents v. Antitrust: Preempting Conflict”; <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1958&context=aulr>; American University Law Review, Vol. 66, Issue 2; accessed 10/12/21; TV]

The Credit Suisse Court additionally noted the risk that antitrust courts, “with different nonexpert judges and different nonexpert juries” will find it difficult to “reach consistent results” as a reason why antitrust law and securities law, if simultaneously applicable, would be likely to produce conflicting guidance and requirements.251 This risk looms large in the patent context as well. As outlined above, the need for expertise in adjudicating patent disputes is substantial;252 as a result, nonexpert judges dealing with cases involving patents are apt to produce inconsistent results. But there is also uncertainty and inconsistency built into the applicable antitrust doctrine itself: in antitrust cases involving patents, courts have increasingly abandoned predictable rules and eliminated useful presumptions that might otherwise create consistency.

Over the past few decades, the Supreme Court has eliminated a number of specialized antitrust rules and analytical carve-outs created for patents in favor of bringing patents into the general antitrust fold.253 The Court has largely accomplished this task by folding patent cases into the relatively unpredictable rule of reason.254 The rule of reason is a holistic test to determine whether certain conduct constitutes an illegal restraint of trade, eschewing clear standards in favor of flexibility and totality:

[T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.255

The trend towards an all-encompassing rule of reason approach to antitrust has produced costly,256 fact-intensive litigation with highly uncertain outcomes.257 As Professor Robin Feldman summarized, “[T]here is nothing messier than the rule of reason . . . [whose] analysis is so complex that it is a burden on litigants and the judicial system.”258 Perhaps ironically, some of the most strident criticism of the all-encompassing rule of reason has come from the Supreme Court itself.259 To the extent that bringing antitrust cases involving patents into the general, all-purpose rule of reason eliminates otherwise bright-line rules and presumptions, it inevitably generates uncertainty in its own right.260 More importantly for the purposes of this Article, the rule of reason forces antitrust courts in practice to analyze more and more patent law issues—analysis for which antitrust courts are ill-equipped.261

For example, the existence of “market power”262 is a necessary predicate to certain antitrust violations, such as tying.263 In Illinois Tool Works Inc. v. Independent Ink, Inc., 264 the Supreme Court eliminated the presumption that a patent confers “market power” over the products covered by the patent; in doing so, the Court moved tying cases to a rule of reason analysis.265 Legal academics and economists had long criticized that presumption as inaccurate in many cases.266 But the marginal gain in accuracy267 has come at the loss of consistency and predictability268 and an increase in the need for antitrust courts to delve into patent interpretation. The question of whether market power exists over a certain product forces courts to consider potential substitutes for that product;269 so when patents are involved, the courts must—at least implicitly—determine the precise scope of the patent: What hypothetical substitute products or uses would not be infringing?270 This act of “translating the words of the [patent] into a meaningful technological context [is] one of the most difficult problems in patent law.”271 And yet, in these antitrust cases, it would be the inconsistent regional circuits, rather than the Federal Circuit, reviewing patent interpretations.272

In short, the Credit Suisse Court recognized the “risk that antitrust courts, with different nonexpert judges and different nonexpert juries, will produce inconsistent results” in areas of law where significant expertise is required, such as patent law.273 This threat of inconsistency has only been heightened by the trend to eliminate specialized antitrust rules and analytical carve-outs for patents that might otherwise prevent nonexpert courts from having to deal with patent intricacies. The end result is a high probability of conflicting guidance and requirements where patent law and antitrust law are simultaneously applicable, counseling in favor of preemption.

### AT: Unfair Patent Standard Bad (McFeely 8)

#### This is a straw-person card – they cut the part of the article where the author talks about potential barriers, but then the author answers the objections in that paragraph and says regulating patent trolls is still effective and doesn’t link to the pharma DA!

[Dartmouth reads yellow]

[Harvard’s tag: Unfair patent use standard is too vague and links to the net benefit]

McFeely 8 (J.D. candidate, Sandra Day O'Connor College of Law, Arizona State University, 2008, An Argument for Restricting the Patent Rights of Those Who Misuse the U.S. Patent System to Earn Money Through Litigation, 40 Ariz. St. L.J. 289, y2k)

B. A Potential Solution - Expand the Equitable Doctrine of Patent Misuse to Include an Affirmative Defense for Failure to Practice

Other commentators have recognized the harm caused by the business practices of the patent troll and have proposed solutions to deal with this problem. 4 ' While some of these solutions are quite exotic, and others call for wholesale reform of the patent system, one alternative not yet explored that shows some promise is the established equitable doctrine of patent misuse.

The patent misuse doctrine evolved from the "equitable doctrine of unclean hands whereby a court of equity will not lend its support to enforcement of a patent that has been misused."'' This doctrine has been applied most often to cases of unfair competition, in which a patent holder attempted to use its patent in ways that did not violate the law, but nonetheless resulted in anticompetitive practices that were "deemed contrary to public policy." '42 The patent misuse doctrine provides an alleged infringer an affirmative defense to patent infringement claims, "rendering the patent unenforceable until the misuse is purged. 1, 43 For the misuse to be purged, the patent holder must show that its "improper practice has been abandoned and that the consequences of the misuse of the patent have been dissipated."'

To address the negative effects of the patent troll's litigious business practices, the courts could expand the current definition of "patent misuse." Patent misuse could be expanded to include situations in which the patent holder fails to practice, or license another who does actually practice, the innovation to which it holds exclusive patent rights. Failing to practice, or failing to license others who practice, denies the fruits of the invention to society and is against public policy, thereby establishing a parallel between the litigious business practices of the patent troll and the anticompetitive practices that courts have been willing to constrain under the doctrine of patent misuse. A patent holder who fails to put its patents into practice should not be permitted to prevent another-who has made the fruits of the innovation available for the benefit of society-from exercising its common law right to imitate in good faith. As long as the patent holder is not prepared to deliver products and services to market, public policy requires that society be permitted to continue to enjoy the fruits of the innovation the alleged infringer has provided in its place. Society gains nothing by granting exclusive patent rights to those who do not act to its benefit.

Under this expansion of the doctrine of patent misuse, the fact the patent holder is seeking licensing from the alleged infringer would not be sufficient to overcome the affirmative defense of patent misuse: the patent holder must either commence practice itself, or license the right to practice to another who subsequently does practice. In so doing, the patent holder makes available the fruits of its invention to society, thereby upholding its part of the "carefully crafted bargain." '45 Once the patent holder or its licensee puts the invention into practice, the patent holder would have its full patent rights restored as it will have abandoned its improper practices, and the consequences of its misuse will have dissipated. At that point, the patent holder would be able to initiate infringement actions against unauthorized practitioners for any infringement occurring after the date the patent originally issued. Allowing the patent holder to assert its rights effective the original patent issue date provides the practicing patent holder with the full economic value of its patent.

This approach is somewhat less intrusive than those offered by other commentators.1 46 This approach restricts the misusing patent holder's rights where appropriate and allows their full reinstatement when the patent holder satisfies the policy goals justifying the grant of those powerful patent rights. This approach also addresses concerns about fundamental fairness by enforcing all the provisions of the "carefully crafted bargain" between the patent holder and society.4 This approach is less intrusive in that its provisions would not be triggered until the commencement of a patent infringement lawsuit. Further, this approach does not require the promise, or likelihood, of commercialization before a patent is granted, allowing the patent system to continue to operate as it has: patents may continue to be granted and patent rights may continue to be vested under the current patent law scheme. Inventors who innovate and sell their patent rights to others may continue to do so as the value of a patent will not be diminished to those who put their patent rights into practice. The only patent holders who will be hurt are those who attempt to use the patent system for negative or offensive purposes. 48 However, even this type of patent holder can be made whole on its investment upon a showing of cessation of its nonproductive use of its patent rights, at which point the right to sue for patent infringement would be fully reinstated.

Because the patent troll's business model is revenue realization through the threat of litigation, the most effective way to influence its behavior and limit its negative effects upon society is to limit its ability to profit by bringing litigation against others. Through an expanded doctrine of patent misuse, a patent troll may be stopped early in the litigation through a motion for summary judgment under Federal Rule of Civil Procedure 56.149 Alleged infringement could be refuted by an affirmative defense that the plaintiff was misusing its patent rights by failing to make its innovation available in the market. Since affidavits to show evidence of actual practice or licensing to put the innovation into practice would suffice for summary judgment,15 time consuming and costly discovery could be avoided, along with expensive, drawn-out litigation.

**[HARVARD CARD BEGINS]**

C. Challenges to the Implementation

While pursuing an expanded doctrine of patent misuse may help solve the problem of the patent troll in its quest for profits through litigation, such a scheme is not without its own set of potential problems. Small inventors with limited resources may be disadvantaged by such a scheme when up against larger competitors with greater access to capital. At the same time, businesses in **general** may face more **uncertainty** with an expanded doctrine of **patent misuse** that may in turn lead to **more**, rather than less, **litigation**. In addition, there is an argument that the suggested expansion of the doctrine of **patent misuse** could reduce an inventor's **incentive** to **disclose** new **inventions**, thereby leading to **a net decrease in innovation** and **concomitant harm** to society. Finally, it would be naive to ignore the fact that implementing the proposed scheme may itself incentivize other **unintended undesirable behaviors** that may be just as troublesome as those currently engaged in by the **patent troll**. These potential drawbacks are discussed in the paragraphs that follow.

**[HARVARD CARD ENDS]**

1. Disadvantages to the Small Inventor

Permitting the affirmative defense of failure to practice may lead to situations in which an inventor with a patented innovation, but no access to the capital required to fully develop it, gets robbed of his invention by a larger, better-capitalized competitor that does have the resources to bring the innovation to market. Under this scenario, the inventor is forced to sit by and watch as another profits from the fruits of its labor. Small inventors, such as university researchers, garage tinkerers, or early-stage start-ups, could lose substantially under the proposed scheme to expand the doctrine of patent misuse.

The image of large competitors circling like vultures to pick the flesh off undercapitalized innovations seems fundamentally unfair. Perhaps the discomfort comes from the notion that the proposed scheme may cause something to be taken away from the small inventor against his will. While the fact the small inventor may lose something under the proposed expansion of the doctrine of patent misuse is certainly unfortunate for that inventor, the U.S. patent system does not exist for the purpose of providing protection of the individual inventor. In fact, quite the opposite is true. Patent law is very much biased toward limiting what may be patented and keeping as much as possible freely available in the public domain.15 " ' The federal patent system only provides the limited monopoly of exclusive patent rights to the extent necessary to encourage innovation and have the fruits of that innovation made available to society.'52 In those situations in which patent law declines to award exclusive patent rights, the small inventor is subject to the same common law right to imitate in good faith applicable to everyone else; there is no right of others to be treated differently because of a lack of access to capital. Expanding the doctrine of patent misuse to include failure to practice is arguably nothing more than another reasonable restriction on the grant of exclusive patent rights, much like the prior public use or sale restrictions currently in force.'53 The proposed scheme is also arguably less restrictive because once a patent holder cures its deficiency, full exclusive patent rights are reinstated.

A more difficult problem for the small inventor to overcome is marshalling the resources required to cure its failure to practice so it may exercise its full exclusive patent rights. The small inventor who takes some time to get funding may have significant difficulty getting financed if a large company has already cornered the market using its innovation-who wants to fund the production infrastructure to take on AT&T? In this situation, the small inventor is at a significant disadvantage relative to the larger competitor who may be in a position due to its sheer size to effectively dispossess the small inventor of its patent. The proposed scheme offers no remedy to address this situation; the small inventor is left to its own devices to garner the resources needed to satisfy the prerequisites to exercise its patent rights. However, the presence of a large competitor will not always lead to insurmountable obstacles for the small inventor, and in some situations, may actually work in its favor. The small inventor able to get financing, or find a third-party licensee willing to put its innovation into practice, may actually benefit from the situation in which a larger competitor has appropriated its patent. The larger competitor will have already paved the road and proved the market: reducing the risk, making the up-front investment in marketing, and creating demand. In addition, once the small inventor puts its innovation into practice, it will be able to fully exercise its exclusive patent rights from the date the patent issued, allowing the small inventor to recover damages through an infringement suit against its larger competitor.

One obvious question arises: How is this different from what the patent troll does now? The difference lies in the purpose behind the litigation. In bringing litigation, the small inventor exercises its exclusive patent rights to defend the investment it made in delivering a benefit to society. The patent troll, however, merely seeks to profit from litigation, without any concern for delivering the benefit of the innovation to society. Under the proposed scheme, if the small inventor prevails, society continues to receive the benefit of the innovation since practicing the innovation is a prerequisite to the right to bring an infringement suit. Under current patent law, if the patent troll prevails, its litigation target will either be forced to stop delivering the innovation, depriving society of its benefits, or continue to deliver the innovation, while passing along to the consumer the costs associated with the damages or licensing fees paid to the patent troll.

2. The Problem of Increased Uncertainty

In addition to the disadvantages it may create for the small inventor, the proposed scheme of expanding the doctrine of patent misuse also has the potential to create problems for the business community as a whole. Perhaps the greatest challenge is the proposed scheme's tendency to increase uncertainty surrounding the question of constructive ownership of the subject matter of issued patents. Along with increased uncertainty comes increased risk, and increased opportunities for litigation as the courts are engaged to decide the disputes that arise from the areas of ambiguity.

Under current patent law, exclusive rights to an invention vest the date the patent issues and expire twenty years after the date the patent application was filed. 154 As soon as the patent issues, there is no question that a patent holder may legitimately enforce its exclusive rights, thereby establishing concrete ownership of the invention. A third party interested in the subject matter covered by a patent owned by another can be fairly certain about where the lines are drawn, and the likely outcome if it attempts to infringe upon the patent rights held by another.

Under the proposed scheme, there is less certainty of the ability of the patent holder to enforce its exclusive patent rights. Expanding the doctrine of patent misuse to include a defense of failure to practice the invention effectively leads to a suspension of the nonpracticing patent holder's right to exclude others from using its invention. Might this also mean the proposed scheme leads to a suspension of ownership? If so, are others free to exploit the patent's subject matter while its ownership rights are in limbo, awaiting the patent holder to cure its failure to practice the invention? The answer to the second question is both yes and no. Under the proposed scheme, third parties that take advantage of a patent holder's failure to practice its invention will have what amounts to unfettered access to the subject matter of the patent since the patent holder will lack a mechanism (litigation) to enforce its ownership rights. This is bad for the patent holder, but not necessarily bad for society. From a utilitarian viewpoint, it does not matter who delivers the innovation to market, as long as the benefit to society is maximized. However, the infringing third party is not quite so free to maneuver. If the patent holder cures its failure to practice, its ability to fully assert its ownership rights is reinstated, and the infringing third party is then liable to the patent holder for damages as far back as the date the patent issued. While the proposed scheme creates a tempting opportunity to free ride on the work of others, it retains a strong disincentive for those tempted to do so.

How businesses in general will react to this situation is not entirely clear. Most rational businesses make decisions by balancing the risk and reward associated with a particular course of action. Under the proposed scheme, there is no way for a business to determine how long unfettered use of an "in-limbo" patent may be sustained. Businesses that previously may have designed around a published patent to avoid infringement may now opt for the more expedient path of wholesale adoption of a currently unenforceable patent. Businesses that do so will be betting that the patent holder will never be able to enforce its rights, or that the revenues earned during the period the patent holder is unable to enforce its rights will offset any infringement damages that might come due in the future. This strategy may pay off for some, but could prove disastrous for others, leading to increased litigation and significant business disruptions due to forced shut downs of product and service offerings. The problem of business disruption could theoretically be addressed by a scheme of compulsory licensing similar to that for copyrighted musical works.'55 Under a compulsory licensing scheme, businesses using the patents of another would be free to continue to do so without the patent holder's permission, but would pay a set royalty fee to satisfy the economic interests of the patent holder. However, such a scheme would be very difficult to implement given the heterogeneity of the subject matter covered by patent law. It is difficult to see how one might develop a comprehensive licensing scheme that appropriately values the royalty payments due for a genetically modified cotton seed, the architecture of a new microprocessor, the next blockbuster drug for heart disease, or the myriad of other patentable inventions.

The problem of uncertainty is perhaps best illustrated by examples at the extremes. At one end of the spectrum, consider the business that makes the decision to appropriate the subject matter of an unprotected patent, but that must make an up-front investment before it can reap the expected financial benefits of the innovation. If the patent holder gains the ability to enforce its exclusive patent rights after the business has made the investment, but before the business has recognized any revenue, the business is likely to suffer a financial loss and a business disruption. In the case of a semiconductor or biotechnology manufacturing line, that loss and disruption could be quite substantial, making the business likely to bring litigation to challenge the patent in the hope of salvaging its investment. Without the uncertainty created by an unprotected patent, that same business may have been more likely to pursue a strategy of designing around the patent, thereby avoiding the business disruption and the corresponding motivation to bring litigation.

At the other end of the spectrum, consider the business that may have been lulled into a false sense of security after years of using an unprotected patent, only to have the patent holder emerge and demand infringement damages back to the date the patent issued.'56 The proposed scheme to expand the doctrine of patent misuse permits this result on the theory that a patent holder that makes the fruits of its innovation available to society is entitled to realize the full economic value of its patent. While the result may seem somewhat unfair to the business that has relied upon the unprotected patent, it should be remembered that the business was aware of the risk of using a patent issued to another, and ventured forth regardless. The business should have discounted its earnings to account for the likelihood of having to pay future infringement damages when it made its decision to proceed. Much like the business in the first example that was motivated to bring litigation to salvage its investment, the business finding itself in the latter position will likely be motivated to litigate to preserve its cash cow. Business disruption and litigation again raise their heads as a potential result of implementing the proposed expansion of the doctrine of patent misuse.

As these examples illustrate, there is a strong argument that society has an economic interest in resolving uncertainty surrounding property ownership, and that a scheme that increases uncertainly may lead to more problems than it solves. There is no doubt that increased uncertainty increases risk, but that does not mean a scheme that increases uncertainty should be rejected out of hand. Businesses operate in an uncertain world, and are well-equipped to make the risk-reward trade-offs the proposed scheme may present with respect to unpracticed patents. It would be overly paternalistic to reject the proposed scheme merely because it is feared that some businesses may make poor choices. Perhaps some assistance might be rendered, however, by allowing a right of adverse possession to properly enure after a certain period of open and notorious use of a patent by another. Although the law of adverse possession is well-established in the area of real property law,157 it has not yet been applied in the intellectual property areas of copyright or patent law.158 There is a roughly comparable construct in trademark law, 159 and perhaps this, combined with real property adverse possession jurisprudence, could be used to fashion a solution that places reasonable limits upon a patent holder's period of recovery, thereby reducing a measure of the uncertainty associated with the proposal to expand the doctrine of patent misuse.

3. The Problem of Reduced Incentive to Innovate

Along with the potential for increased uncertainty, the proposed scheme to expand the doctrine of patent misuse has the potential to reduce the incentive to innovate. It could be argued that the constraints the proposed scheme puts upon the immediate exercise of exclusive patent rights will disincentivize inventors, leading to a net decrease in the creation of new products and services. However, such a scenario assumes that the promise of patent protection is the engine that drives innovation, and that absent this mechanism, inventors will cease to innovate. There are commentators who support this theory, 6 but there are others who question the degree to which patents encourage innovation. 161 One empirical study of a hundred companies spread across twelve industries concluded that with respect to encouraging innovation, "patents were essential only in the biotechnology and pharmaceutical industries."' 162 Understandably, the prospect of immediate exclusive patent rights is a strong motivator given the investment required for biotechnology and pharmaceutical research and development, in addition to the years of clinical trials required to bring a new drug to market. 63 However, the proposed scheme is unlikely to affect these businesses since the huge investments that must be made to bring a drug to market make it imperative that these businesses put their patents into practice, in which case full patent rights enure. For the industries in which patents provide the greatest incentive for innovation, the disincentives the proposed expansion of the doctrine of patent misuse may create are moot.

Another way in which innovation might arguably be negatively affected is through a reduced incentive to disclose innovations through the patent system. This phenomenon is perhaps best illustrated by considering the situation of a business (or small inventor) that has an innovation, but is not quite ready to introduce it to market. Under the proposed scheme, fearing that a competitor might be able to steal its innovation and quickly capitalize upon it before the business is able to enforce its patent rights, the business may forego disclosing the innovation, electing instead to keep its innovation a secret. As a result, the innovation may never be known to the world, and others may never have the opportunity to study it, build upon it, and further innovate. Under the current patent system, however, a business that makes such a disclosure is protected by patent rights that are enforceable the date the patent issues. The business does not have to fear that its competitors will steal its innovation since litigation is immediately available to enforce its rights.

It is unclear what effect a reduced incentive to disclose inventions will actually have on innovation. Assuming, arguendo, that the proposed scheme does in fact cause inventors to stop disclosing inventions, it is questionable as to the extent to which businesses actually rely upon the disclosures in the patent filings of others to build upon and create new products and services of their own. It has been this author's experience that product development teams in technology companies are not spending their time studying patent filings in the hope of finding some innovation to build upon.' 64 In fact, in many companies the product development teams are specifically told not to review patent filings as they create new products and services. 65 Anecdotal evidence also suggests that the reduced incentive to disclose inventions is unlikely to have an overall chilling effect on innovation in the market. This author, after spending months at a whiteboard conceiving a new product offering, went to a trade show only to find eleven other companies exhibiting the same "unique, cutting-edge" product offering this author's company had independently derived on its own. In a technologically-advanced, globally-connected economy, it is unlikely that any real loss of innovation will occur, or that society will be deprived of any benefits as a result of a reduced incentive to disclose. The global competitive forces are too strong.

Even if the proposed scheme does make some businesses less likely to disclose the innovations they are not prepared to practice, there is an upside: someone else might independently come up with the innovation and new products and services will not be shut out by a business that uses the patent system to build walls around its product lines, or exclude competitors from the market. While the prospect of the loss of an innovation forever due to a reluctance to disclose an invention may cause some discomfort, it is far too speculative to say that the innovation would not have inevitably come from some other source.

While the potential exists that the proposed scheme to expand the doctrine of patent misuse may change some aspects of patent system incentives, it is important to note that the proposed scheme does not fundamentally alter the inventor's incentive to disclose. Rather, it better aligns the incentive to disclose with what best serves the interest of society. Under the proposed scheme, in return for disclosure now, the patent holder continues to enjoy exclusive rights to the innovation in the future, provided it takes the steps necessary to make the fruits of its innovation available to society. In addition, the patent holder retains the ability to claim exclusive rights and damages for infringement beginning the date the patent issues. The proposed scheme preserves the incentive to disclose, but only for those who will put their patents to productive use.

4. Incentivizing Unintended Undesirable Behaviors

In proposing an expansion of the doctrine of patent misuse, this Comment seeks to address the patent troll's undesirable behavior of using the federal patent system to profit from litigation. There is no guarantee that making such a change to the patent system would not in itself give rise to other unintended undesirable behaviors, perhaps making the cure worse than the disease. Past history has shown the ingenuity of those determined to exploit the patent system for their own benefit, from submarine patents to the patent trolls. However, the fact that there might be unintended negative consequences should not act as a bar to action in the face of the known negative effects caused by the patent troll.

Although the proposed expansion of the doctrine of patent misuse is not without its potential challenges, it does present a viable solution to the problems caused by the patent troll's litigation-based business strategy. It is true that the possibility exists that some small inventors may effectively get maneuvered out of their patents by better-capitalized competitors, or that increased uncertainty may cause some businesses to engage in risky behavior, exposing themselves to greater liability. However, as discussed above, these challenges are not insurmountable. While the proposed scheme may incentivize some unintended undesirable behaviors, as with any complex system, these will have to be dealt with as they arise. It is difficult to say what level of success the proposed scheme will enjoy in the long run, but from the current vantage point, expanding the doctrine of patent misuse to include the affirmative defense of failure to practice appears to offer an alternative that is better than the status quo.

### AT: First Amendment Blocks

#### We’re reading the actual proposal from the Gugliuzza cards – Noerr began as an antitrust doctrine but has been imported into patent law to hold that patent trolls can’t be regulated. The counterplan reverses the importation of First Amendment protections into patent law but doesn’t affect Noerr as applied to antitrust law.

Gugliuzza 15 – Paul Gugliuzza, Professor of Law, Temple University Beasley School of Law, “Patent Trolls and Preemption,” 2015, 101 VA. L. REV. 1579

Although patents are usually thought to be the domain of the federal government alone,24 Congress has only recently begun to consider bills that would outlaw unfair or deceptive patent demand letters. 25 The states' growing role in the patent system is reflected on the website of the U.S. Patent and Trademark Office, which counsels persons who receive demand letters that are "deceptive, predatory, or in bad faith" to, among other things, "fil[e] a complaint with your state attorney general's office."26 The states, by taking aggressive steps to regulate patent enforcement, are thus poised to erode the federal government's monopoly over the patent system.

Doctrines of federal constitutional law, however, may invalidate the new state statutes and limit the law enforcement authority of state officials. For decades, businesses and individuals accused of patent infringement have tried to assert state law tort claims against overzealous patent holders, but the U.S. Court of Appeals for the Federal Circuit, which has exclusive appellate jurisdiction over patent cases, 27 has held that those claims are mostly preempted by the federal Patent Act. According to the Federal Circuit, to avoid preemption, the accused infringer must prove not only the elements of its state law claim, it must also prove, by clear and convincing evidence, (1) that the patent holder's infringement allegations were "objectively baseless," meaning that no reasonable litigant could have expected to succeed, and (2) that the patent holder made its infringement allegations with knowledge of their inaccuracy or with reckless disregard for their accuracy.28 Cases challenging the constitutionality of the new state statutes and state law enforcement actions are just getting underway. 29 But the Federal Circuit's two-part test will almost certainly prohibit the states from condemning any but the most frivolous assertions of patent infringement." This Article argues, however, that the Federal Circuit's preemption rule is wrong as a matter of doctrine, is misguided as a matter of policy, and ignores important lessons from the history of patent enforcement.

As a matter of doctrine, courts usually identify the Constitution's Supremacy Clause as the source of preemption law,3 1 and the Federal Circuit has sometimes invoked the Supremacy Clause as grounds for immunizing acts of patent enforcement from state law liability.32 A closer examination of Federal Circuit case law, however, reveals that the most significant constitutional barrier to state regulation of patent enforcement is not preemption pursuant to the Supremacy Clause; it is the Federal Circuit's erroneous interpretation of the First Amendment's Petition Clause.33

Under an orthodox, Supremacy Clause-based preemption analysis, state laws regulating patent enforcement likely avoid preemption. Although the state laws create some disuniformity in the patent system, they arguably do not conflict with the core objectives of federal patent law, such as incentivizing invention and inducing the disclosure of inventions. 34 And it is difficult to say that federal law fully occupies the field of patent-enforcement regulation: The Patent Act is entirely silent on the issue of unfair or deceptive enforcement-it neither condemns nor immunizes it." Moreover, courts have consistently refused to find field preemption of state law tort claims that impose liability on patent holders. Rather than analyzing preemption under the Supremacy Clause, however, the Federal Circuit has imported as its preemption test the nearly insurmountable requirements imposed by the Supreme Court on plaintiffs who seek to inflict antitrust liability on defendants based on those defendants' pursuit of litigation.37 This doctrine, often called the Noerr-Pennington doctrine (or Noerr doctrine, for short), 8 stems from the Supreme Court's interpretation of the federal antitrust statute, the Sherman Act, in the light of the First Amendment's Petition Clause.39

To strip an antitrust defendant of the immunity conferred by the Noerr doctrine, the plaintiff must show that the defendant's underlying lawsuit was a "sham" by proving both that the lawsuit was objectively baseless and that it was filed with the subjective intent to impair competition. 40 The Federal Circuit, in adopting as its preemption rule the same requirements of objective baselessness and subjective bad intent, has thus expanded Noerr immunity by allowing patent holders to invoke the doctrine to avoid any type of civil liability, not just liability under the antitrust laws, based on any conduct related to patent enforcement, not just the pursuit of litigation.4 ' This expansion of Noerr immunity is a mistake. Letters sent from one private party to another, such as letters threatening patent infringement litigation, are not "petition[s]" to "the government" within the meaning of the First Amendment. Moreover, the Federal Circuit's use of Noerr as a preemption rule gets the federalism analysis exactly backwards. The Supreme Court has often articulated a presumption against preemption,42 but the Federal Circuit insists that a patent holder seeking to avoid preemption "has a heavy burden to carry. 4 3

The Federal Circuit's erroneous expansion of Noerr immunity is not only wrong as a matter of doctrine, it also has several destructive policy implications. For instance, it grants patent holders a license to lie in their demand letters, so long as those letters also contain objectively plausible allegations of infringement. Thus, patent holders can lawfully send letters stating that many recipients have already purchased licenses to the asserted patents even if, in fact, few if any recipients have done so.4 And patent holders can lawfully claim that the validity of the asserted patents have been upheld in court or in reexamination at the Patent and Trademark Office, even if that is not true.45 In addition, because the Federal Circuit purports to derive its Noerr-based immunity standard from the First Amendment,46 that standard makes it unconstitutional for not just states but also the federal government to condemn any but the most fantastical allegations of patent infringement. Thus, although the President, members of Congress, and the Federal Trade Commission have all recently voiced concerns about "patent trolls," 47 Federal Circuit law significantly limits the regulatory options.

Fortunately, history provides a useful lesson on how courts can strike an appropriate balance between protecting patent holders from liability when they make legitimate allegations of infringement and punishing patent holders when they engage in unfair or deceptive enforcement tactics. Specifically, a long line of federal judicial decisions-which the Federal Circuit has mostly ignored-addresses the precise question of when a patent holder may be held liable for its enforcement conduct. As early as the nineteenth century, courts sitting in equity enjoined patent holders from making infringement assertions in bad faith, which could be established through evidence of the patent holder's "malicious intent." 48 Although a patent holder's intent is a subjective question, courts often inferred subjective intent from objective evidence, such as the patent holder's threatening a large number of accused infringers 49 and the patent holder's failure to follow its threats with actual lawsuits.50 This flexible, equity-based immunity standard-as opposed to the rigid twopart test mandated by the Federal Circuit-would empower all three branches of government at both the state and federal levels to impose reasonable restrictions on patent enforcement. At the same time, cases in which enforcement conduct was enjoined under the traditional standard were usually egregious and often involved claims that were objectively weak on the merits, so a revitalized good faith immunity doctrine would protect patent holders' ability to provide legitimate notice of their patent rights.

#### That means the counterplan produces flexible patent regulation that reduces trolling but doesn’t expose legitimate patent lawsuits to crushing antitrust liability

Gugliuzza 15 – Paul Gugliuzza, Professor of Law, Temple University Beasley School of Law, “Patent Trolls and Preemption,” 2015, 101 VA. L. REV. 1579

In sum, reasonable minds might differ about whether policing unfair or deceptive patent assertions is a function that should be handled by an administrative agency, such as the FTC, or through legislation. Those who support a legislative solution might also reasonably disagree about the precise terms of any new statute and, of course, whether such a statute should be passed by Congress or by state legislatures. But the Federal Circuit's expansive immunity standard precludes all three branches of government at both the state and federal levels from regulating the enforcement tactic that is most troublesome: sending demand letters that contain weak (but not frivolous) allegations of infringement and that use misleading, deceptive, or false statements in an attempt to intimidate recipients into quickly purchasing a license. Fortunately, federal law already contains an alternative immunity standard that would allow governments to outlaw those tactics: the flexible good faith standard applied by courts before the Federal Circuit adopted its current, Noerr-based immunity rule.

V. RETHINKING PETITIONING IMMUNITY IN PATENT CASES

Although state governments and the federal government are increasingly interested in regulating patent enforcement, the Federal Circuit has left them powerless. Yet the court has offered no persuasive justification for extending the broad antitrust immunity conferred by Noerr to all civil claims challenging patent enforcement conduct. Accordingly, the Federal Circuit en banc or the Supreme Court should force a return to a narrower, more flexible immunity standard that accommodates the courts' historical practice of condemning unfair and deceptive acts of patent enforcement.

A. Returning to Good Faith

Some scholars have argued that Noerr should never protect litigation conduct as petitioning activity.355 They contend that Noerr immunity should be limited to its original context of petitions directed toward the legislative and executive branches. Under that view, the Supreme Court erred in cases such as California Motor Transport and Professional Real Estate Inventors, which immunized defendants from antitrust claims based on the pursuit of litigation. If that position is correct, then the Federal Circuit is almost certainly wrong in applying Noerr to claims that seek to impose civil liability based on patent enforcement activity. If documents that are actually filed in court are not protected by Noerr, then surely patent demand letters, which are ostensibly a precursor to the filing of litigation, should likewise not be entitled to Noerr immunity.

But even if Noerr does protect litigation or litigation-related conduct as petitioning activity, there is, as discussed above, a reasonable argument that defendants should not be able to invoke Noerr as a defense against claims not grounded in antitrust. 1 6 The holding in Noerr was "a construction of the Sherman Act" adopted to avoid "important . .. questions" about the right to petition, informed by the Sherman Act's purpose to regulate "business activity," not "political activity." 5 Most civil claims challenging patent enforcement are not asserted under the antitrust laws, however. And the purpose behind laws on wrongful civil proceedings and abuse of process-unlike antitrust law-is plainly to regulate litigation conduct. Likewise, laws governing unfair competition are designed to ensure the accuracy of information in the marketplace, 35 8 and so are plausibly aimed at eliminating false or deceptive allegations of patent infringement that influence the market. Disparagement claims similarly target false statements intended to cause pecuniary harm,35 9 so it is conceivable that false allegations of patent infringement come within the purpose of that tort. And the intent of the new state patent assertion statutes is obviously to regulate litigation-related conduct. Thus, the statutory justification for Noerr immunity, that is, that regulation of litigation conduct is outside the purpose of the Sherman Act, is absent in the context of many civil claims used to challenge patent enforcement, leaving defendants reliant solely on the First Amendment rights to petition and to free speech. Case law under those constitutional provisions-unlike the Noerr doctrine-permits courts and legislatures to condemn false and deceptive statements,36 even if those statements are attached to plausible legal claims."'

When it comes to claims based on statements made in pre-litigation communications, such as demand letters, the case for conferring Noerr immunity is even weaker. The basic reasoning for extending Noerr to pre-litigation communications has been clearly articulated by the Fifth Circuit:

Given that petitioning immunity protects ... litigation, it would be absurd to hold that it does not protect those acts reasonably and normally attendant upon effective litigation. The litigator should not be protected only when he strikes without warning. If litigation is in good faith, a token of that sincerity is a warning that it will be commenced and a possible effort to compromise the dispute.362

Although pre-filing communications make it possible to resolve a dispute without calling on the public resources of the courts, there are reasons to pause before extending Noerr immunity to all pre-litigation communications. To begin with, there is the constitutional text. Assuming that Noerr immunity is based on the First Amendment, as the Federal Circuit has indicated,363 it is absurd to say that a letter between private parties is a "petition" to "the government" within the meaning of the Petition Clause. 36 4 The Tenth Circuit, in a decision that represents a minority view, has held that "[a] letter from one private party to another private party simply does not implicate the right to petition."36 But ignoring the constitutional text is usually justified based on the policy argument, embraced by the Fifth Circuit in the passage quoted above, that immunizing threats to sue encourages out-of-court settlement, saving the courts' time and effort.3 66

If, however, the sender is using the threat itself to extract a payment and has no intention to actually file suit, then it is not clear that the threat should be protected.36 7 Similarly, even if the infringement allegations made in a demand letter are considered to constitute petitioning activity protected by the First Amendment, ancillary statements that have nothing to do with the infringement claim seem less worthy of immunity, particularly when those ancillary statements are false or misleading or are designed to induce the recipient to purchase a license without retain- ing an attorney to investigate the infringement allegations. 368 Punishing patent holders who send those types of letters will not discourage or inhibit patent holders who make assertions of patent infringement in a legitimate attempt to avoid going to court.

This is not to say that patent holders should have no leeway when making infringement allegations. Indeed, the law should protect patent holders who make plausible but unsuccessful allegations of infringement, so long as the allegations are made in a way that is neither unfair nor deceptive. Fortunately, those goals can be attained without granting patent holders the broad immunity that Noerr confers on antitrust defendants. Rather, courts can and should return to first principles: the flexible, equitable good faith standard to which the Federal Circuit's current immunity doctrine traces its roots. As discussed, pre-Federal Circuit decisions allowed patent holders to make legitimate assertions of patent infringement while also permitting injunctions against patent holders based on their bad faith. That bad faith standard included both subjective considerations (such as the patent holder's lack of intent to file a threatened infringement suit) and objective considerations (such as the weakness of the infringement claim on the merits). Returning to this flexible standard would allow governments, both state and federal, to condemn the assertions of infringement that are most troublesome.

## Adv 1

### XT 1 – Innovation High

#### Innovation’s taking off now – fundamentals are strong.

Alex Keown 2/2/22. Senior Life Sciences Writer at BioSpace, BA in Political Science from Appalachian. “Report: External Partnerships, Infectious Disease Research Drives Biopharma Innovation”. BioSpace. Feb 2 2022. https://www.biospace.com/article/external-partnerships-infectious-disease-research-drives-biopharma-innovation-report-shows/

For biopharmaceutical companies, innovation is a crucial concept. According to a new analysis assessing the return on innovation from R&D investments made within the top 5 pharmaceutical companies within the industry, innovation is paying off.

In a new “Measuring the Return from Pharmaceutical Innovation” report conducted by Deloitte’s Center for Health Solutions, returns from R&D innovation are up by 7% across the industry. The increase is largely driven by assets granted Emergency Use Authorization against the COVID-19 pandemic. However, if products in use without full regulatory approval are excluded, Deloitte said the projected internal rate of return is 3.2%, which shows the industry has improved its core productivity.

Deloitte used two key measuring sticks to develop the report. First, Deloitte assessed total R&D expenditures incurred by a company to bring a product to commercial launch based on publicly-available data. Secondly, the report estimates the forecasted projection of potential revenue that these products might generate.

Some key highlights from the report show that the average cost to develop a pharmaceutical asset in 2021 was $2.006 billion, down $370 million from the previous year. That cost is an average across the 15 companies examined in the report, taking into account different forms of therapeutic approaches made. Deloitte said the decrease from 2020 is primarily due to the “overall increase in the number of assets in the late-stage pipeline.”

As could be expected given the pandemic, infectious disease targets have increased for companies over the past year by an average of 4%. Infectious disease assets now make up 14% of the combined pipelines of the 15 companies. With Emergency Use Authorization on the table, assets aimed at COVID-19 went through clinical trials 3.7 times faster than other infectious disease studies.

Oncology remains a primary driver of innovation. Since 2013, the first year Deloitte conducted its Measuring the Return report, the oncology pipeline has doubled across these 15 companies. From 2020 to 2021, the pipeline has mainly remained the same.

While average R&D costs for 2021 declined, Deloitte noted that the average forecast peak sales per pipeline asset increased from $422 million in 2020 to $521 million in 2021. The range of forecast peak sales across companies has also increased, driven by the sales forecasts for COVID-19 vaccines.

The Deloitte report notes that the primary sources of innovation for companies are being developed by external sources, which continues a trend for the past several years. According to the report, the external development increased from 32% in 2020 to 46% in 2021, meaning almost half of the assets in the late-stage pipeline are now being developed through collaborations and scientific partnerships.

#### The patent cliff has spurred increased innovation but puts the industry on the brink

Ryan 1/11 – Barbara Ryan, founder of Barbara Ryan Advisors, life sciences consulting firm, “Biopharma Reaches New Heights as Calendar Turns,” 1/11/22, https://www.pharmexec.com/view/biopharma-reaches-new-heights-as-calendar-turns

A decade ago, my colleagues at EY (where I am a senior advisor) created the Firepower Index to understand a company’s total capacity to fund deals to achieve their growth goals. EY defines Firepower by the strength of a company’s balance sheet and market capitalization.

In 2021, the biopharma industry’s M&A Firepower reached a whopping $1.2 trillion, a level not seen since 2014, and 14% ahead of 2020. M&A, alliances, and partnerships have always been core to driving the industry’s growth strategies and satisfy their need to access innovation and talent, and this will remain the case.

However, the nature of dealmaking does shift with the times. The looming loss of exclusivity for many companies’ largest revenue-generating products increases the current urgency behind accessing external innovation and new products. EY’s findings show a shift in how they are deploying their available Firepower—away from outright M&A transactions toward strategic partnerships and alliances—and the team expects this trend to continue.

What’s driving the shift in how Firepower is deployed?

One, an innovation renaissance is clearly underway with the promise of novel cell and gene therapies and RNA- and DNA-based medicines to cure, not just treat illness. In order to remain competitive, the larger biopharma companies will need to aggressively pursue external innovation. The challenges to M&A are that many of the new innovators are extremely well funded, thanks to an open spigot of capital flowing into the sector. Through November 2021, biopharmas raised more than $80 billion through venture funding, follow-on offerings, and IPOs. That’s in addition to the $90 billion raised in 2020. Additionally, SPACs acquired many other biopharma innovators, and as of November 2021, there are more than 80 healthcare SPACs with money to deploy.

#### U.S. innovation is high and globally dominant---big business is key.

Wolf ’21 [Martin; April 27; Chief Economics Commentator, M.A. in Economics from Oxford University; Financial Times, “China is wrong to think the US faces inevitable decline,” <https://www.ft.com/content/8336169e-d1a8-4be8-b143-308e5b52e355>]

The Chinese elite are convinced that the US is in irreversible decline. So reports Jude Blanchette of the Center for Strategic and International Studies, a respected Washington-based think-tank. What has been happening in the US in recent years, particularly in politics, supports this perspective. A stable liberal democracy would not elect Donald Trump — a man lacking all necessary qualities and abilities — to national leadership. Nevertheless, the notion of US decline is exaggerated. The US retains big assets, notably in economics.

For one and half centuries, the US has been the world’s most innovative economy. That has been the basis of its global power and influence. So how does its innovative power look today? The answer is: rather good, despite competition from China.

Stock markets are imperfect. But the value investors put on companies is at least a relatively impartial assessment of their prospects. At the end of last week, 7 of the 10 most valuable companies in the world and 14 of the top 20, were headquartered in the US.

If it were not for Saudi Arabian oil, the five most valuable companies in the world would be US technology giants: Apple, Microsoft, Amazon, Alphabet and Facebook. China has two valuable technology companies: Tencent (at seventh position) and Alibaba (at ninth). But those are China’s only companies in the top 20. The most valuable European company is LVMH at 17th. Yet LVMH is just a collection of established luxury brands. That ought to worry Europeans.

When we look only at technology companies, the US has 12 of the top 20; China (with Hong Kong but excluding Taiwan) has three; and there are two Dutch companies, one of which, ASML, is the largest manufacturer of machines that make integrated circuits. Taiwan has the Taiwan Semiconductor Manufacturing Company, the world’s biggest contract computer chipmaker, and South Korea has Samsung Electronics.

Life sciences are another crucial sector for future prosperity. Here there are seven European companies (with Switzerland and the UK included) in the top 20. But the US has seven of the top 10, and 11 of the top 20. There is also one Australian and one Japanese company, but no Chinese businesses.

In sum, US companies are globally dominant and nearly all the most valuable non-US firms are headquartered in allied countries.

### XT 2 – Trolls Solvency – 2NC

#### Troll behavior is too varied for antitrust to solve

Sipe ’16 [Matthew; 2016; J.D. at Yale Law School; Michigan Telecommunications and Technology Law Review, “Patent Privateers and Antitrust Fears,” Vol. 2, No. 1, http://repository.law.umich.edu/mttlr/vol22/iss2/1]

At first glance, the nexus between antitrust law and patent trolls seems clear: if litigious patent trolls are unfairly deteriorating the markets for various patented goods, antitrust law can step in and reassert the proper rules for efficient competition. Thus far, however, the popular and scholarly literature surrounding antitrust law’s proposed role in policing patent trolls has suffered from two key failures.

First, antitrust scholars have largely failed to distinguish between different types of patent trolls and patent troll activities.9 Whether antitrust law can provide a solution—if a problem indeed exists—may vary greatly depending on, among other things: the particular patent owner’s conduct; its “relationships or connections to operating entities;” the nature of “downstream product” markets; and potential “upstream technology markets.”10 In this way, patent troll behavior varies too much to allow for a single conclusory answer:

Along one continuum, unilateral [patent troll] conduct may vary from acquiring a single patent or unrelated patents to amassing a thicket of closely related patents covering multiple facets of a single product or industry. The [assertion] strategy may vary as well, from blanketing an industry with demands for royalty payments . . . to engaging in more targeted demands, accompanied by claim charts. . . . Along another continuum, [patent trolls] may cooperate with one or more operating entities when asserting patents, ranging from unspoken agreements to explicit royalty- or revenue-sharing provisions.11

Footnote 9 begins:

9. Many pieces draw no distinctions or make no acknowledgement of the different potential types of patent trolls and their divergent activities at all. See, e.g., Michael A. Carrier, Patent Assertion Entities: Six Actions the Antitrust Agencies Can Take, 2013 CPI ANTITRUST CHRON. 1 (2013); Collin A. Rose, A Match Made for Court: Patent Assertion Entities and the Federal Trade Commission, 48 COLUM. J.L. & SOC. PROBS. 95 (2014); NAT’L ECON. COUNCIL ET AL., PATENT ASSERTION AND U.S. INNOVATION (June 2013), https://www.whitehouse.gov/ sites/default/files/docs/patent\_report.pdf; Bert Foer & Sandeep Vaheesan, Patent Trolls in the Cross Hairs, AM. ANTITRUST INST. (Jan. 16, 2014), http://www.antitrustinstitute.org/content/ patent-trolls-cross-hairs.

### XT 3-5 – Patent Trolls Defense – 2NC

#### Investors have adapted to patent trolls, and they don’t have long-term effects on innovation

Giudici 17 – Emiliano Giudici, Associate Professor of Finance, Rusche College of Business, Stephen F. Austin State University, “Evaluating Market Reactions to Non-Practicing Entity Litigation,” 2017, <https://scholarship.law.vanderbilt.edu/cgi/viewcontent.cgi?article=1083&context=jetlaw>

[NPEs = non-practicing entities = patent trolls]

Overall, the empirical results of this study are in sharp contrast with the findings of Bessen, Ford, and Meurer. They examined a large sample of firms across six industries, with firms of a wide range of market capitalizations. 16 7 Their findings indicate that for the period spanning 1990-2010, markets reacted negatively to the filing of lawsuits by NPEs. 168 Bessen, Ford, and Meurer suggest technology and software are more likely targets because patents in that sector tend to be more vulnerable to inadvertent breaches. 169 This study, by contrast, selects firms among the most targeted in those sectors and spans more recent times. Consistent with Bessen, Ford, and Meurer, this study finds the number of filings has increased over time; however, we find that equity investors do not react as sharply as they suggest. The negative skewness of aggregate abnormal returns the day after the filing indicates that in some instances investors' reactions are quite strong; 170 however, this also indicates parametric statistical tests could be inappropriate. 171 The nonparametric tests conducted in this study confirm the weak reactions of investors.

A number of hypotheses could be consistent with these findings of weak abnormal returns and negative skewness. Suppose with the passage of time, investors now realize that the lawsuits will be quickly settled and the NPEs do not have a real intention to halt the production of a particular product of the target firm; then, filing would produce no abnormal returns and no visible change in the skewness, as a technology-based firm's stock price may already reflect its investors' expectation that it will have to settle some patent lawsuits. This would ameliorate the impact of any information that another NPE patent lawsuit has been filed, as long as that lawsuit is of the type to which investors have become accustomed.

The negative skew at the aggregate level, however, suggests two alternative hypotheses: either some lawsuits are associated with significant sell-off or investors in some firms perceive the lawsuits as being detrimental in the long run. The tests at the firm level demonstrate that, using parametric and nonparametric tests, the majority of the firms do not experience significant negative returns on the day of filing. 172 All except one of the firms (VZ) experience negative skew the day after the filing.173 These two findings support the second of the previous hypotheses: investors perceive some filings as being a threat to the target's future profitability and others as nonthreats. These findings suggest further event studies may need to focus on the types of patent filings that are most likely to be used opportunistically by NPEs and could potentially cause unnecessary economic harm.

These findings do not completely contradict those of Bessen, Ford, and Meurer, but shed a different light. Perhaps the increased media coverage on NPEs' activity has educated investors, who realize the true intent of these organizations is to collect monetary compensation rather than prevent the development of a product in its entirety. Investors would perceive this as a one-time expense rather than a permanent hurdle to the firm's ability to innovate and benefit from R&D. The skewness of the results suggests that perhaps investors have become more sophisticated over the years, and instead of initiating selloffs large enough to depress the price of the target's common stock, they evaluate each case and react more conservatively.

## Adv 2

### XT 1 – No Patent Thickets

#### No patent thickets in pharma

Hutson 9 – Stu Hutson, Nature Medicine magazine, “Pharma ‘patent trolls’ remain mostly the stuff of myth,” November 2009, Volume 15, Number 11, p. 1240

[NPEs = non-practicing entities = patent trolls]

What many call ’patent trolls’ are most properly referred to as nonproducing entities, or NPEs. They’re typically defined as companies or individuals that horde patents not for actual use, but simply as tools to squeeze other companies for lawsuit settlements and licensing fees. They operate within the law and yet pose a big problem for high-tech industries. Legal actions can take successful technologies off the market and drain money that often would be otherwise devoted to research and development. However, thus far, NPE-type activities have been relatively absent in the pharmaceutical industry—though some predict this could change.

“We need to look honestly at these perfectly legal companies, because they’re an element of a patent system that is becoming more and more abused,” says Ravicher.

Pejoratively, the simplest abstract example of an NPE would be a group of lawyers with a bank account and catalog of patents, explains Chris Reohr, cofounder of Patent Freedom, a company that tracks NPEs. The most commonly cited case of what’s typically referred to as NPE litigation, however, is the 2006 US Supreme Court case eBay, Inc. v. MercExchange, LLC, in which the latter had an extensive catalog of unused patents that described web-based tools for online auctions, including one that covered eBay’s ‘Buy-it-Now’ function. The case set a legal precedent for how courts should deal with NPE-type companies. What’s more, it implemented a set of rules that had the result of limiting NPEs’ bargaining power. Nevertheless, such activity continues to grow.

According to Patent Freedom’s estimates, the percentage of patent lawsuits involving NPEs has risen from just 2% in 1998 to 13% in 2008. The jump has even been cited by the Obama administration as a need for patent reform. However, the boom has been almost entirely within high-tech industries involving computer hardware and software. Patent Freedom’s system of charting litigation has yet to pick up on any litigation specifically relating to pharmaceuticals.  
Matthew Rimmer, a senior lecturer at the Australian National University in Canberra and author of Intellectual Property and Biotechnology, says that NPEs are much more troublesome in the field of information technology (IT), because an individual IT product tends to have many components that would require many patents. So, it’s easy for an NPE to have one vague patent that may cover one aspect of another entity’s device or software. Pharmaceuticals, in contrast, tend to deal with products that have one patent for one arduously researched chemical. Further protection of pharmaceuticals in the US is provided by the country’s issuance of data exclusivity by the Food and Drug Administration and by regulation of generic drugs.

#### Patent trolls affect the tech sector because it has tons of low-quality patents that all overlap, but not pharma because pharma patents are high-quality and unique to specific drugs

Kramer 14 – Thomas H. Kramer, intellectual property lawyer, “Proposed Legislative Solutions to the Non-Practicing Entity Patent Assertion Problem: The Risks for Biotechnology and Pharmaceuticals,” 2014, 39 DEL. J. CORP. L. 467

[NPEs = non-practicing entities = patent trolls]

Patents in pharmaceuticals and biotechnology pose significantly different issues, in the context of infringement actions, from those posed by information technology patents.' 6 As they can be precisely described by their distinct molecular structures, pharmaceutical patents often attract a relatively small number of infringement claims.' 7 The investment required to produce pharmaceutical patents is often very large.' 8 The process of bringing pharmaceutical products to market is highly regulated.' 9 As a result of these factors, pharmaceutical patents tend to be highly valued throughout their lifespans, and litigation over these patents tends to take place in the setting of disputes between large manufacturing companies, often involving the process of introducing generic drugs in conformance with the Hatch-Waxman Act.'

Information technology, by contrast, may involve large numbers of claims or patents which are "stacked" together in covering a marketed product.'5' The rate of development in the information technology industry is higher, and product turnover correspondingly faster, than in the pharmaceutical industry.'5 2 The investment needed to produce patented technologies in the information technology field is often less than that needed for other types of patents.' Information technology is also less constrained by regulatory requirements.'54 These factors combine to produce patents that often do not hold their value for their full lives, and are often not highly valued.' There are also strong suggestions that as a class, these patents are weak in terms of their "notice" function-they can be relatively ambiguous in terms of the breadth of the right to exclude that they convey.'56

These distinctions underlie the observation, detailed previously, that NPE assertion activity almost never involves pharmaceutical patents.5 NPE patent assertion activity is largely focused in the information technology area, because the characteristics of the patents in that area make them suitable for assertion.'58 The "stacking" of many patented technologies within a given marketed product make manufacturers of those products easy targets for "patent holdup" through the threat of injunction.' 9 The low value of many information technology patents makes them easy to acquire in quantity, and minimizes the financial risk to the owner in the event of invalidation. 60 The low ."notice" quality of these kinds of patents makes defense of infringement actions costly in the context of current discovery and pleading practices."' The legislative reforms previously discussed are a response to the litigation activity associated with a particular technology sector, and not the broader landscape of the entire patent law. ,62

### XT 2 – Prices Solvency – 2NC

#### Generic prices high inevitably because of market failure unrelated to citizen petitions

Tessema 20 – Frazer A. Tessema, Research Assistant, Program on Regulation, Therapeutics, and Law, Brigham and Women’s Hospital, with Aaron S. Kesselheim, Professor of Medicine, Harvard Medical School, “Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs,” May 2020, *Hastings Law Journal*, https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3898&context=hastings\_law\_journal

Generic manufacturers can make their drugs available at considerably lower cost because of various market advantages they have over brand-name drugs. First, generic manufacturers have an abbreviated pathway to market in which they can receive FDA approval upon demonstrating bioequivalence to the brand-name version, which involves less clinical testing than is required for new drug approval. Second, upon market entry, generics can achieve high levels of market penetration because state drug product selection laws allow pharmacists to dispense them when a patient receives a prescription for the brand-name version. As such, generics need not rely on changing physician prescribing practices—often influenced by substantial marketing budgets of brand-name manufacturers—to gain market share.

When this process does not operate as intended, drug prices do not fall after market exclusivity expiration. Prices for generic drugs may actually increase. For example, some drugs may not attract many generic competitors— perhaps because fewer patients use the prescription—which reduces the size of the potential revenue stream. A 2017 study demonstrated that between 2008 and 2014, prices of generic drugs with three or fewer competitors remained considerably higher than those in more competitive markets.7 In some cases, pharmaceutical manufacturers have acquired marketing rights to off-patent products with little to no generic competition, subsequently increasing the price of those products abruptly and substantially, which has resulted in public and political outcry.8 As part of its investigation into the problem of high generic drug prices, the U.S. Senate Special Committee on Aging produced a bipartisan report identifying sole-source drug status and small patient market size as two key factors leading to generic drug price increases.9 Such products can be susceptible to disruptions in drug supply, leading to shortages and price increases that often persist even after the shortage is resolved.10

Other factors may also contribute to generic drug price increases. Recent antitrust litigation alleges that a variety of anticompetitive practices by several generic manufacturers have contributed to increases in the price of many common generic drugs.11 Another cause of intentional disruption to the generic drug marketplace came as a result of the FDA’s Unapproved Drugs Initiative (UDI), which awarded three years of market exclusivity to manufacturers who conducted studies of older, off-patent drugs.12 The program, which ran from 2006 to 2015, resulted in higher prices and an increase in both the number and duration of drug shortages because generic competitors were forced to discontinue production.13

These examples underscore the important point that generic drug cost reductions emerge through robust competition among generic manufacturers. However, even if generic competition has been established and the price of the drug has settled at a level closer to its production cost, prices can increase once again if generic competitors leave the market and remaining competitors seek to leverage increased market share. The severity and frequency of price increases affecting the generic drug market is becoming a source of alarm. One study found price increases of over 400% for at least fifty older generic medications between 2012 and 2015.14 Between 2010 and 2015, prices increased by 100% or more for 315 of 1441 (22%) generic drugs sold in the United States. 15 Price increases can detrimentally impact the ability of patients to access these products and lead to negative health outcomes, all while increasing the cost to government and private payors.

#### They don’t solve anticompetitive mergers, which have nothing to do with Noerr-Pennington

Tessema 20 – Frazer A. Tessema, Research Assistant, Program on Regulation, Therapeutics, and Law, Brigham and Women’s Hospital, with Aaron S. Kesselheim, Professor of Medicine, Harvard Medical School, “Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs,” May 2020, *Hastings Law Journal*, https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3898&context=hastings\_law\_journal

Another factor that contributes to high generic drug prices is market consolidation, which most frequently occurs via mergers of pharmaceutical manufacturers or acquisitions of pharmaceutical product lines.34 In the generics sector, market consolidation can leave certain generic drugs susceptible to price increases. Subpoenaed email exchanges between corporate officials have uncovered corporate pricing strategies after mergers and acquisitions; corporate executives will often reevaluate the drug’s competition and demand, raising prices accordingly.35 This may be to recoup the costs of the merger or acquisition or to obtain maximal revenues from a noncompetitive marketplace.36 Merger activity attracts particular scrutiny by the Federal Trade Commission when it involves acquisitions of direct competitor products, as in 2005 when Ovation Pharmaceuticals acquired the sole competitor to an indomethacin formulation used in neonatal cardiac care.37

A 2018 analysis of recent pharmaceutical merger and acquisition activity found that the median price for a cohort of thirty-seven off-patent, brand-name drugs (with either monopoly or duopoly levels of competition) more than doubled after acquisition.38 As shown in Table 1, generic drug price increases often follow merger or acquisition activity. In fact, the 2016 U.S. Senate report noted that manufacturers such as Retrophin, Turing, and Valeant attributed their price increases on acquired product lines to profit motives.39 Subpoenaed internal company documents revealed that executives pursued acquisitions with the explicit intent to raise the price in consolidated niche drug markets with few or no competitors.40 Retrophin acquired tiopronin because it was “woefully underpriced;” Valeant admitted to a “patient as hostage” model of drug pricing, focused on acquiring drugs for rare diseases and raising the price dramatically.41

Other studies demonstrate that targeted acquisition of non-patent-protected products is a common business strategy. A 2017 study of market consolidation found that in 2008, nearly half (546 of 1120 drugs) were at duopoly or near-monopoly levels of competition, and by 2013, the average level of market concentration for the cohort remained at duopoly-level.42 There was also a noticeable uptick in mergers and acquisitions among generic manufacturers from 2014 to 2016, increasing from twenty-two deals to fortytwo deals.43

### XT 3 – Innovation Turn – 2NC

#### Best data and statistics prove – the aff undermines both innovation and access

Branstetter 14 – Lee Branstetter, professor of economics and public policy at Carnegie Mellon University, “Starving (or Fattening) the Golden Goose? Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation,” September 2014, https://www.nber.org/system/files/working\_papers/w20532/w20532.pdf

For many years, researchers and industry observers have conjectured that rising generic penetration might have an impact on the rate and direction of pharmaceutical innovation. Using a new combination of data sets, we are able to estimate the effects of rising generic penetration on early-stage pharmaceutical innovation. While the overall level of early-stage drug development has continued to increase, generics have had a statistically and economically significant impact on where that development activity is concentrated and how it is done. In the full sample, we find that, as our baseline measure of generic penetration increases by 10% within a therapeutic market, we observe a decrease of 7.9% in early-stage innovation in that market. This implies that drug development activity is moving out of markets where generic competition is increasing and into domains where it is relatively less intense.

Our preferred interpretation of this relationship, namely that a rise in generic penetration leads to a decline in drug development in that market, is strengthened by the finding that this relationship varies across therapeutic areas in ways that conform to our prior expectations. In earlier work (Branstetter et al., 2013), we pointed out that the degree of substitution between generics and branded products can vary substantially across therapeutic areas. In markets where the substitution possibilities between generics and branded drugs are more limited, changes in generic penetration could be expected to have a weaker impact on innovation. This is indeed what we observe when we focus on three markets containing drugs that treat neurological and psychiatric disorders, where clinicians are sometimes reluctant to move away from a good "match" between a patient and a drug, even when a cheaper generic alternative (of a different drug) becomes available. In these markets, we find no statistically significant effect of generics on earlystage innovations. However, in markets with high levels of cross-molecular substitution we see the opposite.

In a similar manner, we would expect the measured negative correlation between rising generic penetration and new drug development to be strong and significant for early-stage drug development, where it is still feasible to redirect research efforts, but much weaker in late-stage drug development, where candidate drugs have already proved their safety and efficacy in a series of increasingly expensive and stringent clinical trials and are generally introduced even if the market is known to be limited by increasing generic competition. We find exactly this pattern in the data, providing further support for our preferred interpretation of the statistical relationship. The robustness of our results is also confirmed when we limit our sample to drugs candidates designated as "novel" by our Pharmaprojects database. These drugs are first in their class. This shows that our results are not driven by generic competition simply pushing out "me-to" drugs or reformulation/recombinations of existing therapies. For better or worse, the rise in generic penetration is associated with a decline in novel drug development. The elasticity from our results implies that a 10% increase in generic penetration in a particular market will lower early-stage novel drug development, in that same market, by 4.6%.

We also note that, in a linear specification, the negative relationship between drug development and rising generic penetration is robust to the inclusion of a full set of ATC 2-digit dummy variables and the interaction of these dummy variables with our year dummy variables. In this specification, where all the unobserved factors impacting a 2-digit therapeutic area over time in a common way across firms are effectively removed, the key empirical relationship remains negative, strong, and statistically robust, regardless of how we measure it. The elasticity from our results implies that a 10% increase in generic penetration in a particular market will lower early-stage innovation, in that same market, by 4.1%.

Finally, we also consider the economic incentives created by regulation to shift, within therapeutic markets, from chemical-based to biologic-based products. Currently, data exclusivity is much longer for biologic-based products, and the regulatory pathway to market for biosimilars has yet to be finalized. We conjecture that as chemical-based products are pressured by generics, pharmaceutical firms will begin to change the nature of their innovation by shifting to biologics. This is indeed what we observe. Increases in generic penetration in market j appear to lead to an increase in the relative amount of biologic-based drug development. As generic penetration in market j rises, firms do not appear to be abandoning market j completely, but rather changing the nature of the innovation they pursue.

We have shown that the rise of generic competition is reshaping the locus of drug development activity. Is this a good thing? In this paper, we have refrained from taking a strong stand on the welfare impact of this shift. The data we would need to determine this are not yet available, and, at this point, we can only speculate on the sign of the ultimate welfare impact. On the positive side, one can argue that social welfare is enhanced when pharmaceutical firms are induced to shift development efforts away from markets where a broad range of effective and cheap generic therapies already exist to ones with far fewer treatment options. This can be true even if the probabilities of research success are lower in the domains into which research effort is being pushed, because the social returns to expanding the range of treatment options is so relatively high. Even an increasing shift to more expensive biologic-based drugs may be beneficial in the long run if much of the potential for further advance in small-molecule drugs has already been exhausted. However, it is equally easy - and for us, equally plausible - to imagine a less positive outcome. Rising generic competition could be eliminating the development of new drugs that have all the benefits of existing therapies without the side effects. Such new drugs would have social value, even in markets with an extensive range of existing therapies. The less explored domains into which the pharmaceutical industry's small-molecule developments are being pushed may yield little or no success. Such pessimism would be consistent with much of the discussion of the pharmaceutical industry's longstanding "productivity crisis." Finally, by tilting the regulatory playing field so heavily against smallmolecule drug development and in favor of biologics, we may be inducing the global industry to give up on the former domain that has done so much to advance global health through the provision of cheap, relatively simple, effective drugs long before the potential benefits of further research have been exhausted.21

#### They cause increased access now but decreased access in the future

Branstetter 14 – Lee Branstetter, professor of economics and public policy at Carnegie Mellon University, “Starving (or Fattening) the Golden Goose? Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation,” September 2014, https://www.nber.org/system/files/working\_papers/w20532/w20532.pdf

The possibility that rising generic penetration could undermine the incentives to undertake new drug development has been recognized in prior work. For example, Hughes et al. (2002) show in a theoretical model that providing greater access to a current stock of branded prescription drugs yields large benefits to existing customers. However, this access comes at a cost in terms of lost consumer benefits from reductions in the flow of future drugs. Other papers have also discussed this possibility, including Grabowski and Kyle (2007), Higgins and Graham (2009), Knowles (2010), and Panattoni (2011). This research stream has provided (mostly indirect or anecdotal) evidence suggesting that an intensification of generic competition has undermined incentives for R&D. However, to the best of our knowledge, no published study has yet provided direct econometric evidence demonstrating that generic 11 entry has caused a change in the rate or direction of new drug development.8 The extent to which this occurs in practice remains an open question.

## Adv 3

### XT – Business Confidence High

#### Capital spending is up because of increased confidence

Ezrati 1/17 – Milton Ezrati, Senior Contributor to Forbes, “Capital Spending Points To Growth, At Least For The Time Being,” 1/17/22, https://www.forbes.com/sites/miltonezrati/2022/01/17/capital-spending-points-to-growth-at-least-for-the-time-being/?sh=48d13bea2369

Among other signs of economic recovery, the Commerce Department has added a positive report on capital spending. Orders for capital goods from business and industry surged in November. Growth was more pronounced in some areas than others, but the general strength was undeniable and offers economic encouragement on three fronts: First, the spending will directly buoy economic activity. Second, it will enlarge the economy’s capacity to produce over the longer term. Third, it speaks to business confidence, a necessary component of any economic expansion.

#### Decreases in confidence are limited and sector-specific

Mourgelas 1/10 – Isabella Mourgelas, research analyst with Chief Executive Group, “CEO Confidence Jumps At Start Of 2022,” 1/10/22, https://chiefexecutive.net/ceo-confidence-jumps-at-start-of-2022/

January polling shows that confidence has improved across most industries with the exceptions of consumer manufacturing and retail trade, whose ratings fell by 7.1 percent and 2.6 percent, respectively. CEOs in consumer manufacturing are discouraged by raw material inflation and the labor shortage preventing them from reaching their full potential, even though demand remains high. Retail CEOs, who gave the lowest rating this month of 6.33, share that material and inventory shortages, coupled with inflation and worker resignations are creating a volatile business environment.

The largest gain in confidence was seen by CEOs in the construction sector. Many are motivated by increased investment in infrastructure and see the end of Covid in sight.

Alan Pramuk, Chairman of Gresham Smith, in the construction industry, shares what is encouraging him: “The need and will to improve the US infrastructure, specifically with energy, renewables, power distribution, transportation, water quality and resiliency.”

Comparing ratings by company size, measured in annual revenues, only CEOs running companies with $100 to $999.9 million in revenues lost confidence this month, with their rating down 5 percent. CEOs’ ratings in both the smallest companies with revenues under $10 million and those in companies with revenues over $1 billion increased by double digits, at 16 and 12 percent, respectively.

### XT – Thumpers

#### CWS solves predictability now.

Keating 21 – Raymond J. Keating, chief economist for the Small Business & Entrepreneurship Council, “The Treacherous Turn on Antitrust Regulation of U.S. Tech Companies,” 2/24/21, <https://sbecouncil.org/2021/02/24/the-treacherous-turn-on-antitrust-regulation-of-u-s-tech-companies/>

[Modified for objectionable language]

Nonetheless, in the end, the consumer welfare standard is, by far, the best we have in terms of some consistency and reasonableness in applying vague antitrust laws.

Antitrust and Congress: A Bad System May Become Far Worse

Given the formidable shortcomings of antitrust law and regulation, one would hope that if Congress was going to consider reform or updating, the effort would be focused on at least trying to somehow better connect the law and enforcement with economic realities and how markets actually function.

That is not the case with the reports presented by Democrats and Republicans in the House Subcommittee on Antitrust, Commercial and Administrative Law of the Committee on the Judiciary. In fact, each report, and largely the Democrats’ analysis, serves up recommendations that would create far greater distance between how markets work and antitrust regulation.

Let’s be perfectly clear: Neither report offers recommendations that will improve antitrust law and enforcement. Most of the proposals labor under mistaken assumptions; and would actually inject more politics and uncertainty into the antitrust equation, while moving antitrust law, regulation and enforcement further away from sound economics.

The Democrats’ majority report is intent on a vast expansion of antitrust regulation and enforcement, including tossing out the consumer welfare standard in favor of, effectively, more politics over economics; while the Republican report also argues for expanded regulation and enforcement, but more tentatively so at least in terms of the language used.

The overwhelming tendency in the Democrats’ report is to make sweeping declarations about increased and inevitable monopolization (such as: “Over the past decade, the digital economy has become highly concentrated and prone to monopolization.”), along with “weakened innovation and entrepreneurship,” that ignore the dynamism of the tech economy, the enormous benefits derived by consumers, actual consumer decisions, and the definition of a monopoly.

As for the Republican report, it is willing to go along with the Democrats on a number of proposals, raises questions about others, and rejects some. As stated, “We prefer a targeted approach, the scalpel of antitrust, rather than the chainsaw of regulation.”

As it turns out, though, the Republican “scalpel” is far from targeted. The report expresses political disagreements with the firms involved (for example: “Most notably, the report does not address how Big Tech has used its monopolistic position in the marketplace to censor speech. This censorship is experienced by groups and ideologies on all wings of the political spectrum but is most notably realized through tech platforms exerting overt bias against conservative outlets and personalities.”)

Consider some key proposals from the Democrats’ report and our responses.

• Proposal: “Reasserting the anti-monopoly goals of the antitrust laws and their centrality to ensuring a healthy and vibrant democracy.” – “[T]he Subcommittee recommends that Congress consider reasserting the original intent and broad goals of the antitrust laws by clarifying that they are designed to protect not just consumers, but also workers, entrepreneurs, independent businesses, open markets, a fair economy, and democratic ideals.”

Response: This proposal would toss out the consumer welfare standard, and replace it with a broad basis for undermining businesses that have earned considerable market share. Antitrust actions would return to a period in which politics, special interest influences, rent-seekers, and uncertainty held even greater sway over the realm of antitrust – even more so than it does today. By effectively giving more control over business decisions and models to a political class that often fails to understand current business and market conditions, never mind where industries and markets are headed in the future, there inevitably will be losses in terms of innovation, investment, efficiency, and growth.

• Proposal: “Structural separations and prohibitions of certain dominant platforms from operating in adjacent lines of business.” – “Structural separations prohibit a dominant intermediary from operating in markets that place the intermediary in competition with the firms dependent on its infrastructure. Line of business restrictions, meanwhile, generally limit the markets in which a dominant firm can engage.”

Response: Again, having government determine and dictate business decisions, rather than having decisions made by businesses and entrepreneurs subject to market competition and consumer sovereignty would mean lost innovation, productivity and consumer benefits.

• Proposal: “Interoperability and data portability, requiring dominant platforms to make their services compatible with various networks and to make content and information easily portable between them.”

Response: Investments in engineering and information often are the lifeblood of businesses in the digital economy. It’s how they provide added value to customers. To have government impose assorted mandates on the use and availability of such investments inevitably will reduce and/or redirect such investments, with consumers, again, suffering.

• Proposal: “Presumptive prohibition against future mergers and acquisitions by the dominant platforms.” – “Under this change, any acquisition by a dominant platform would be presumed anticompetitive unless the merging parties could show that the transaction was necessary for serving the public interest and that similar benefits could not be achieved through internal growth and expansion.” – “[T]he Subcommittee recommends that Members consider codifying bright-line rules for merger enforcement, including structural presumptions. Under a structural presumption, mergers resulting in a single firm controlling an outsized market share, or resulting in a significant increase in concentration, would be presumptively prohibited…”

Response: The basis for justifying such random impositions on mergers certainly does not rest with sound economics, nor with how the market works, including that any mergers ultimately will be put to the test of competition and consumer decision-making in the marketplace. Instead, this is simply about a political preference or bias against mergers and “bigness” per se.

• Proposal: “To strengthen the law relating to potential rivals and nascent competitors, Subcommittee staff recommends strengthening the Clayton Act to prohibit acquisitions of potential rivals and nascent competitors.” – “Since startups can be an important source of potential and nascent competition, the antitrust laws should also look unfavorably upon incumbents purchasing innovative startups. One way that Congress could do so is by codifying a presumption against acquisitions of startups by dominant firms, particularly those that serve as direct competitors, as well as those operating in adjacent or related markets.”

Response: A surefire way to ~~cripple~~ [destroy] startups is to reduce or disincentivize investment in such ventures. This proposal seems designed specifically to undermine entrepreneurship. It is rather commonplace in an assortment of industries for a certain portion of startups to eventually be purchased and merged into larger businesses. Indeed, that possibility or option provides incentives for investing in such enterprises.

• Proposal: “Clarifying that market definition is not required for proving an antitrust violation, especially in the presence of direct evidence of market power” and “Clarifying that ‘false positives’—or erroneous enforcement—are not more costly than ‘false negatives’—or erroneous non-enforcement—and that, in relation to conduct or mergers involving dominant firms, ‘false negatives’ are costlier.”

Response: These measures are simply meant to make it easier to impose politically-driven antitrust regulation or actions against businesses. After all, why bother with defining the market or even considering “false positives” when one is so sure that large businesses and mergers are inherently evil – again, despite the fact that large businesses gained their notable market share by serving consumers well?

• Proposal: “Restoring the federal antitrust agencies to full strength, by triggering civil penalties and other relief for ‘unfair methods of competition’ rules, requiring the Federal Trade Commission to engage in regular data collection on concentration, enhancing public transparency and accountability of the agencies, requiring regular merger retrospectives, codifying stricter prohibitions on the revolving door, and increasing the budgets of the FTC and the Antitrust Division.”

Response: The assumption with these proposals is that antitrust agencies are not doing everything that this Democratic report seeks to do at least in part due to a lack of power, dollars and/or staff. The fact that some administrations might see matters differently, and have a dissimilar antitrust philosophy, seems to be ignored. Also, the number of rather absurd antitrust cases brought by such agencies belies the lack-of-power and/or lack-of-funding assumptions. Consider for example, the FTC suing to stop Edgewell Personal Care Co., maker of Schick razors, from buying razor rival Harry’s Inc., or the FTC challenging Post Holdings, Inc.’s proposed acquisition of TreeHouse Foods, Inc.’s “private label ready-to-eat cereal business.” Private label products are made by one company and offered for sale by a different firm under its brand, and the FTC argued for government action to stop a merger in a small portion of the breakfast foods market. Also, there don’t seem to be high barriers to entry in the razor market. In each case, government antitrust action led to the mergers being called off – after all, challenging a federal agency’s antitrust intrusion gets quite pricey. So much for federal antitrust agencies lacking power and resources.

• Proposal: “Strengthening private enforcement through elimination of obstacles such as forced arbitration clauses, limits on class action formation, judicially created standards constraining what constitutes an antitrust injury, and unduly high pleading standards.”

Response: The objectives here not only include an expansion of antitrust actions and special interest interference, but clearly, serving the interests of trial lawyers.

And, the list goes on. As noted already, the two reports do not make recommendations that would improve antitrust law and regulation.

As for the Republican report, while the language is more tentative in expanding antitrust regulation, and does not go as far as the Democrats, the effort in effect would ramp up antitrust regulation, which would lay the groundwork for political allies and opponents to use this as a stepping stone to greater antitrust interference. Most striking from the Republican report was where they clearly went beyond the idea of using a “scalpel” to improve antitrust enforcement. Consider the following for example:

• “The Clayton, Sherman, and Federal Trade Commission Acts were all written with broad interpretations to ensure antitrust regulators would not be hamstrung by future market developments. However, antitrust enforcers have boxed themselves in by relying on judicial interpretations instead of statutory language and Congressional intent. The report accurately describes how these changes have hamstrung true oversight efforts, granting Big Tech a de facto immunity from antitrust scrutiny…

• “By reinforcing presumptions that certain behaviors are likely to reduce competition, lowering evidentiary burdens in litigated cases, and emphasizing that anticompetitive effects are not limited to price effects and include innovation competition, quality, output, and consumer choice, Congress can make a meaningful difference.”

• “We also agree with a number of the majority’s other legislative recommendations, including proposals to shift the burden of proof for companies pursuing mergers and acquisitions and empowering consumers to take control of their user data through data portability and interoperability standards.”

• “The report makes a good case for the need to strengthen our nation’s antitrust agencies with regard to resources. We agree wholeheartedly with this recommendation. We need to give our nation’s antitrust enforcers the resources needed to succeed in litigation against Big Tech.”

Response: Recommendations to expand the powers and discretion of regulators; to increase unnecessary and burdensome regulatory requirements; to reduce checks and balances on regulatory undertakings; and to increase the budget for regulators, all in order to increase regulation of U.S. technology firms seems otherworldly. Missing is a healthy skepticism of governmental power and regulation.

And then there is the willingness to use antitrust action to engage in political disagreements with private companies, as noted earlier. For example:

• “Google used its dominant advertising technology product to demonetize conservative media outlets, including The Federalist. YouTube, a Google subsidiary, blocked videos from Republican politicians and media groups. Amazon censored conservative organizations, including the Family Research Council and the Alliance Defending Freedom by blocking Americans’ ability to donate to these groups through the AmazonSmile tool. Facebook’s algorithms, advertising policies, and content moderation rules have all combined to discriminate against conservative viewpoints, shadow ban conservative organizations and individuals, and suppress political speech… Unfortunately, the majority missed an opportunity to fully scrutinize Big Tech’s use of monopoly power to silence Americans’ First Amendment right to free speech. It is difficult to consider the subcommittee’s investigation into platform behaviors and anticompetitive behavior complete without a robust discussion about platforms using their monopoly power to engage in editorial decisions that silence free speech.”

Response: While one can agree or disagree with particular decisions being made by private companies, they are private companies. And bringing governmental power down upon such decision-making should always be deeply troubling. For good measure, this certainly is not an area for antitrust regulation.

On the more positive aspects of their recommendations, Republicans were unwilling to go along with their Democratic colleagues in other areas. For example:

• “However, the majority also offers policy prescriptions that are non-starters for conservatives. These proposals include eliminating arbitration clauses and further opening companies up to class action lawsuits. Similarly, the majority’s desire to institute Glass-Steagall for America’s tech sector and modeling the majority’s equal terms for equal services recommendation on President Obama’s net neutrality rule will not garner support from Republicans.”

• “The majority report also includes a recommended presumption that any vertical merger by a dominant platform is unlawful. We are concerned that the presumption against vertical mergers, in particular, will chill venture capital investment in a way that will further harm innovative startups and reduce their ability to get their product to market.”

As far as these criticisms of the majority report go, they generally are on target. However, the overall friendliness of the minority report, or response to the Democrats’ majority report, is troubling, and would help to lay the groundwork for a potential vast expansion in antitrust regulation that, in the end, will undermine investment, innovation, dynamism and entrepreneurship in the economy, which, of course, would harm consumers.

# 1NR

## CSR DA

### 1NR – AT: Link Turn

#### Noerr does not extend to denial

The Climate Docket 19, 5-22-2019, "Oil industry supporters argue cities cannot sue for climate liability," Climate Docket, <https://www.climatedocket.com/2019/05/22/oil-industry-support-climate-liability-chevron/>

Chevron attorney [Theodore J. Boutrous Jr](https://www.gibsondunn.com/lawyer/boutrous-jr-theodore-j/)., who specializes in First Amendment law, argues in the brief that “the so-called ‘promotional’ activity Defendants allegedly undertook to ‘discredit the growing body of scientific evidence’ would be nothing more than constitutionally protected lobbying activity.” Boutros cites the Noerr-Pennington doctrine, originally formulated to protect businesses from anti-trust liability but which companies have often tried to use to justify other lobbying efforts. Boutrous argues that the doctrine protects lobbying against climate action, even if it involves deception.

But several climate law experts say that doctrine does not extend to product liability claims.

“Cities and counties filing lawsuits seeking compensation or abatement under a range of theories ranging from public nuisance to failure to warn simply does not amount to an infringement on First Amendment rights,” said Michael Burger, executive director of the Sabin Center for Climate Change Law at Columbia Law School. “There is no First Amendment protection for failing to warn consumers of known harms from products.”

Oakland City Attorney Barbara J. Parker also referenced this point in a [press release](https://www.sfcityattorney.org/2019/03/14/san-francisco-and-oakland-appeal-to-9th-circuit-hold-fossil-fuel-companies-accountable-in-state-court-for-costs-of-climate-change/) announcing the cities’ brief in their appeal filed in March. “Companies cannot lie to their customers for decades about the dangers of their products and walk away with impunity,” she wrote.

#### The legal opinion in this case proves that plaintiffs can still use public nuisance doctrine

Alsup 18 – (William, ORDER GRANTING MOTION TO DISMISS AMENDED COMPLAINTS, Oakland et al vs BP, IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 6/25/18, http://columbiaclimatelaw.com/files/2018/06/oakland-v-bp-order-6-25-18.pdf)//gcd

The scope of plaintiffs’ theory is breathtaking. It would reach the sale of fossil fuels anywhere in the world, including all past and otherwise lawful sales, where the seller knew that the combustion of fossil fuels contributed to the phenomenon of global warming. While these actions are brought against the first, second, fourth, sixth and ninth largest producers of fossil fuels, anyone who supplied fossil fuels with knowledge of the problem would be liable. At one point, counsel seemed to limit liability to those who had promoted allegedly phony science to deny climate change. But at oral argument, plaintiffs’ counsel clarified that any such promotion remained merely a “plus factor.” Their theory rests on the sweeping proposition that otherwise lawful and everyday sales of fossil fuels, combined with an awareness that greenhouse gas emissions lead to increased global temperatures, constitute a public nuisance.6

CITATIONS

6. This clarification seems to have been aimed at avoiding the Noerr-Pennington doctrine and other free speech issues inherent in predicating liability on publications designed to influence public policy. See E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965)

## Pharma DA

### 1NR – O/V

#### Innovation key to solve crop diseases that result in global famine

Clark 10 – David Clark, Professor of Microbiology at Southern Illinois University, David, Germs, Genes, and Civilization, p. 250-251

One way to combat resistance is to replace old antibiotics with newly invented ones. Soon after they were first discovered, there was a big rush to discover new antibiotics or modify old ones chemically, yielding new variants. When most known bacterial diseases had cures, complacency set in. Recently, drug resistance has hit the headlines and research has picked up again. Although some new antibiotics are now in the pipeline, it takes several years to get a new drug from laboratory to hospital. As new antibiotics are deployed, resistance will inevitably appear. We can look forward to a permanent cold war between bacteria and pharmaceutical companies. Where do the resistance genes on plasmids come from? They are gifts from Mother Nature, like most antibiotics. Long before humans isolated penicillin from the mold Penicillium, or streptomycin from the bacterium Streptomyces, these antibiotics were deployed to wage biological warfare in the soil. Bacteria and molds have been slugging it out for eons before humans joined in the fray. Not only did microorganisms develop antibiotics to kill each other, but they developed resistance mechanisms to counter each other’s attacks. Some bacterial cultures stored before penicillin was discovered already had resistance genes. Thus, resistance to most antibiotics probably predates their use by humans. Increased use has led to the spread of these resistance genes. Disease and the food supply We have focused on human disease, but remember that livestock and crop plants suffer from infections, too. Modern farmers tend to rely heavily on a few main crops, with little crop rotation. Large areas of a single crop provide the same opportunities for plant diseases that overcrowded cities provide for human infections. The warmer, wetter weather that is becoming more prevalent favors fungal infections that attack plants. For example, wheat scab outbreaks in the United States and Canada caused massive losses in the 1990s. Decreased surpluses in the major grain exporters undermine the safety net for overpopulated third world nations. If major drought in tropical areas such as Africa or India coincides with major crop losses in the grain exporters, the result could be widespread famine. In 2006-2007, world grain reserves fell to 57 days of consumption, the lowest since 1972. Perhaps the most serious current threat to our food supply is the wheat rust fungus (Puccinia graminis). A new and highly virulent strain emerged from Uganda in 1999 and was, therefore, named Ug99. It is presently in Africa and parts of Asia. Because the spores are airborne, this fungus will inevitably spread worldwide. Breeding resistant wheat varieties is in progress but takes several years. Overpopulation and microbial evolution Overpopulation does not merely threaten starvation; it sets the scene for the evolution of new infectious diseases. The more people there are—and the more crowded, unhygienic, and malnourished they are—the greater the opportunity for some new and virulent plague to emerge. So far, we have kept ahead.

#### Extinction

Carr 10 – Gad Loebenstein, Professor of Plant Pathology at the Agricultural Research Organization and John P. Carr, Head of the Department of Plant Sciences at the University of Cambridge, Advances in Virus Research, Volume 75, 2009, Pages ix–x, Science Direct

Since the very earliest developments in agriculture, and probably even before then, diseases affecting crop plants have posed an ever-present, yet ever changing, threat to human survival. The Bible, for example, explicitly mentions blights, blasts, and mildew diseases of wheat. Not surprisingly, people sought to understand and mitigate the effects of disease on crop productivity, and many earlier cultures have sought divine aid in the fight against crop disease. The Romans, according to some historians, celebrated the festival of Robigalia: an attempt to mollify Robigus, the god thought to protect crops from disease, and his less benign sister Robiga (or Robigo), a primary goddess of Roman farmers, known as the spirit of mildews and rusts. However, even during this period there were attempts to understand plant diseases through the application of reason: an approach exemplified in the writings of Theophrastus (372–287 BC), who theorized about the nature of the diseases of cereals and other plants. Meanwhile, over many centuries farmers all over the world practiced domestication of plants from wild populations and selected the best and hardiest plants grown under agricultural conditions, thereby incidentally breeding plants resistant to disease. In the modern world the deployment of crops possessing genetically based resistance is generally considered the best and most economical approach for disease control. This is especially true for protection against viruses because, so far at least, no chemicals are available that could provide the same degree of protection in the field against these pathogens, as fungicides do against fungi and oomycetes. The transfer by breeding of naturally occurring resistance genes from wild plants or land races to cultivated lines is still an ongoing process, and has been supplemented with other methods such as mutation, polyploidy breeding, and the generation of haploids. Genetic resistance against virus diseases can be surprisingly durable. A good example is that of cucumbers bred for resistance to Cucumber mosaic virus. This resistance, which depends on several genes, was found to be stable for many decades against different strains of this virus. Even though the majority of plants are resistant to most viruses (the phenomenon of non-host or basal resistance), when viruses are able to infect a crop plant, obtaining durable resistance by breeding is not always possible. In certain cases, new virus strains overcome the resistance and once again may cause severe crop losses. In addition, for some crops and viruses, no suitable sources of resistance can be identified among the wild relatives of a crop plant. Hence the need for greater understanding of natural resistance, and for the insights its study can provide for the development of novel crop protection approaches. In the last few years, much has been learned concerning the mechanisms underlying several natural resistance mechanisms including inter alia RNA silencing, induced resistance, and resistance conferred by recessive and dominant genes, which will be discussed in this and the following volume of the Advances. In addition, research over the last two decades has made it possible to move resistance–conferring gene sequences between plants from different botanical genera, or into plants from other organisms, and even from the viruses themselves (pathogen-derived resistance). This work opened a new vista for plant virus control, and if combined with engineering for insect resistance could potentially provide protection not only against the viruses themselves, but also against their vectors. The work on pathogen-derived resistance also led directly to the discovery of a natural resistance and gene regulation mechanism, RNA silencing, that has ramifications throughout the whole of biomedicine. Nevertheless, these technologies face technical and sociological challenges, which are also addressed in these volumes. In all parts of the world, but especially among the developing nations, agriculture faces the looming problems of emerging virus diseases, population growth, and ecological change. We hope that the articles in this volume and the following one will inform and stimulate research on natural and engineered resistance, and thereby contribute to the development of new approaches to disease control and the creation of new resistant varieties that are desperately needed.

### 1NR – AT: Link Turn

#### The threats of treble damages and disgorgement under antitrust law have a unique chilling effect

Eisenstein 21 – Ilana H. Eisenstein, Co-Chair of Appellate Advocacy Practice at DLA Piper, “BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF PETITIONERS,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176027/20210419132645500\_Chamber%20of%20Commerce%20of%20the%20United%20States%20of%20America%20Amicus%20Curiae%20Brief.pdf

Companies face significant enforcement and litigation risks without Noerr-Pennington immunity— risks that will undoubtedly deter their exercise of First Amendment protected activity absent intervention by this Court to establish clear rules for the doctrine’s scope and the narrow “sham” litigation exception.

In the antitrust context, companies face liability for treble damages in suits brought by government enforcers, their competitors, or customers. Octane Fitness, 572 U.S. at 556 (observing the “chilling” effect of the threat of treble damages pursuant to 15 U.S.C. 15). The $500 million dollar disgorgement award obtained by the FTC in this case, on top of a private settlement, demonstrates the substantial risks a company faces when deciding whether it may proceed with efforts to petition the courts or other governmental agencies.

Additionally, unfair competition laws similarly may impose punitive and substantial liability. See, e.g., ADP, LLC v. Ultimate Software Grp., Inc., No. 16-8664-KM-MAH, Dkt. Entry No. 119 (D.N.J., Mar. 5, 2018) (assessing Noerr Pennington immunity in light of claimed punitive damages and attorneys’ fees under various federal and state trade secret and unfair competition laws); Boydstun Equip. Mfg., LLC v. Cottrell, Inc., No. 3:16-cv-790-SI, 2017 WL 4803938, at \*9-\*13 (D. Or. Oct. 24, 2017) (applying Noerr-Pennington immunity to alleged violations of state and federal anti-monopolization laws and “Walker Process” fraud, citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965), which permits treble damages).

The FTC, moreover, has vigorously asserted its claimed right not only to damages, but also to disgorgement. See Shari Ross Lahlou, Greg Luib, & Michael Weiner, HIGH STAKES AT THE HIGH COURT: THE FTC’S DISGORGEMENT AUTHORITY COMES BEFORE THE SUPREME COURT, 35 Antitrust 71, 72 (Fall 2020) (“Since 2012, however, the FTC has routinely sought disgorgement in antitrust cases”); see also AMG Cap. Mgmt., LLC v. Fed. Trade Comm’n, 141 S. Ct. 194, No. 19-508 (argued Jan. 13, 2021).6 Regardless of how this Court decides that question in AMG, private parties may be able to seek disgorgement and other equitable remedies under state law, resulting in substantial exposure. Such a risk is particularly dangerous, when the “sham” exception has been traditionally limited to “those rare instances where other conduct or incriminating documents” show bad faith. Lars Noah, Sham Petitioning as a Threat to the Integrity of the Regulatory Process, 74 N.C. L. REV. 1, 41 (1995).

#### Antitrust liability is distinct from other forms of liability – the massive damages associated with antitrust judgements increases the potential cost of all conduct – the counterplan is a lighter touch

Delrahim ’20 [Makan; JD, former Assistant Attorney General for the Antitrust Division of the United States Department of Justice; “Assistant Attorney General Makan Delrahim Delivers Remarks at IAM’s Patent Licensing Conference in San Francisco,” September 18, <https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-iam-s-patent-licensing>]

It can be a serious mistake for a court to allow either type of claim to proceed under the Sherman Act. To understand why that is the case, one should consider the policies underlying Section 2 of the Sherman Act.

One crucial element in establishing any claim of unlawful monopolization under Section 2 is a showing that a defendant acquired, enhanced, or maintained monopoly power in the relevant market through anticompetitive conduct that is “exclusionary” or “predatory” in nature. I will focus on so-called “exclusionary” conduct—the umbrella concept often invoked by licensees bringing Section 2 claims premised on FRAND violations.

The term exclusionary conduct in antitrust law is potentially misleading because there is a difference under the Sherman Act between “lawful” and “unlawful” conduct that results in exclusion of a competitive alternative. In market economies, every rational business wants to exclude and defeat its competitors, and indeed antitrust law encourages fierce competition among companies aiming for as high a market share as they can achieve. That is why courts applying Section 2 are careful not to condemn “exclusionary” conduct that is driven by competition on the merits such as innovation. Most obviously, legitimate competition on the merits can be “exclusionary” in the sense that consumers choose a superior product or service. That conduct does not violate Section 2. By comparison, conduct that “excludes” a competitor by hindering its ability to offer a superior product or service, without offering any benefit to competition, likely would constitute a Section 2 violation.

When courts police the line between lawful and unlawful “exclusionary” conduct, a few themes emerge.

First, courts have recognized that not every type of conduct that may enhance a business’s market power is actionable, such as when the application of Section 2 would impose a duty that contravenes the policies of the antitrust laws themselves. For example, in Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, the plaintiff alleged that Verizon refused to deal with a rival in order to limit competitive entry, thereby enhancing its monopoly position. The Supreme Court held that the claim did not satisfy Section 2 as a matter of law. That is because the claim would condemn a monopolist’s refusal to share its resources and effectively would create an antitrust duty to help a competitor. Such a duty, the Court explained, is in “tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities.” The Court applied a legal rule, rather than a fact-specific rule, to protect conduct that may have an exclusionary, monopoly-enhancing effect.

Second, the Supreme Court has cautioned against antitrust standards that would create an unacceptable risk of “false positives” or condemnations of lawful pro-competitive conduct. As the Court has explained, “Mistaken inferences and the resulting false condemnations ‘are especially costly, because they chill the very conduct the antitrust laws are designed to protect.’” Judge Robert Bork, in his famous Antitrust Paradox, highlighted the same risk in the application of Section 2 theories, explaining with respect to exclusive dealing that “[t]he real danger for the law is less that predation will be missed than that normal competitive behavior will be wrongly classified as predatory and suppressed.”

This backdrop helps frame the question whether a unilateral refusal to license a lawful patent on “FRAND” terms after committing to do so constitutes a form of unlawful exclusionary conduct. A unilateral violation of a FRAND commitment should not give rise to a cause of action under Section 2 of the Sherman Act, even if a patent holder is alleged to have misled or deceived a standard-setting organization with respect to its licensing intentions. Applying Section 2 to this sort of unilateral conduct would contravene the underlying policies of the antitrust laws. This conduct may warrant remedies under contract law, but the important difference is that contract remedies do not involve the threat of treble damages that can deter lawful, pro-competitive conduct.

In the context of legitimate standard setting, the collective decision to incorporate a patented technology into a standard necessarily involves the “exclusion” of rival technologies. Moreover, as a result of having its technology incorporated into a standard, a patent holder may gain incremental market power beyond any power that holding a patent would already convey. By voluntarily participating in the standard setting process, however, owners of rival technologies and prospective licensees assume the risk that the outcome of that process may have an exclusionary effect where there are patents covering the “winning” technology. Simply winning selection by a standard setting process does not constitute unlawful exclusionary conduct under the antitrust laws. This is because that selection, regardless the reason for it, contributes to unification around a single standard, which creates interoperability benefits for consumers that could not be achieved without unification.

This form of lawful and pro-competitive exclusionary conduct should not be condemned as unlawful under the Sherman Act when a licensee believes that a patent-holder opportunistically has reneged on its commitment to license on “FRAND” terms and engaged in so-called “hold-up.” That is also true even where a patent holder never allegedly intended to license on the terms that a court ultimately determines are “FRAND.” I will explain why.

There is no duty under the antitrust laws for a patent holder to license on FRAND terms, even after having committed to do so. A FRAND commitment is a contractual representation that a patent holder will license on “fair,” “reasonable,” and “non-discriminatory” terms. It is not the same as a promise to pay a specific price in a final contract. Indeed, commentators have noted that by failing to specify a specific price, a FRAND commitment is an incomplete contract term.

To be clear, a FRAND commitment may create a duty under contract law to fulfill that obligation, and courts may be tasked with determining the relevant FRAND rate where parties disagree over this contract term. Section 2, however, is agnostic to the price that a patent-holder seeks to charge after committing to such a term. Breaking down “FRAND” by its component terms makes clear why this is so.

First, the Sherman Act does not police “fair” prices or competition; it protects the competitive process. Judge Easterbrook once asked, “Who says that competition is supposed to be fair, that we judge the behavior of the marketplace by the ethics of the courtroom? . . . When economic pressure must give way to fair conduct . . . rivals will trim their sails”; introducing conceptions of “fairness” into the Sherman Act “is to turn antitrust law on its head.”

Second, having undertaken a contractual duty to charge “nondiscriminatory” rates, the Sherman Act does not compel a patent-holder to abide by this promise. The Sherman Act is indifferent to price discrimination; indeed, in some circumstances price discrimination may be pro-competitive.

Third, the Sherman Act does not authorize courts to determine “reasonable” licensing rates. The Supreme Court has emphasized repeatedly that antitrust law does not recognize a cause of action that would “require[] antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill-suited.”

It, therefore, would be a mistake to infer that a contractual FRAND commitment somehow establishes a duty under the antitrust laws to license on terms demanded by a licensee or that violations of an ambiguous FRAND term become an antitrust violation. Transforming such a contract obligation into an antitrust duty would undermine the purpose of the antitrust laws and the patent laws themselves, both of which serve the same goal of increasing dynamic competition by fostering greater investment in research and development, and ultimately in innovation.

Making the duty to license on FRAND terms enforceable under the antitrust laws would contravene the policies of the Sherman Act. As the Supreme Court recognized in Trinko, a business has no antitrust duty to deal with another company, and only in limited circumstances will a refusal to deal give rise to a potential antitrust claim. As then-Tenth Circuit Judge Neil Gorsuch explained in Novell v. Microsoft, following Trinko, a monopolist’s refusal to license its intellectual property is actionable under the antitrust laws only if it terminates a “presumably profitable course of dealing between the monopolist and the rival” and that termination is “irrational but for its anticompetitive effect.”

I would note that then-Judge Gorsuch’s standard echoes what the United States and FTC advocated to the Supreme Court in its amicus brief in the Trinko case. The brief stated:

Where, as here, the plaintiff asserts that the defendant was under a duty to assist a rival, the inquiry into whether conduct is “exclusionary” or “predatory” requires a sharper focus. In that context, conduct is not exclusionary or predatory unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition.

That narrow window for a refusal to deal claim is irreconcilable with the broader contention that Section 2 obligates an SEP-holder subject to a contractual FRAND commitment to license its technology to any comer—much less on FRAND terms. An antitrust duty to license on FRAND terms would also contravene the patent laws’ policy of promoting innovation by offering incentives for holders of valid patents to seek the greatest rewards possible for their inventions.

To be clear, contract law may very well require an SEP-holder to deal with any willing licensee, but the Sherman Act does not convert FRAND commitments into a compulsory licensing scheme. It logically follows that there is no antitrust liability for proposing to deal at terms that are above FRAND rates.

Nor should an antitrust duty spring into being if a patent holder allegedly “deceives” an SSO when it commits to license on FRAND terms and its participants rely on that representation in deciding to adopt the technology. That is because Section 2 should not condemn a patent holder’s profit-maximizing intentions or aspirations at the time it makes a FRAND commitment, particularly where remedies are already available to an unhappy licensee or SSO participant.

Suppose that, hypothetically, the holder of a standard-essential patent knew upfront precisely what price would satisfy the vague definition of “FRAND” and planned to demand a much higher price after the SSO incorporated its technology into a standard. By making a legally binding commitment, a patent-holder acknowledges that it will be required under contract law to license at a rate determined by a court if a disagreement over that rate arises later. A licensee, for its part, understands that it can bring suit if a price does not fit its own subjective understanding of “FRAND.” Because both patent-holders and licensees participating in a standard-setting process recognize that the proper “FRAND” rate will be determined after the fact—in court, if necessary—there is therefore no meaningful ex ante “deception” that should give rise to an antitrust claim.

To be sure, having one’s technology incorporated into a standard, in some circumstances, may increase a patent-holder’s market power. The same could be said, of course, about a monopolist’s refusal to deal with a rival who might gain market share if it had access to the monopolist’s inputs. Even if this occurs as a result of a patent holder’s so-called “deception” about its licensing obligations, this is not the sort of market-power-enhancing conduct that Section 2 should reach because a cause of action for treble damages would impede the policies underlying the Sherman Act. Even worse, such a cause of action would “require[] the court to assume the day-to-day controls characteristic of a regulatory agency.”

More fundamentally, recognizing a Section 2 cause of action for violations of a FRAND commitment would create an unacceptable risk of “false positive” condemnations of pro-competitive conduct by licensees. The prospect of antitrust liability and treble damages for breaching a potentially vague FRAND term—or allegedly “misrepresenting” one’s intentions to offer some FRAND rate—threatens to chill incentives for innovators to develop new technologies that fuel dynamic competition.

Where contract law remedies exist to remedy and deter breaches of a FRAND commitment, the additional deterrence that Sherman Act remedies offer could deter lawful, pro-competitive conduct—that is, research and development by innovators who make careful cost-benefit calculations as to how much to invest in technologies that may not pay off. Demanding a high price for one’s patented technology is permissible, and expected, conduct in a free market negotiation. A Section 2 cause of action would skew the patent licensing bargain away from the bargaining outcome that a free market dictates.

In particular, where the parties have a subjective disagreement over the meaning of an incomplete contract term, a Section 2 remedy threatens the patent holder with the risk of enormously costly litigation and a possible treble damages award. Bargaining in the shadow of litigation, a patent holder would be wary that a high license demand could be penalized by a significant damages award, whereas a prospective licensee’s low-ball offer would do no such thing. Such a remedy would bestow any putative licensee with disproportionate negotiating power. In turn, the cost-benefit calculation for innovators would change and the prospect of additional dynamic competition likely would decline.

#### That specifically chills pharmaceutical R&D – the threat of these high damages means that pharmaceutical companies won’t defend their patent rights, which crushes the revenue required for R&D

Mosier 21 – Mark Mosier, Partner at Covington & Burling LLP, “BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176010/20210419114711882\_Main%20Document.pdf

If the decision below were permitted to stand, innovators would be placed in an untenable position. Faced with an entity potentially infringing on its patent rights, a patent holder would have to decide whether filing suit to protect its rights is worth the risk of incurring treble-damage liability in a subsequent antitrust lawsuit simply because an experienced attorney authorized the suit that triggered the automatic stay provision of the Hatch- Waxman Act and the lawsuit ultimately proved to be unsuccessful. Given the widely acknowledged uncertainty inherent in the outcomes of patent litigation under the Hatch-Waxman Act, patent holders will be deterred from filing suit to enforce their patent rights, undermining a critical component of patent protection. See Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 556 (2014) (recognizing that the threat of antitrust liability can significantly chill patent holders’ exercise of their First Amendment right to petition the government). This deterrence is also contrary to the legislative compromise embodied in the Hatch-Waxman Act, which balances patent protections for pharmaceutical innovators with the encouragement of generic entry. The consequence of discouraging Hatch-Waxman lawsuits will be to discourage the substantial investments required to innovate in the biopharmaceutical industry, with negative consequences for scientific progress, public health, and the economy.

### 1NR – AT: Generic Drugs Solve DA

#### The case can’t turn the DA – even if they solve access in the short term, declining innovation crushes health care and drug access long term

Holman 18 – Christopher Holman Professor at the University of Missouri-Kansas City School of Law, “Patentability Standards for Follow-On Pharmaceutical Innovation,” *Biotechnology Law Report*, 6/1/2018, Number 3, 10.1089/blr.2018.29073.cmh131

The high nonobviousness standard promoted in the Guidelines are unabashedly policy-driven; in the view of their author, the extreme importance of immediate access to pharmaceuticals justifies a uniquely rigorous nonobviousness standard for follow-on pharmaceutical inventions. However, the underlying premise that healthcare would be improved by effectively reducing the availability of patents for pharmaceutical inventions fails to account for the high risk, cost, and uncertainty attendant to the development of an approved drug capable of delivering potentially huge improvements in health. When the entire drug development process is properly considered, some commentators actually argue in favor of a relatively permissive standard of nonobviousness that accounts for the unusually high cost and risk associated with drug development, compared to other types of patent eligible innovations. In that regard, it is important to bear in mind that while a reduction in the availability of patent protection for pharmaceuticals might promote access in the short term, the resultant decrease in the incentive for pharmaceutical development will ultimately harm medium and long-term access.

#### The whole point of generic drugs is that they are first developed as brand-name innovations by pharma companies, so the DA turns the case and not the other way around

Schacht 12 – Wendy Schacht, Specialist in Science and Technology Policy, “Drug Patent Expirations: Potential Effects on Pharmaceutical Innovation,” 3/2/12, https://ipmall.law.unh.edu/sites/default/files/hosted\_resources/crs/R42399\_120302.pdf

While many factors contribute to innovation in the brand pharmaceutical industry and its ability to bring new and inventive products to the marketplace, this sector is facing significant issues associated with the loss of revenue available for additional R&D due to patent expirations and generic competition. Generic versions of brand pharmaceuticals benefit the public due to their lower cost and greater availability. However, experts point out that without the research, development, and testing performed by the brand name pharmaceutical companies, generic drugs would not exist. Thus, there is ongoing congressional interest in striking the proper balance between lower cost drugs and maintaining an innovative domestic pharmaceutical sector.

#### They may strengthen pre-existing innovations, but they destroy key future innovation

McDole 21 – Jaci McDole, senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation, “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic,” 4/29/21, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through>

[Italics in original]

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some *pre-existing innovations*, but it would absolutely limit *future innovations*. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

#### The benefits of the aff would quickly disappear

McDole 21 – Jaci McDole, senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation, “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic,” 4/29/21, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through>

Without the assurance of knowing that other entrepreneurs or companies cannot simply copy their innovation or tarnish their reputation through counterfeit products, innovators will be much less likely to take the risks involved in innovating, and start-ups will be unable to generate capital to bring innovations to market. Whatever supposed benefits are reaped from waiving IP would be very short lived, and consumers would wind up missing out on potential future innovations as entrepreneurs and companies would be significantly challenged to make the investments needed. Strong IP rights have enabled innovators around the world to meet the unique challenges brought on by the COVID-19 pandemic. From start-ups and small enterprises to multinationals, innovators are fighting to end the pandemic and move society forward, and they are able to do this because of IP protection.

### 1NR – AT: Innovation Low

#### The patent cliff has spurred increased innovation but puts the industry on the brink

Ryan 1/11 – Barbara Ryan, founder of Barbara Ryan Advisors, life sciences consulting firm, “Biopharma Reaches New Heights as Calendar Turns,” 1/11/22, https://www.pharmexec.com/view/biopharma-reaches-new-heights-as-calendar-turns

A decade ago, my colleagues at EY (where I am a senior advisor) created the Firepower Index to understand a company’s total capacity to fund deals to achieve their growth goals. EY defines Firepower by the strength of a company’s balance sheet and market capitalization.

In 2021, the biopharma industry’s M&A Firepower reached a whopping $1.2 trillion, a level not seen since 2014, and 14% ahead of 2020. M&A, alliances, and partnerships have always been core to driving the industry’s growth strategies and satisfy their need to access innovation and talent, and this will remain the case.

However, the nature of dealmaking does shift with the times. The looming loss of exclusivity for many companies’ largest revenue-generating products increases the current urgency behind accessing external innovation and new products. EY’s findings show a shift in how they are deploying their available Firepower—away from outright M&A transactions toward strategic partnerships and alliances—and the team expects this trend to continue.

What’s driving the shift in how Firepower is deployed?

One, an innovation renaissance is clearly underway with the promise of novel cell and gene therapies and RNA- and DNA-based medicines to cure, not just treat illness. In order to remain competitive, the larger biopharma companies will need to aggressively pursue external innovation. The challenges to M&A are that many of the new innovators are extremely well funded, thanks to an open spigot of capital flowing into the sector. Through November 2021, biopharmas raised more than $80 billion through venture funding, follow-on offerings, and IPOs. That’s in addition to the $90 billion raised in 2020. Additionally, SPACs acquired many other biopharma innovators, and as of November 2021, there are more than 80 healthcare SPACs with money to deploy.

#### COVID forced innovation that propels the industry forward.

Jenni Spinner 22. Editor. “Road ahead paved with innovation, opportunities: Syneos Health”. Outsourcing Pharma. Jan 4 2022. https://www.outsourcing-pharma.com/Article/2022/01/04/Road-ahead-paved-with-innovation-opportunities-Syneos-Health?utm\_source=copyright&utm\_medium=OnSite&utm\_campaign=copyright

“If there’s one through-line in this year’s report, it’s this: we are an industry working toward sustainable acceleration​,” Householder said. “The pandemic forced fast-moving innovation, prompting biopharma organizations around the world to validate real-time insights and learnings that are now fueling industry change and value creation​.”

The report also touches upon how despite the incredible disruptions and challenges (like burnout and talent retention) emerging in recent months, new product development models are holding up. Further, factors like the drive to elevate diversity, equity, and inclusion (DE&I) are having an effect on how industry professionals are working to improve access and build organizations.

“The human toll from the pace and scale of disruption demands a re-examination of every aspect of product development​,” commented Alistair Macdonald, CEO of Syneos Health. “Simplifying the complex for patients, care providers, scientists, customers, and every employee is essential. These trends are driving much-needed change including exploring new models for enhancing stakeholder value, accelerating digital transformation, and advancing DE&I to propel innovation.​”

The top trends mentioned in the report focus on three themes: value creation, human centricity, and industry change. First, the report predicts that the industry will see increased value creation (which involves working to make sure data and related insights reach all across the product lifecycle to innovate and generate greater value for all stakeholders), covering the following:

Appropriate acceleration in clinical development: according to the report, acceleration in the coming months will be driven by innovative study design and execution, real-world data (RWD) engines, flexible decentralized engagement, and dynamic contracting.

Engagement optimization loop: emerging commercial models, the report holds, will consist of two primary dimensions: human and digital, and players will use omnichannel engagement to both elevate human interactions and deliver insights on how and when to act most efficiently.

Patient-powered design: increasing integration of the patient voice will narrow the long-standing gap between patients and industry professionals, according to the Syneos report.

Aspects of human centricity (which is prioritizing personal relationships and enhancing with tech-enabled insights), will include:

Changing customer interface: the report advises looking for important disruptions in how important stakeholders engage with each other; these include a newly hybrid field, changing roles for clinical research associates (CRAs), new paths to recruitment, and simplification of the complex.

Engaging burned-out healthcare professionals: while people working in this field were already exhausted before the pandemic, the effects of COVID-19 have complicated the situation even more, according to Syneos, changing the way they need to be engaged with. Burned-Out Healthcare Professional

High talent expectations: after a period of unprecedented hiring, many organizations now are short-staffed, changing expectations about employees, and expectations placed on them.

Personal, tailored, and possible: Syneos reports in a recent company study, industry leaders rate their use of modern customer engagement and omnichannel infrastructure at 6/10—better than before the pandemic; company leaders expect this trend to continue in 2022.

Also, in the area of industry change, the report authors expect the field to step up to deal with social policy public health directly, leading by example for other areas of innovation.

Urgency for representation: increasing DE&I within the industry will become an even more critical priority, Syneos anticipates.

Pharma industry reputation: the brightening of the pharmaceutical industry’s reputation (thanks to its rapid COVID-19 response) and waning trust in government to deliver solutions likely will drive a need to maintain and increase the reputation, according to the report.

Dynamic market: Syneos holds that, after years of being responsive and reactive, biopharma will take the lead; this could include leveraging new levels of funding, coming up with novel resourcing models and partners, new global centers of excellence, and more.

#### BUT, 2022 is key – COVID also created industry-wide strains that make now crucial for recovery and sustainability of industry.

Sarah Rickwood 22. Pharma consultant for 30 years, vice president, European thought leadership at IQVIA. “Nine for 2022: innovation and opportunities in healthcare”. Pharma Phorum. Jan 6 2022. https://pharmaphorum.com/digital/2022-innovation-opportunities-healthcare-digital/

Healthcare systems reshape to digitise

The pandemic sharply accelerated progress towards digitisation of healthcare, from remote care to digital monitoring and data collection. Consequently, 2022 will be the year in which the real impacts of the acceleration of digitisation will start to become apparent.

Whilst direction is common digital maturity varies significantly by country. A recent IQVIA evaluation of the relative digital maturity of different European and Middle Eastern Health systems found that while there was a weak general trend towards increasing maturity with increasing GDP/capita, there were clear standouts above and below the line. Early, national-level policy making, followed through with structural investment and local implementation is the formula that brings about the best results.

As the full fallout from the pandemic hits health systems in the form of squeezed budgets, patient backlogs and serious resource shortages, we should expect to see concerted efforts aimed at a leap in digital maturity. In 2022, digital transformation may offer the only way for stressed health systems to move towards a sustainable, post-pandemic future.

RNA Therapeutics come to the fore

For the decade to 2020, RNA therapeutics made few headlines, few deals and little revenue compared to Cell and Gene Therapies. However, introduction of mRNA COVID-19 vaccines transformed the fortunes of the whole sector, as they demonstrated that mRNA therapeutics were manufacturable, deliverable, and safe at an unprecedented scale.

Dealmaking in RNA Therapeutics rose 13-fold from 2019 to 2020. Top 20 pharma such as Sanofi have made significant bets on RNA acquisitions and RNA Vaccine players Moderna and BioNTech now have billions of their own in cash to fund development projects using their RNA technologies beyond COVID-19 vaccines and into non-vaccine areas.

A promising but hitherto slowly evolving technology is now turbo-charged to shake up the vaccines field, which would have significant impact in oncology, rare disease and high prevalent, primary care conditions. 2022 may see further deal-making, although valuations will be high. This year will also see the key RNA players future strategy take shape, and the long-term impact of RNA across therapy areas become apparent.

The new reality for innovative launch

In our nine for 2021 predictions, we called out post-pandemic launch as a key area of concern. We saw the pandemic trigger environmental challenges, including reduced opportunities to prescribe new products and less interactive engagement between pharmaceutical companies and healthcare professionals to learn about new launches being significant inhibitors of launch uptake.

Analysing the first six months of innovative launches entering the top eight markets of the US, China, top five Europe, and Japan during 2020 and the first quarter of 2021 shows this concern was justified. Most primary and specialty care innovation entering in this period did not perform as well as the pre-pandemic benchmark of the first six months launch performance.

Orphan medicines were more resilient in 2020, outperforming pre-pandemic benchmarks, although the much smaller Q1 2021 cohort did less well. There’s nothing to suggest that the 2020/2021 cohort of launches are inherently lower potential than those of earlier years – they simply came into the market at a uniquely challenging time.

Unfortunately, IQVIA’s analyses of more than two decades of launches suggest that the first six months of a launch’s commercial life disproportionately influences its subsequent commercial performance. As such, 2022 will provide the first data read out on whether pandemic launches can recover from a lower than expected first six months is available.

As health systems continue to face significant financial and operational pressures, which are directly and indirectly related to the pandemic, 2022 will define a new reality for innovative launches that will stay with us well into this decade.

Pharma’s Battle Chest

The most interesting events of 2022 may be in Pharma’s investment choices to prepare for the coming changes to healthcare. Many companies have a considerable battle chest to spend – by one estimate, 18 pharma majors accumulated a total of $500bn cash by the end of 2021. But what will they do with this in 2022?

A single answer is not necessarily immediately obvious. Acquisitions in hot areas are expensive; large to large mergers don’t solve fundamental issues, share buybacks and dividends are safe but don’t prepare a company for future challenges or growth.

We’ve already seen bolt-on acquisitions, led by AZ’s massive $39bn acquisition of Alexion, which closed in 2021, and 2022 is likely to bring more bolt-on acquisitions. What will matter is not so much size as the quality of investments. If the quality of opportunity is not there at the right price, though, will pharma instead opt for share buybacks, as showcased by BMS’s proposed $15bn share buyback plan?

Pharma’s 2022 investments are likely to be increasingly digital: these may not be the largest investments, but they may be the most crucial, laying the foundations for increased convergence between molecular therapeutics and digital. For example, Biogen’s December 2021 investment in the digital health company TherPanacea, to find digital health tools for neurological conditions.

It is highly likely that 2022 will be a pivotal year for the pharmaceutical industry as it lays the foundations to thrive in a radically altered future.

#### Pharma innovation high – COVID spurred revolutionary advances

Young 21 – Peter Young, President of Young and Partners, chemical and life science investment banking firm, “Doubling Down On Innovation, Recovery,” 9/14/21, https://www.pharmexec.com/view/doubling-down-on-innovation-recovery

Not that long ago, the overall mood in the pharmaceutical and biotechnology industries was somewhat gloomy. The public image of the industry had fallen from being one of the most respected to being characterized as the greedy villain behind high drug prices. Innovation by the large pharma companies had slowed dramatically, even with a slew of innovations focused on speeding up the drug discovery process and on new technologies. The stock market valuations had relentlessly fallen and IPOs of biotech companies were few and far between.

Dialing forward to the picture over the last two years or so and the situation is far more positive. A flurry of new and innovative drugs has shown a global audience that the biopharma industry serves a critical role in fighting diseases. This has been highlighted by new, high-profile discoveries and effective solutions to the current coronavirus crisis, whether it is vaccines or drugs that reduce the severity of the disease for those who are infected. The hugely important development of vaccines to combat COVID-19 has saved millions of lives and, at the same time, changed the attitude of the general public in a more positive direction. Innovation has exploded in all parts of the ecosystem: large pharma, biotech, and collaborations between large pharma and biotech companies, research organizations, and universities. Many of the innovations have been revolutionary (mRNA, immuno-oncology, CRISPR, stem cells, etc.) and others have been evolutionary advances. Drugs and drug delivery systems are being approved in numbers that are very strong. The shift into orphan drugs has created opportunities for biopharma companies of all sizes and has changed the relationship between biotechs and big pharma. Funding for biotech organizations via private investors and institutions and the public markets has been robust, including record numbers of IPOs.

#### No innovation crisis – prefer metrics based on structural novelty

Wills 20 – Todd Wills, Managing Director in the Chemical Abstract Service, a division of the American Chemical Society, “Structural Approach to Assessing the Innovativeness of New Drugs

Finds Accelerating Rate of Innovation,” *ACS Medicinal Chemistry Letters*, 2020, Volume 11, pp. 2114-2119

[NME = new molecular entity]

Although there has been little consensus as to what constitutes drug innovation, an innovation crisis has been a popular topic in the pharmaceutical industry over the past decade.1,2 The total number of new molecular entities (NMEs) approved by the Food and Drug Administration (FDA) each year is a common benchmark used to measure the pace of innovation in pharmaceuticals.3,4 However, a count based measure of innovation is focused on output and is not necessarily indicative of the innovativeness of the NMEs as not all NMEs are equally innovative.

Various attempts at assessing innovativeness have been made using such noncount based criteria as new mechanisms of action (first-in-class), therapeutic need (orphan drug), or improvement over the existing standard of care (breakthrough therapy). Depending on the definition utilized, various studies have found a positive or negative trend in drug innovation. Studies focused on first-in-class and orphan drugs have reported increasing innovation as first-in-class drugs as well as orphan drugs have been found to encompass an increasing and meaningful portion of new drug approvals.5−8 However, studies evaluating improvements in therapeutic benefit report declining innovation as most new drugs were found to only offer minor clinical advantages over existing treatments.2

Although these noncount based indicators can be used to highlight important advancements in the pharmaceutical industry, they may underestimate the rate of innovation occurring as they focus on an outcome rather than the means to achieve a desired outcome. For example, measuring innovation using first-in-class or orphan drug designations will categorize all subsequent drugs in an area as “me-too” drugs, even if they are truly innovative. To more completely measure pharmaceutical innovation, we propose a new indicator of innovation for small molecule and peptide drugs based on structural novelty. This new indicator does not conflate innovativeness with the degree of success achieved as it is based on the structure of a NME at the time of its approval compared to the structures of prior FDA-approved NMEs.

Using our classification scheme based on structural novelty, we evaluated historical pharmaceutical innovation trends over the last 80 years and find that drug innovativeness has significantly increased over the last several decades. An important caveat is that our new indicator is not applicable to biologics which are complex in structure and are usually not fully characterized as they are generally derived from living material. Biologics represent a vibrant area of research. However, small molecules have historically represented a majority of approved new therapeutic drugs and continue to be the dominant drug modality of new drugs.

#### Marginal innovations have declined but major, disruptive innovations are high

Lanthier 13 – Michael Lanthier, operations research analyst in the Office of Planning at the Food and Drug Administration, “An Improved Approach To Measuring Drug Innovation Finds Steady Rates Of First-In-Class Pharmaceuticals, 1987–2011,” *Health Affairs*, 2013, Volume 32, Number 8, pp. 1433-1439

ABSTRACT For more than a decade, industry analysts and policy makers have raised concerns about declining pharmaceutical innovation, citing declining numbers of new molecular entities (NMEs) approved in the United States each year. Yet there is little consensus on whether this is the best measure of “innovation.” We examined NME approvals during 1987–2011 and propose the three distinct subcategories of NMEs—first-inclass, advance-in-class, and addition-to-class—to provide more nuanced and informative insights into underlying trends. We found that trends in NME approvals were largely driven by addition-to-class, or “me too,” drug approvals, while first-in-class approvals remained fairly steady over the study period. Moreover, the higher proportion of first-in-class drug approvals over the most recent decade is an encouraging sign of the health of the industry as a whole.

Innovation in the pharmaceutical industry plays a vital role in improving public health. Major advances in the treatment of cardiovascular disease, infections, cancer, and a host of other medical conditions during the past five decades are attributable to new drug therapies.1 Nevertheless, many serious illnesses lack effective therapies. Recent advances in basic biomedical science and resulting technologies, such as the use of genomics to personalize therapy to individuals, hold great promise for addressing unmet medical needs. An innovative pharmaceutical industry is critical to achieving this public health goal.

The conventional benchmark for measuring the pace of pharmaceutical innovation has been the total number of new molecular entities (NMEs) approved by the Food and Drug Administration (FDA) each year.2–5 Generally, NMEs are considered to be chemically novel drugs and biologics that have not been previously marketed in the United States. The pace of NME approvals since 2000 has been sluggish, raising questions about the state of innovation in the pharmaceutical industry.6,7 Given that investment in pharmaceutical research and development increased greatly over the same time period, this suggests a lower rate of return on investment and raises concerns about the health of the industry as a whole.8,9

However, measuring innovation based solely on the number of new drugs approved has considerable limitations. Although each NME is a chemically unique compound, a new entity could be similar in function and effectiveness to a drug already on the market or a major breakthrough in technology or treatment. To study truly innovative drugs approved since 1987, we proposed an improved approach for measuring innovation by defining three distinct categories of newly approved drugs. These categories separate drugs based on their degree of novelty compared to the existing base of pharmaceuticals. We determined whether an NME was the first drug approved in its class; whether it was a therapeutic advance within an existing drug class; or whether it was an addition to a drug class, providing only modest additional benefit relative to other drugs. Using these definitions, we evaluated long-term trends in innovation during 1987–2011 to determine whether pharmaceutical innovation was really on the decline or whether the outlook was more favorable.

### 1NR – AT: Patent Thickets

#### Patent thickets affect the tech sector because it has tons of low-quality patents that all overlap, but not pharma because pharma patents are high-quality and unique to specific drugs

Kramer 14 – Thomas H. Kramer, intellectual property lawyer, “Proposed Legislative Solutions to the Non-Practicing Entity Patent Assertion Problem: The Risks for Biotechnology and Pharmaceuticals,” 2014, 39 DEL. J. CORP. L. 467

Patents in pharmaceuticals and biotechnology pose significantly different issues, in the context of infringement actions, from those posed by information technology patents.' 6 As they can be precisely described by their distinct molecular structures, pharmaceutical patents often attract a relatively small number of infringement claims.' 7 The investment required to produce pharmaceutical patents is often very large.' 8 The process of bringing pharmaceutical products to market is highly regulated.' 9 As a result of these factors, pharmaceutical patents tend to be highly valued throughout their lifespans, and litigation over these patents tends to take place in the setting of disputes between large manufacturing companies, often involving the process of introducing generic drugs in conformance with the Hatch-Waxman Act.'

Information technology, by contrast, may involve large numbers of claims or patents which are "stacked" together in covering a marketed product.'5' The rate of development in the information technology industry is higher, and product turnover correspondingly faster, than in the pharmaceutical industry.'5 2 The investment needed to produce patented technologies in the information technology field is often less than that needed for other types of patents.' Information technology is also less constrained by regulatory requirements.'54 These factors combine to produce patents that often do not hold their value for their full lives, and are often not highly valued.' There are also strong suggestions that as a class, these patents are weak in terms of their "notice" function-they can be relatively ambiguous in terms of the breadth of the right to exclude that they convey.'56

These distinctions underlie the observation, detailed previously, that NPE assertion activity almost never involves pharmaceutical patents.5 NPE patent assertion activity is largely focused in the information technology area, because the characteristics of the patents in that area make them suitable for assertion.'58 The "stacking" of many patented technologies within a given marketed product make manufacturers of those products easy targets for "patent holdup" through the threat of injunction.' 9 The low value of many information technology patents makes them easy to acquire in quantity, and minimizes the financial risk to the owner in the event of invalidation. 60 The low ."notice" quality of these kinds of patents makes defense of infringement actions costly in the context of current discovery and pleading practices."' The legislative reforms previously discussed are a response to the litigation activity associated with a particular technology sector, and not the broader landscape of the entire patent law. ,62

### 1NR – AT: Link is Pharma Lobby

#### We’ll insert this list

Gidley 21 – J. Mark Gidley, White & Case LLP, “BRIEF OF AMICI CURIAE LAW PROFESSORS IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176016/20210419113917235\_2021-04-19%20AbbVie%20v.%20FTC%20No.%2020-1293%20Law%20Professors%20Amicus%20Brief.pdf

APPENDIX: LIST OF AMICI CURIAE1

Richard A. Epstein

Laurence A. Tisch Professor of Law

New York University School of Law

James Parker Hall Distinguished Service Professor

of Law Emeritus

University of Chicago Law School

Adam Mossoff

Professor of Law

Antonin Scalia Law School

George Mason University

Kristen Osenga

Austin E. Owen Research Scholar & Professor of Law

University of Richmond School of Law

Justin (Gus) Hurwitz

Associate Professor of Law

University of Nebraska College of Law

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