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## 1NC

### T-Prohibit---1NC

#### ‘Prohibiting’ a practice requires per se illegality.

Lee Mendelsohn 6, Director at Edward Nathan, “KIPA Conduct Amounts to Price Fixing”, Business Day (South Africa), 6/12/2006, Lexis

The first step in any competition law analysis is to define the relevant market. There are two components to an analysis of the relevant market, namely the relevant product market and the geographic market.

The relevant product market consists of those products and services that operate as a competitive constraint on the behaviour of the suppliers of those products and/or services.

The relevant product market is determined by ascertaining whether a small but significant non-transient increase in pricing of the product in question would cause buyers to substitute the product with another product or would cause suppliers of other products to begin producing the product in question.

The relevant geographic market is determined by ascertaining whether a small but significant non-transient increase in pricing of the product in question would cause buyers to purchase the product from other geographic areas, alternatively suppliers of the product in other geographic areas to supply those products into the area in question.

For the purposes of this case study, we are instructed to accept that each medical speciality constitutes a relevant product market and that the relevant geographic market for each of them is Kleindorpie.

The Competition Act provides that "an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if … it involves … directly or indirectly fixing a purchase or selling price or any other trading condition".

An "agreement" is defined as including a contract, arrangement or understanding, whether or not legally enforceable. The term agreement is very widely defined. A "horizontal relationship" is defined as a "relationship between competitors".

The prohibition on the fixing of a purchase or selling price or any other trading condition is one of the so-called "per se" prohibitions which are included in our Competition Act. The prohibition is automatic and absolute and the fixing of prices or other trading condition cannot be justified on the basis of any technological, efficiency or other procompetitive gains that could outweigh the potential anticompetitive effect of the fixing of the price or trading condition. If the capitation plan of KIPA falls within the restrictive horizontal practice prohibiting price fixing and the fixing of other trading conditions, such practice will be a contravention of the act.

#### Limits---many standards, requiring distinct answers, make the topic unmanageable.

#### Ground---fringe standards dodge links and allow bidirectional permissiveness.

### T-Private---1NC

#### The plan doesn’t limit “anticompetitive business practices by the private sector”

Bruce H. Kobayashi and Joshua D. Wright 20. George Mason University - Antonin Scalia Law School. “Antitrust Exemptions and Immunities in the Digital Economy” https://gaidigitalreport.com/wp-content/uploads/2020/11/Kobayashi-Wright-Antitrust-Exemptions-and-Immunities-in-the-Digital-Economy.pdf

Noerr-Pennington’s scope reflects the assumption that the Sherman Act applies to private conduct—generally, the Act does not apply to anticompetitive government action.141 As an extension, private conduct aimed at influencing government action, even if it is anticompetitive, receives protection because the Constitution preserves the right to petition. Immunity is not extended in cases where the private conduct itself causes the anticompetitive harm. Nor is immunity extended where the private conduct directly influences private conduct which, in turn, indirectly influences government action. These distinctions are not always clear, but each has been addressed by the Court.

#### Vote neg for limits and ground---the aff explodes the topic beyond private sector business practices, which makes it completely unpredictable for the neg, and guts core DA ground based on private-sector practices.

### Chilling DA---1NC

#### The economy is growing now.

Tim Smart 1/21/22. Contributing Editor for News at U.S. News & World Report. “Leading Indicators Suggest Economy Will Keep Growing.” https://www.usnews.com/news/economy/articles/2022-01-21/leading-indicators-suggest-economy-will-keep-growing

A forward-looking gauge of the economy’s health rose 0.8% in December, the Conference Board reported on Friday.

The organization’s Leading Economic Index now stands at 120.8, following a 0.7% increase in November. The move is consistent with many reports that foresee steady, if slower, growth ahead for the economy.

“The U.S. LEI ended 2021 on a rising trajectory, suggesting the economy will continue to expand well into the spring,” said Ataman Ozyildirim, senior director of economic research at The Conference Board. “For the first quarter, headwinds from the Omicron variant, labor shortages, and inflationary pressures – as well as the Federal Reserve’s expected interest rate hikes – may moderate economic growth.”

“The Conference Board forecasts GDP growth for Q1 2022 to slow to a relatively healthy 2.2% percent (annualized),” he added. “Still, for all of 2022, we forecast the US economy will expand by a robust 3.5 percent – well above the pre-pandemic trend growth.”

#### The plan deters all petitioning.

James M. Sabovich 08. Senior associate in Gibson, Dunn & Crutcher, LLP's Environmental and Natural Resources Practice Group. J.D. from UCLA in 2001. "Petition without Prejudice: Against the Fraud Exception to Noerr-Pennington Immunity from the Toxic Tort Perspective." Penn State Environmental Law Review 17, no. 1 (Fall 2008): 1-54

V. The Political Speech Lessons of Toxic Torts: Why a Fraud Exception Begets Folly

Noerr-Pennington immunity is premised on the recognition that the specter of tort liability for petitioning is a powerful and undesirable 226 deterrent. The longstanding constitutional edict in the United States is that an atmosphere of freedom to petition, on the whole, is a societal good,227

---FOOTNOTE 227 STARTS, MID-PARAGRAPH---

227. See, e.g., E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 139-40 (1961) ("A construction of the Sherman Act that would disqualify people from taking a public position on matters in which they are financially interested would thus deprive the government of a valuable source of information and, at the same time, deprive the people of their right to petition in the very instances in which that right may be of the most importance to them.").

---FOOTNOTE 227 ENDS, PARAGRAPH CONTINUES---

while systematic inhibitors of petitioning are a detriment.22 8

There are two lessons relevant to political speech to be taken from the Bendectin and breast implant litigation, and another from sitespecific lobbying. First, neither the causative allegations nor verdicts in toxic torts are particularly good indicators of scientific truth. As a society, we would be foolish to allow either to set the bounds of our political discourse. Second, the toxic tort is politicized such that it influences and is itself influenced by regulatory and legislative determinations. This is to be expected, but becomes problematic if a fraud exception to Noerr-Pennington immunity allows one side to be systematically deterred from participating in the political process. It is undemocratic and contrary to Noerr-Pennington for any tort allegation or finding to circumscribe political debate. Those of the toxic tort are uniquely unsuited to do so because each party can potentially enhance its litigation position through political success. Lastly, a fraud exception to petition immunity undermines site-specific lobbying by stifling necessary communication between PRPs and agencies with the threat of voyeuristic fraud claims.

#### That collapses the economy---removes incentives for innovation.

Mary Fales 16. Patent attorney & founder of San Diego Patent Prep & Pros, Inc., has been practicing U.S. and foreign patent preparation and prosecution for over ten years. She started out as a registered patent agent in 2008. “The Truth About Patent Trolls – An Honest Look at What's Really Happening and at Stake” SSRN. 1-1-2016. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2709493

What Do we Know?

IP is Critical to the U.S. Economy

Even before the U.S. Constitution colonies allowed for patent monopolies in order to attract valuable technology and resources to newly undeveloped lands.154 Individual States seeing the benefit of patents allowed patent monopolies in a variety of terms and conditions before the national system under the Constitution.155 Since the Constitution our country has been developing our patent system for hundreds of years. There have been turbulent times throughout,156 but the undisputed fact is IP is necessary for economic growth.157 As the U.S. trade deficit increased from labor moving offshore, in the 1980s President Reagan’s administration fought for patent laws that would protect not only our IP, but the IP of other countries.158 The courts who had been traditionally anti-monopoly began upholding patents in court.159 The U.S. emerged as global IP leader. In the mid 1990s the U.S. IP exports were well over 50% of all U.S. exports.160 In 2012, using only IP royalties and license fees, it was estimated that the U.S. exported $120.8 billion.161 Without the financial incentives of being able to obtain patents, most companies and individuals would not invest their time and money into innovation.162 The U.S. economic power is rooted firmly in IP. “IP-intensive industries accounted for about $5.06 trillion in value added, or 34.8 percent of U.S. gross domestic product (GDP), in 2010.”163 We need to protect our IP system in order to maintain our economy, and we need to make sure that going after an annoyance like trolls won’t jeopardize it, because a lot is at stake.

The Supreme Court Opened the Software Patent Doors and Can Close Them

I’m not arrogant enough to claim to be able to read The Supreme Court Justice’s minds, but it doesn’t take much thought to realize trolls may be a consideration in regards to Alice Corporation v. CLS Bank International. 164 The strong relationship between software patents and trolls can’t be overlooked. Let’s face it, the facts are trolls acquire software and business method patents, because they lend themselves to being broad and infringed by many users. Software patents increased as a result of Diamond v. Dierh. Other countries that have stricter patent laws regarding software like India and Japan, don’t seem to have much of a Troll problem at all.165 In fact, India’s 2005 Patent Act greatly reduced the amount of troll issues they were having.166 Plus, it’s not the first time the Court has made efforts to reign in the overly broad patents that have a high social cost. 167 This is what the court does well according to Cass & Hylton.168 It seems reasonable the Supreme Court could be reconsidering their previous decision on allowing software patents to be patent eligible subject matter under 35 U.S.C. § 101.

The issues surrounding software patents are complicated. Many large companies that heavily support the U.S. economy rely on them.169 However, they have been controversial and many think they should never have been patentable subject matter in the first place.170 The truth is we have them now, companies have invested and become dependent on them, and taking away their protection completely under 35 U.S.C. § 101 seems catastrophic. It’s like thinking we can pluck Mercury out of our solar system and nothing negative will result. More is at stake than troll attacks. What’s at stake is the U.S. economy itself. We’ve put into action safe anti-troll changes, but we need to give them time to work.

Conclusion

Trolls, are a problem, but the truth is no one knows just how big of a problem they are. We need more accurate data and well reasoned educated thought to address them. We’ve already moved to good places for the long run with AIA, the market, and court support. We just need to give these measures time to work. Let’s not harm the U.S.’s economy and global IP leadership by trying to swat away some trolls. If we make hasty decisions, we could be in a lot more trouble than we are today.

#### Economic decline cascades and goes nuclear---defense doesn’t assume post-COVID shifts.

Dr. Mathew Maavak 21, PhD in Risk Foresight from the Universiti Teknologi Malaysia, External Researcher (PLATBIDAFO) at the Kazimieras Simonavicius University, Expert and Regular Commentator on Risk-Related Geostrategic Issues at the Russian International Affairs Council, “Horizon 2030: Will Emerging Risks Unravel Our Global Systems?”, Salus Journal – The Australian Journal for Law Enforcement, Security and Intelligence Professionals, Volume 9, Number 1, p. 2-8

Various scholars and institutions regard global social instability as the greatest threat facing this decade. The catalyst has been postulated to be a Second Great Depression which, in turn, will have profound implications for global security and national integrity. This paper, written from a broad systems perspective, illustrates how emerging risks are getting more complex and intertwined; blurring boundaries between the economic, environmental, geopolitical, societal and technological taxonomy used by the World Economic Forum for its annual global risk forecasts. Tight couplings in our global systems have also enabled risks accrued in one area to snowball into a full-blown crisis elsewhere. The COVID-19 pandemic and its socioeconomic fallouts exemplify this systemic chain-reaction. Onceinexorable forces of globalization are rupturing as the current global system can no longer be sustained due to poor governance and runaway wealth fractionation. The coronavirus pandemic is also enabling Big Tech to expropriate the levers of governments and mass communications worldwide. This paper concludes by highlighting how this development poses a dilemma for security professionals.

Key Words: Global Systems, Emergence, VUCA, COVID-9, Social Instability, Big Tech, Great Reset

INTRODUCTION

The new decade is witnessing rising volatility across global systems. Pick any random “system” today and chart out its trajectory: Are our education systems becoming more robust and affordable? What about food security? Are our healthcare systems improving? Are our pension systems sound? Wherever one looks, there are dark clouds gathering on a global horizon marked by volatility, uncertainty, complexity and ambiguity (VUCA).

But what exactly is a global system? Our planet itself is an autonomous and selfsustaining mega-system, marked by periodic cycles and elemental vagaries. Human activities within however are not system isolates as our banking, utility, farming, healthcare and retail sectors etc. are increasingly entwined. Risks accrued in one system may cascade into an unforeseen crisis within and/or without (Choo, Smith & McCusker, 2007). Scholars call this phenomenon “emergence”; one where the behaviour of intersecting systems is determined by complex and largely invisible interactions at the substratum (Goldstein, 1999; Holland, 1998).

The ongoing COVID-19 pandemic is a case in point. While experts remain divided over the source and morphology of the virus, the contagion has ramified into a global health crisis and supply chain nightmare. It is also tilting the geopolitical balance. China is the largest exporter of intermediate products, and had generated nearly 20% of global imports in 2015 alone (Cousin, 2020). The pharmaceutical sector is particularly vulnerable. Nearly “85% of medicines in the U.S. strategic national stockpile” sources components from China (Owens, 2020).

An initial run on respiratory masks has now been eclipsed by rowdy queues at supermarkets and the bankruptcy of small businesses. The entire global population – save for major pockets such as Sweden, Belarus, Taiwan and Japan – have been subjected to cyclical lockdowns and quarantines. Never before in history have humans faced such a systemic, borderless calamity.

COVID-19 represents a classic emergent crisis that necessitates real-time response and adaptivity in a real-time world, particularly since the global Just-in-Time (JIT) production and delivery system serves as both an enabler and vector for transboundary risks. From a systems thinking perspective, emerging risk management should therefore address a whole spectrum of activity across the economic, environmental, geopolitical, societal and technological (EEGST) taxonomy. Every emerging threat can be slotted into this taxonomy – a reason why it is used by the World Economic Forum (WEF) for its annual global risk exercises (Maavak, 2019a). As traditional forces of globalization unravel, security professionals should take cognizance of emerging threats through a systems thinking approach.

METHODOLOGY

An EEGST sectional breakdown was adopted to illustrate a sampling of extreme risks facing the world for the 2020-2030 decade. The transcendental quality of emerging risks, as outlined on Figure 1, below, was primarily informed by the following pillars of systems thinking (Rickards, 2020):

• Diminishing diversity (or increasing homogeneity) of actors in the global system (Boli & Thomas, 1997; Meyer, 2000; Young et al, 2006);

• Interconnections in the global system (Homer-Dixon et al, 2015; Lee & Preston, 2012);

• Interactions of actors, events and components in the global system (Buldyrev et al, 2010; Bashan et al, 2013; Homer-Dixon et al, 2015); and

• Adaptive qualities in particular systems (Bodin & Norberg, 2005; Scheffer et al, 2012) Since scholastic material on this topic remains somewhat inchoate, this paper buttresses many of its contentions through secondary (i.e. news/institutional) sources.

ECONOMY

According to Professor Stanislaw Drozdz (2018) of the Polish Academy of Sciences, “a global financial crash of a previously unprecedented scale is highly probable” by the mid- 2020s. This will lead to a trickle-down meltdown, impacting all areas of human activity.

The economist John Mauldin (2018) similarly warns that the “2020s might be the worst decade in US history” and may lead to a Second Great Depression. Other forecasts are equally alarming. According to the International Institute of Finance, global debt may have surpassed $255 trillion by 2020 (IIF, 2019). Yet another study revealed that global debts and liabilities amounted to a staggering $2.5 quadrillion (Ausman, 2018). The reader should note that these figures were tabulated before the COVID-19 outbreak.

The IMF singles out widening income inequality as the trigger for the next Great Depression (Georgieva, 2020). The wealthiest 1% now own more than twice as much wealth as 6.9 billion people (Coffey et al, 2020) and this chasm is widening with each passing month. COVID-19 had, in fact, boosted global billionaire wealth to an unprecedented $10.2 trillion by July 2020 (UBS-PWC, 2020). Global GDP, worth $88 trillion in 2019, may have contracted by 5.2% in 2020 (World Bank, 2020).

As the Greek historian Plutarch warned in the 1st century AD: “An imbalance between rich and poor is the oldest and most fatal ailment of all republics” (Mauldin, 2014). The stability of a society, as Aristotle argued even earlier, depends on a robust middle element or middle class. At the rate the global middle class is facing catastrophic debt and unemployment levels, widespread social disaffection may morph into outright anarchy (Maavak, 2012; DCDC, 2007).

Economic stressors, in transcendent VUCA fashion, may also induce radical geopolitical realignments. Bullions now carry more weight than NATO’s security guarantees in Eastern Europe. After Poland repatriated 100 tons of gold from the Bank of England in 2019, Slovakia, Serbia and Hungary quickly followed suit.

According to former Slovak Premier Robert Fico, this erosion in regional trust was based on historical precedents – in particular the 1938 Munich Agreement which ceded Czechoslovakia’s Sudetenland to Nazi Germany. As Fico reiterated (Dudik & Tomek, 2019):

“You can hardly trust even the closest allies after the Munich Agreement… I guarantee that if something happens, we won’t see a single gram of this (offshore-held) gold. Let’s do it (repatriation) as quickly as possible.” (Parenthesis added by author).

President Aleksandar Vucic of Serbia (a non-NATO nation) justified his central bank’s gold-repatriation program by hinting at economic headwinds ahead: “We see in which direction the crisis in the world is moving” (Dudik & Tomek, 2019). Indeed, with two global Titanics – the United States and China – set on a collision course with a quadrillions-denominated iceberg in the middle, and a viral outbreak on its tip, the seismic ripples will be felt far, wide and for a considerable period.

A reality check is nonetheless needed here: Can additional bullions realistically circumvallate the economies of 80 million plus peoples in these Eastern European nations, worth a collective $1.8 trillion by purchasing power parity? Gold however is a potent psychological symbol as it represents national sovereignty and economic reassurance in a potentially hyperinflationary world. The portents are clear: The current global economic system will be weakened by rising nationalism and autarkic demands. Much uncertainty remains ahead. Mauldin (2018) proposes the introduction of Old Testament-style debt jubilees to facilitate gradual national recoveries. The World Economic Forum, on the other hand, has long proposed a “Great Reset” by 2030; a socialist utopia where “you’ll own nothing and you’ll be happy” (WEF, 2016).

In the final analysis, COVID-19 is not the root cause of the current global economic turmoil; it is merely an accelerant to a burning house of cards that was left smouldering since the 2008 Great Recession (Maavak, 2020a). We also see how the four main pillars of systems thinking (diversity, interconnectivity, interactivity and “adaptivity”) form the mise en scene in a VUCA decade.

ENVIRONMENTAL

What happens to the environment when our economies implode? Think of a debt-laden workforce at sensitive nuclear and chemical plants, along with a concomitant surge in industrial accidents? Economic stressors, workforce demoralization and rampant profiteering – rather than manmade climate change – arguably pose the biggest threats to the environment. In a WEF report, Buehler et al (2017) made the following pre-COVID-19 observation:

The ILO estimates that the annual cost to the global economy from accidents and work-related diseases alone is a staggering $3 trillion. Moreover, a recent report suggests the world’s 3.2 billion workers are increasingly unwell, with the vast majority facing significant economic insecurity: 77% work in part-time, temporary, “vulnerable” or unpaid jobs.

Shouldn’t this phenomenon be better categorized as a societal or economic risk rather than an environmental one? In line with the systems thinking approach, however, global risks can no longer be boxed into a taxonomical silo. Frazzled workforces may precipitate another Bhopal (1984), Chernobyl (1986), Deepwater Horizon (2010) or Flint water crisis (2014). These disasters were notably not the result of manmade climate change. Neither was the Fukushima nuclear disaster (2011) nor the Indian Ocean tsunami (2004). Indeed, the combustion of a long-overlooked cargo of 2,750 tonnes of ammonium nitrate had nearly levelled the city of Beirut, Lebanon, on Aug 4 2020. The explosion left 204 dead; 7,500 injured; US$15 billion in property damages; and an estimated 300,000 people homeless (Urbina, 2020). The environmental costs have yet to be adequately tabulated.

Environmental disasters are more attributable to Black Swan events, systems breakdowns and corporate greed rather than to mundane human activity.

Our JIT world aggravates the cascading potential of risks (Korowicz, 2012). Production and delivery delays, caused by the COVID-19 outbreak, will eventually require industrial overcompensation. This will further stress senior executives, workers, machines and a variety of computerized systems. The trickle-down effects will likely include substandard products, contaminated food and a general lowering in health and safety standards (Maavak, 2019a). Unpaid or demoralized sanitation workers may also resort to indiscriminate waste dumping. Many cities across the United States (and elsewhere in the world) are no longer recycling wastes due to prohibitive costs in the global corona-economy (Liacko, 2021).

Even in good times, strict protocols on waste disposals were routinely ignored. While Sweden championed the global climate change narrative, its clothing flagship H&M was busy covering up toxic effluences disgorged by vendors along the Citarum River in Java, Indonesia. As a result, countless children among 14 million Indonesians straddling the “world’s most polluted river” began to suffer from dermatitis, intestinal problems, developmental disorders, renal failure, chronic bronchitis and cancer (DW, 2020). It is also in cauldrons like the Citarum River where pathogens may mutate with emergent ramifications.

On an equally alarming note, depressed economic conditions have traditionally provided a waste disposal boon for organized crime elements. Throughout 1980s, the Calabriabased ‘Ndrangheta mafia – in collusion with governments in Europe and North America – began to dump radioactive wastes along the coast of Somalia. Reeling from pollution and revenue loss, Somali fisherman eventually resorted to mass piracy (Knaup, 2008).

The coast of Somalia is now a maritime hotspot, and exemplifies an entwined form of economic-environmental-geopolitical-societal emergence. In a VUCA world, indiscriminate waste dumping can unexpectedly morph into a Black Hawk Down incident. The laws of unintended consequences are governed by actors, interconnections, interactions and adaptations in a system under study – as outlined in the methodology section.

Environmentally-devastating industrial sabotages – whether by disgruntled workers, industrial competitors, ideological maniacs or terrorist groups – cannot be discounted in a VUCA world. Immiserated societies, in stark defiance of climate change diktats, may resort to dirty coal plants and wood stoves for survival. Interlinked ecosystems, particularly water resources, may be hijacked by nationalist sentiments. The environmental fallouts of critical infrastructure (CI) breakdowns loom like a Sword of Damocles over this decade.

GEOPOLITICAL

The primary catalyst behind WWII was the Great Depression. Since history often repeats itself, expect familiar bogeymen to reappear in societies roiling with impoverishment and ideological clefts. Anti-Semitism – a societal risk on its own – may reach alarming proportions in the West (Reuters, 2019), possibly forcing Israel to undertake reprisal operations inside allied nations. If that happens, how will affected nations react? Will security resources be reallocated to protect certain minorities (or the Top 1%) while larger segments of society are exposed to restive forces? Balloon effects like these present a classic VUCA problematic.

Contemporary geopolitical risks include a possible Iran-Israel war; US-China military confrontation over Taiwan or the South China Sea; North Korean proliferation of nuclear and missile technologies; an India-Pakistan nuclear war; an Iranian closure of the Straits of Hormuz; fundamentalist-driven implosion in the Islamic world; or a nuclear confrontation between NATO and Russia. Fears that the Jan 3 2020 assassination of Iranian Maj. Gen. Qasem Soleimani might lead to WWIII were grossly overblown. From a systems perspective, the killing of Soleimani did not fundamentally change the actor-interconnection-interaction adaptivity equation in the Middle East. Soleimani was simply a cog who got replaced.

### Taxes CP---1NC

#### The United States federal government should restrict Noerr-Pennington antitrust immunity, enforced by applying a substantial progressive tax on rents from those practices.

#### The CP solves the case by expanding antitrust but, rather than enforcing it with a prohibition, it levies a progressive tax on anticompetitive rents---that’s an instantly effective deterrent AND creates traditional enforcement as follow-on.

Reuven Avi Yonah 21. Irwin I. Cohn Professor of Law and Director of the International Tax LLM Program at the University of Michigan Law School, 7/29/21. “A New Corporate Tax.” https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3743202

If we can regulate our corporations simply through the medium of taxation, we can destroy every trust in a fortnight. It would be a great deal better for the Finance Committee to turn its attention to the imposition of such a tax upon corporations and the persons who actually need regulation, who are exercising powers that are injurious to the American people, destroying competition and invading our prosperity, than to attempt to levy a revenue tax upon all the little shareholders of all the little corporations throughout the length and breadth of the United States.1

I. Introduction: Why Tax Corporations?

Should the U.S. tax corporations? For many academic and political observers, the answer is no.2 The corporate tax is a strange tax because by definition it is not borne by the corporate taxpayer, because corporations are legal entities and cannot economically bear the burden of taxation. Moreover, unlike other indirect taxes (for example, consumption taxes that are passed on to consumers or the employer’s portion of the payroll tax that is passed on to employees), economists after over 50 years of debate are not sure who bears the burden of the corporate tax: shareholders, all capital providers, corporate employees, or consumers. The most likely answer is that all of the above do in varying ratios depending on the current elasticities of capital, labor, and demand in the global economy, and on the degree to which the U.S. economy is open.3

The general public, on the other hand, is convinced that the corporate tax is borne by large corporations, and politicians respond by maintaining the corporate tax as a tax paid by someone other than the voters. But this fiscal illusion, the opponents of the tax pronounce, is hardly a valid reason to maintain a very complicated tax that is the cause of significant deadweight loss (changes in behavior caused by the tax) and transaction costs (tax compliance and avoidance costs).4

This article will argue that we do need a corporate tax, but not for the traditional reason, which is that if we do not tax corporations, rich shareholders will be able to defer tax on their income. Instead, the article will argue that we should tax corporations for the same reason we originally adopted the corporate tax in 1909: to limit the power and regulate the behavior of our largest corporations, which are monopolies or quasi-monopolies that dominate their respective fields and drive their competitors out of business (the best example being Big Tech — that is, Amazon, Apple, Facebook, Google, and Microsoft). But if that is the reason to have a corporate tax, it should have a different structure from the current flat corporate tax of 21 percent. Instead, the tax should be set at zero for normal returns by allowing the expensing of physical capital, but at a sharply progressive rate for supernormal returns (rents), culminating at a rate of 80 percent for income above $10 billion a year.5 After this introduction, Section II of the article discusses and rejects the traditional reason given for taxing corporations. Section III argues that the only reason to maintain a corporate tax is as a tax on monopolistic rents. Section IV develops this proposal in some detail and Section V provides a conclusion.

II. A Tax on Shareholders?

The traditional reason for taxing corporations is that if we did not, rich shareholders would be able to earn their income through corporations and defer the tax until there is a dividend distribution or they sell the shares, or even avoid the tax altogether by holding their shares until death and having their heirs sell at a stepped-up basis.

That is not a valid reason for keeping alive a tax as complicated and costly as the corporate tax, which is why many academic observers have called for its abolition. Given that the corporate tax rate has been sharply cut to 21 percent and that the revenue from the corporate tax is at $230 billion (in 2019) and only a small fraction (below 7 percent) of total federal revenues of $3.4 trillion, it does not appear impossible that some future president could successfully argue for abolishing the corporate tax, despite its public popularity.

There are three reasons why the corporate tax is not a valid way of taxing shareholders. First, despite over 50 years of economic research, economists are still unsure of who bears the burden of the corporate tax.6 Plausible candidates are (a) the shareholders, if the corporate tax reduces corporate profits available to them as dividends or is reflected in the price of their shares (although even that assumes that the tax was not priced in when they bought the shares, in which case only the original shareholders in an initial public offering bear the burden); (b) all capital providers, if the tax causes capital to flow from the corporate to the noncorporate sector, which is influenced by the ever-changing relative tax rates on corporate versus passthrough businesses; (c) employees, if the corporations can effectively reduce wages in response to the tax by, for example, threatening to move production overseas; or (d) consumers, if corporations enjoy a monopolistic or quasimonopolistic position and therefore can raise prices to include the tax without fear of being undercut by competition. The true answer is probably that all of the above bear the burden in different ratios over time depending on the elasticities (response to the tax) of capital, labor, and demand.

Second, as economists have recently emphasized, many shareholders are tax exempt. In fact, a recent study has shown that 70 percent of U.S. equities are held by tax-exempt institutions or individuals (for example, through retirement accounts).7 The authors of the study argue that this is a reason to tax corporations because otherwise capital would not be taxed at all, but it seems to me that if we believe in the reason that we exempt these individuals and institutions from tax, there is no reason to tax them indirectly through a corporate tax (assuming that they do in fact bear the tax burden).

Third, even for taxable shareholders, there are better ways of taxing the shareholders directly, thereby eliminating the incidence issue. For closely held corporations, the answer is to tax the shareholders on their income earned through the corporation — that is, to make passthrough treatment mandatory — because there are no administrability issues for those corporations and most of them are passthroughs in any case. For publicly traded corporations and partnerships, passthrough taxation is not administratively feasible. Instead, the shareholders should be taxed on the changing value of their shares, because liquidity and valuation are not issues for publicly traded shares, and the same tax can be collected on a withholding basis on foreign shareholders and if necessary on tax-exempt domestic shareholders (the government can impose a lien on some of the shares and sell them if the tax is not paid by foreign shareholders).8 Pre-enactment unrealized appreciation can be reached by applying the tax in the year of enactment to the difference between the end-ofyear share value and original basis.

For these reasons, if the only rationale for having a corporate tax is to indirectly tax shareholders, it is not clear that it is worth fighting for against the many voices calling for its abolition. But that is in fact not the only rationale, as the next section explains.

III. A Tax on Monopolistic Rents

When the corporate tax was enacted in 1909, taxing shareholders was not the reason. In fact, taxing shareholders would in 1909 have been unconstitutional under the Supreme Court’s 1895 Pollock decision9 which both President Taft and then-Senate Majority Leader Nelson Aldrich believed precluded a tax on shareholders, although to placate the Progressives they also introduced a constitutional amendment to allow Congress to tax individual income, which neither expected to pass. Instead, the corporate tax was designated as an excise tax on the privilege of conducting business through the corporate form, since the Supreme Court had held such excise taxes on corporations to be constitutional in 1898; but neither Taft nor Aldrich thought that was a good reason to impose a federal tax on corporations, because the privileges of the corporate form derived from state, not federal, law.

Instead, as I have shown elsewhere by examining the legislative history, the corporate tax of 1909 was primarily seen as a vehicle for limiting the power of and regulating the great trusts such as John D. Rockefeller’s Standard Oil Co. or J.P. Morgan’s U.S. Steel Corp.10 The Taft administration was at the same time litigating against Standard Oil and American Tobacco (among many other trusts) to break them up under the Sherman Act of 1890, but the prospects of the litigation were uncertain (the government had lost the E.C. Knight case in the Supreme Court in 1895 and only narrowly won the Northern Securities case in 1904). Thus, as Taft said in his message to Congress, we should have a corporate tax to curb the trusts:

Another merit of this tax is the federal supervision which must be exercised in order to make the law effective over the annual accounts and business transactions of all corporations. While the faculty of assuming a corporate form has been of the utmost utility in the business world, it is also true that substantially all of the abuses and all of the evils which have aroused the public to the necessity of reform were made possible by the use of this very faculty. If now, by a perfectly legitimate and effective system of taxation, we are incidentally able to possess the Government and the stockholders and the public of the knowledge of the real business transactions and the gains and profits of every corporation in the country, we have made a long step toward that supervisory control of corporations which may prevent a further abuse of power.11

The corporate tax of 1909 had several features that were considered potentially effective as antitrust measures. First, even though the tax rate was only 1 percent, both supporters and opponents knew the rate could be increased (as it ultimately was, reaching 52.8 percent in 1968) and the threat of those changes might deter the trusts. Second, the tax returns were to be made public, thus alerting the press and the voters to which corporations were the most profitable and therefore the likeliest targets for antitrust enforcement actions. Third, while intercorporate dividends were exempt (a controversial feature, because the trusts were holding corporations), there were no tax-free reorganizations and no consolidated returns.

Unfortunately, all these antitrust features of the corporate tax were eliminated by 1928. The publicity feature was eliminated in 1910, taxexempt reorganizations were adopted in 1919, and consolidated returns were made elective in 1928. Also, various pro-corporate provisions like accelerated depreciation, percentage depletion, and the foreign tax credit were adopted in the same period. While the Franklin D. Roosevelt administration limited the dividends received deduction and tax-exempt reorganizations in the 1930s, it never eliminated them, and subsequent enactments like investment tax credits reduced the corporate tax even further. As for the rate, it never exceeded 52.8 percent (as opposed to the individual rate, which reached 94 percent during World War II and was still as high as 70 percent when Ronald Reagan was elected president). The effective corporate tax rate was much lower because of interest and depreciation deductions and investment tax credits. In 1986 the corporate rate was reduced from 46 percent to 34 percent (later raised to 35 percent), and despite various base-broadening measures, the effective corporate rate remained low. Corporate tax revenues consequently declined from 25 percent of total federal revenues in the 1960s to less than 10 percent in the 2000s. Finally, in 2017 the corporate tax rate was reduced to 21 percent, and it was a flat rate — all the previous progressivity, which applied only to small corporations with revenues below $15 million, was eliminated.

Other than the rates, we are unlikely to reverse these pro-trust features of the corporate tax, because they are old, well established, and benefit small as well as large corporations, which are not the proper subject of a corporate tax designated to limit the power of monopolies and quasi-monopolies.

Recent research by Edward Fox has shown, however, that most of the existing corporate tax falls on supernormal returns.12 Fox shows this by demonstrating from corporate tax returns for 1995-2013 that if expensing of capital expenditures were allowed before 2017, corporate tax revenues would have been almost identical to actual revenues. Because (as discussed later) expensing is equivalent to exempting the normal return, that means that the corporate tax has historically fallen primarily on supernormal returns, or rents. This finding is consistent with Laura Power and Austin Frerick’s evidence from 2016 that excess returns to corporations have been increasing over time.13 In the current environment, because expensing is in fact allowed until 2022, that finding is even more likely to be true.

In that case, and if the main reason to have a corporate tax is to tax rents and limit monopolies, then the tax should have a different rate structure than we have now. I would suggest that the effective tax rate on normal corporate profits be zero. On supernormal returns, because the main concern is monopolies and quasi-monopolies, the tax should be progressive, with a very high tax rate (for example, 80 percent) for profits above a very high threshold (for example, $10 billion). In between, there should be a series of graduated tax rates, similar to the individual rate schedule before 1980.

#### Using taxes as a new, independent regulatory tool mainstreams them as an instrument to broadly cushion societal responses to inevitable ecological, demographic, and political crises---extinction.

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1. Introduction

Environmental problems are of all times. Yet, over the past two decades, climate change, air pollution, natural resource depletion and biodiversity loss have reached the status of worldwide persistent threats (Foxon, Reed, and Stringer 2009). There is increasing consensus in the literature that common policy responses, which are in the main incremental, will not provide structural solutions to those problems (Elzen and Wieczorek 2005). Transition theory links those challenges to socio-technical systems, which fulfil a societal function using technical components, infrastructure, regulations and networks of organisations (Geels and Kemp 2000). A transition is a radical and structural change with economic, cultural, ecological and institutional developments taking place at different levels of the socio-technical system (Rotmans and Loorbach 2009).

An important discussion in transition literature concerns the question of whether transitions, niches and regimes can be governed, or even steered, in a (sustainable) direction. Most transition scholars see an active role for government, but not in the classical way as the top-down commander who can steer at will using its toolbox of instruments (Paredis 2013). Rather, government is seen as just one group of actors (Geels, Elzen, and Green 2004), who are part of the regime but simultaneously shape its adaptive capacity (Smith, Stirling, and Berkhout 2005). Government actors exert a substantial influence on the functioning of the socio-technical system as they often maintain and reproduce regime functions in an intensive manner (Smith, Stirling, and Berkhout 2005).

To address the complexity and long-term focus (one to two generations) of transitions, “existing policy instruments need to be combined with new approaches” (Elzen and Wieczorek 2005, 657). In addition to command-and-control (CAC) instruments and communicative instruments, economic instruments are used in environmental policy (Howlett and Ramesh 2003; Perman et al. 2003). Geels (2012) indicates, in the context of transport systems, that economic instruments can be used to enhance pressure on an unsustainable regime. Chappin (2011) applies simulation models to study the influence of carbon taxes on energy transitions. Although these studies point at the potential of taxation, the theoretical dynamics behind the impact of a tax on the transition process are not yet well understood, and available studies on the topic are scarce. This paper aims to contribute to the growing literature of transition governance by means of an exploratory analysis of the potential of taxation as an instrument to support sustainability transitions. We will do so by combining the literature on environmental taxation with the literature on sustainability transitions, and by identifying the conditions for a tax to have that potential. In our theoretical exploration, we will combine two heuristic frameworks from transition thinking, the multi-level perspective (MLP) and the multi-phase perspective (MPP), with the neoclassical theory of Pigouvian taxation, which is the basis of environmental taxation theory.

This paper is organised as follows. The MLP and MPP are explained in Section 2, along with other transition concepts. In Section 3, an overview is provided of the theoretical foundations of regulatory taxation. Section 4 shows the results of the combination of the theoretical strands of transitions and environmental taxation. Section 5 is dedicated to the limitations and barriers to the potential of environmental taxation, and in Section 6, we draw conclusions and provide suggestions for future research.

2. Transition theory: the MLP and the MPP

The MLP on sustainability transitions distinguishes between three levels (Geels 2004; Verbong and Geels 2007). At the macro level, the landscape represents the external environment of the system. Changes at the landscape level influence the socio-technical system (Markard and Truffer 2008). Examples of such developments are global warming, global economic growth, political crises or demographic evolutions (Geels 2002). At the meso level, the regime is the dominant form of functioning in the socio-technical system (Avelino and Rotmans 2009). The regime can be a dominant technology, institution, policy, practice or culture. At the micro level, niches present alternative (sustainable) technologies, institutions, policies, practices or cultures that cause disruptions in the functioning of the socio-technical system. By experimenting and growing stronger, niches can eventually overtake the role of the regime and install a new dynamic balance in the socio-technical system (Kemp and Loorbach 2006; Loorbach and Wijsman 2013). For example, learning effects from experiments with niche technologies such as photovoltaic energy and wind power in the energy system may make those technologies increasingly successful. After the growing phase, they may also become cheaper than regime technologies such as nuclear and fossil fuel power generation. Those niches exert pressure on the regime, which could, in combination with other pressures from the landscape, policies, market developments and cultures, lead to a replacement of nuclear and fossil fuel-based power by renewables, ending up in a new equilibrium that will be more sustainable than the previous one.

A transition presents a radical and fundamental change in the dominant structure, culture and practices of a socio-technical system (Loorbach and Rotmans 2006). The structure of the system consists of institutional, infrastructure, legal and economic provisions that are inherent to the functioning of the socio-technical system (de Haan 2010). Culture is regarded as the shared values, norms and perspectives, which may be cognitive, normative or ideological in nature, and which underlie the socio-technical system (de Haan and Rotmans 2011). Practices are the routines, habits and procedures operated by the actors in the system, which interact with the structure and the culture of the system.

The change that is required for a transition will not come about in a linear way. Rather, periods of rapid and slow (or no) change can alternate (de Haan and Rotmans 2011). This implies that there are multiple phases in a transition process. Loorbach (2007) describes four phases that together depict an ideal–typical transition process, the MPP. In the first phase, the pre-development phase, actors are engaged in experiments (Kemp and Loorbach 2006). During the take-off phase, the second phase, the regime will show signs of destabilisation and niches will get an opportunity to position themselves as a viable alternative (van der Brugge and Rotmans 2007). Rapid structural and cultural changes in the socio-technical system become visible in the acceleration phase (van der Brugge 2009). In the last phase, the stabilisation phase, a new sustainable regime is established (Avelino and Rotmans 2009).

Transitions are driven by various endogenous and exogenous developments. Exogenous developments are changes at the landscape level. Endogenous developments, on the other hand, are events occurring at the meso level (regimes) and micro level (niches). According to de Haan and Rotmans (2011), there are three groups of conditions for change: tensions, stress and pressure. Tensions are changes occurring at the landscape level threatening the position of the unsustainable regime. A regime that functions inadequately or inconsistently will experience stress, which can nurture the downfall of the regime. Regime pressure or selection pressure, finally, will appear when niches impose themselves on the regime's position by becoming viable alternatives or by making the regime's functioning obsolete. Regime pressure, along with the reactions of regime and niche actors, will create patterns of change (Frantzeskaki and de Haan 2009). When tensions dominate, a reconstellation pattern will appear. Stress and pressure will result in the patterns of, respectively, adaptation and empowerment. When certain patterns chain together, they create transition paths (de Haan 2010). Choices made in the past will affect the path along which transitions will move. Actors are confronted with path dependencies, which may turn into lock-ins. For example, the choice of the authorities of some countries to invest in nuclear power plants has created path dependencies in the energy systems of these countries, which function as lock-ins that prevent a breakthrough to an energy system based on renewable energy.

Two governance approaches within transition science indicate that belief in classical policy solutions is limited. The two most well-known governance models in transition literature are transition management (Loorbach 2007; Kemp and Loorbach 2006; Loorbach and Rotmans 2010) and strategic niche management (Hoogma 2000). Both these governance approaches emphasise the difficulties in steering socio-technical change. Strategic niche management sees the main role of government in process management, creating room for niche experimentation, making sure that the process is not dominated by certain actors, and in learning and facilitating other actors’ learning possibilities (Kemp, Schot, and Hoogma 1998). The other governance approach, transition management, departs from the same view, but presents a process management method for policy-makers wishing to influence burgeoning transition processes (Loorbach and Rotmans 2006). Transition management has been criticised, mainly because the term ‘management’ seems to suggest that it is possible to steer transitions by “deliberate intervention in pursuit of specific goals” in a top-down way (Shove and Walker 2007, 764). Although transition management scholars such as Loorbach and Rotmans develop a more nuanced perspective on the ‘steerability’ of a transition than the name ‘management’ suggests, they do assert that ‘goal-oriented transitions’, in which the policy goals guide the process, exist. This view is not shared by all transition scholars. For example, Dewulf et al. (2009) think that a multiplicity of theories is needed for addressing such complex issues as sustainability. Shove and Walker (2007) question the very starting point of transition management that it is possible to deliberately steer socio-technical system change in any direction.

Both strategic niche management and transition management focus on policies that are aimed at the level of the niches. However, they largely ignore that the destabilisation of incumbent regimes can equally be a valuable strategy, because this could speed up the upscaling of niche technologies (Kivimaa and Kern 2016). Policies discouraging certain niche technologies or practices can play a role here (Turnheim and Geels 2012). Taxation will be further examined as a regime destabilisation instrument, as the main subject of this paper. In addition, ‘policy mixes for creative destruction’ will be explored in Section 4.2.

3. Regulatory and environmental taxation

A basic idea in economics is that markets allocate resources in an efficient way. However, this thesis is only valid under the condition of the presence of well-defined and enforceable private property rights (Perman et al. 2003). If that condition is not met, the market is not capable of creating or maintaining a socially optimal or desirable situation, and market failures appear (Bator 1958). One example of a market failure is the existence of external costs or environmental externalities (Perman et al. 2003). Externalities are “benefits or costs generated as an unintended by-product of an economic1 activity that do not accrue to the parties involved in the activity and where no compensation takes place” (Owen 2004, 129). Pollution resulting from production activities is a typical example of a negative externality imposed on citizens, because the victims of the pollution have no legal rights to claim any compensation for the damage suffered. To resolve this market failure, governments can create property rights for ‘an unpolluted environment’ and give them to the victims, or even to the polluter. In the latter case, the polluter receives a ‘license to pollute’ a certain amount. Following the Coase theorem (Coase 1960), depending on the specific circumstances, this situation will lead to an equally efficient outcome as compared to victim property rights. However, from an equity point of view, the two solutions generate entirely different outcomes, as in the one case it is the polluter who pays, and in the other it is the victim (Perman et al. 2003). In theory, the polluter and the victims could bargain and agree on compensation for the damage based on the victim's or polluter's property rights, in which case government intervention becomes redundant (Coase 1960). In practice, however, the large number of victims and polluters and the costs of bargaining often prevent an optimal outcome of private bargaining. In that case, government regulation, through the use of CAC instruments, economic instruments or suasion, is needed (Perman et al. 2003). In this paper, we focus on the use of taxation as a regulatory2 policy instrument in response to existing market failures. Regulatory taxes aimed at environmental improvement are called environmental taxes.3 An alternative name is Pigouvian taxation, after the twentieth-century economist Arthur C. Pigou, who developed the idea to use taxation to tackle externalities (Pigou 1920). According to Pigou, an environmental tax equal to the marginal damage at the efficient pollution level maximises allocative efficiency and welfare. The theory of Pigouvian taxation belongs to the neoclassical economic perspective, which assumes that economic agents act in a rational way according to their individual preferences in such a way that their utility (or profit for companies) is maximised (rational choice theory). Moreover, neoclassical economics assumes that preferences are fixed, as an exogenous factor, which was the dominant assumption until the 1990s (Arnsperger and Varoufakis 2006). Later, some economists regarded preferences as fixed in the short run, but subject to change in the long run (Doyle 2004). Others completely dismissed the notion of fixed preferences stating that individual preferences change as a result of past outcomes, and sometimes even rapidly and systematically (Van Boven, Loewenstein, and Dunning 2003).

In a first-best world with no uncertainty, regulatory taxes are statically efficient because the emission reductions are achieved while using a minimum amount of resources (Sandmo 2000). They are dynamically efficient because taxpayers will be inclined to seek further reduction methods due to the fact that the undesirable behaviour remains taxed (Faure and Weishaar 2012). In this theoretically ideal situation, a tax always leads to a more efficient solution than a licence or other CAC type of instrument. However, if complexity or uncertainty is introduced, many authors criticise Pigou's theory on the optimal level of an externality tax. Although a complete review of this literature exceeds the scope of this paper, we present three of the most important critiques. First, Coase (1960) dismissed the idea that a tax equal to the marginal damage cost increases total welfare in all situations. When there is uncertainty about the marginal abatement cost curves of polluting firms, the comparison changes. Taxes keep the edge over CAC instruments when the (absolute value of the) slope of the marginal abatement cost curve is greater than the slope of the marginal damage curve. Conversely, when the marginal abatement cost curve is less steep than the marginal damage curve, CAC instruments are to be preferred to taxes (Perman et al. 2003; Baumol and Oates 1988). Second, Baumol and Oates (1988) add that it is often hard to calculate the monetary value of the marginal damage of the polluting activity, in which case a standard may also be the recommended instrument choice. And third, in case of monopoly or oligopoly, the optimal tax rate may vary from lower to higher than the marginal damage (Ebert and von dem Hagen 1998).

An important element in the discussion on the optimal tax rate is the price elasticity of demand, which is not static. The absolute value of demand elasticities tends to increase over time (Lipsey and Chrystal 2007; Pindyck and Rubinfeld 2009). The reason is that demand elasticity is, in fact, mainly determined by the availability of substitutes. Investment decisions are made with a long-term perspective, and in the long run, more options are available for developing new (clean) technologies than in the short run (OECD 2000). For example, Sterner (2007) estimated that the demand elasticity of petrol and diesel in the long run is about three times higher than in the short run.

In addition to determining the correct tax rate, other tax design elements need to be decided. First, the tax base, which is the object that is taxed (Sandmo 2000), needs to be chosen. This can be input products, output products, production factors (energy), production (processes, activities or techniques), consumption or emissions (Vollebergh 2008; Weber 2011). The most effective way of eliminating externalities is by choosing the externality itself (e.g. CO2 emissions) as the tax base (OECD 2010). In practice, emission-measuring problems often hinder direct taxation of emissions. Proxies, such as petrol sold as a transport fuel, then form alternative tax bases (Dias Soares 2011). Second, tax rates can be differentiated (Määttä 2006), in which case certain products, processes or groups of taxpayers are granted a lower tax rate or are exempt from the tax. Third, a tax can be implemented at one specific moment in time or in multiple phases whereby the tax rate is raised or reduced in each phase.

4.1. (In)compatibility arguments

The transition school sees public authorities as just one group of actors in a socio-technical system. They are an important actor, but they cannot steer a transition in a top-down way (Kemp, Rotmans, and Loorbach 2007). Traditional decision-making models, including neoclassical economics, are mostly rejected based on the following four arguments. First, traditional policy-making is deemed unfit for dealing with high-complexity, long-term, wicked societal problems, because the knowledge on ecological cause–effect relations is often limited and political compromises inevitably lead to incrementalism as opposed to structural system change (Rotmans, Loorbach, and Van derBrugge 2005; Kemp, Rotmans, and Loorbach 2007; Mathijs 2008). Second, the existing policies are the result of outdated legislation, routines and institutional relations and are characterised by path dependency and technological lock-in (Rotmans, Loorbach, and Van der Brugge 2005). Third, the view of neoclassical economics on the preferences of individuals is too static, while instead a transition would require changing preferences (Kemp, Rotmans, and Loorbach 2007). Finally, steering a transition towards sustainability involves a subjective interpretation of sustainability, which “should arise from a multi-actor process, involving a balanced diversity of stakeholders” (van der Brugge, Rotmans, and Loorbach 2005, 167). Geels (2012) describes transitions as co-evolutionary processes, which require the involvement of many social groups. Network management in decision-making would be a step forward, but even those policy networks are not necessarily concerned with the long term (Kemp, Rotmans, and Loorbach 2007).

Transition management is a governance approach based on transition theory, which proposes a bottom-up approach to steer a transition, based on multi-actor involvement. However, it does not offer a full-fledged alternative to traditional policy-making, as it is “not directly solution-oriented, but explorative and design-oriented” (Rotmans, Loorbach, and Van der Brugge 2005, 6). Therefore, some transition scholars revert to other academic fields, such as evolutionary economics to analyse sustainability transitions and related policy strategies. Inspired by the field of biology, this field focuses on three central concepts: diversity, selection and innovation. Models from evolutionary economics can cope with complexity; they deviate from neoclassical economic theories by acknowledging that economic agent behaviour is explained by bounded rationality (van den Bergh, Hofkes, and Oosterhuis 2006). People's rationality is bounded because of a lack of appropriate and reliable information, limited cognitive capacities and limited decision-making time (Kahneman 2003; Simon 1955). Evolutionary economics leaves more room for environmental taxation than most transition studies, although it emphasises the need for a combination of policy instruments or policy mixes (van den Bergh et al. 2006). The role of policy mixes for sustainability transitions is further treated in Section 4.2.

So, if the neoclassical policy instrument of environmental taxation is so hard to reconcile with the bottom-up governance principles of transition theory, is it still worthwhile to study the combination? Four arguments support an affirmative answer. First, as we demonstrated in Section 3, the impact of environmental taxation is much higher in the long run than in the short run, which gives this instrument an interesting appeal considering the fundamental long-term change transition theory describes. Second, when the economy is (threatening to get) stuck in a technology that is not serving the long-run transition goal, a regulatory tax on that technology may unlock (further) lock-in, thus avoiding an important obstacle for a sustainability transition (den Butter and Hofkes 2006). Third, policy attention tends to go to supporting niches but much less to destabilising the dominant regime, which is politically more difficult. However, according to Kivimaa and Kern (2016), niche support policies will need to go hand-in-hand with regime destabilisation policies aimed at internalising externalities. A tax on the dominant regime technology is particularly suitable for that purpose (Geels and Schot 2007). Fourth, the bounded rationality concept embraced by transition theory still incorporates a level of rationality, implying that a price signal may still have an effect.

We conclude that there is no consensus on the use of regulatory taxes to enhance sustainability transitions. Some scholars see a role for taxation, but rather as one part of a more comprehensive policy mix (Geels 2006; Kemp, Schot, and Hoogma 1998; Markard and Truffer 2008).

### Intrastate Pic---1NC

#### The United States federal government should

#### - ban interstate and foreign anticompetitive action grounded in Noerr-Pennington antitrust immunity

#### - Determine that applications of federal antitrust law to intrastate anticompetitive practices violates the Commerce Clause.

#### The fifty states and all relevant territories should uniformly restrict Noerr-Pennington antitrust immunity.

#### It competes---the counterplan retracts the scope of antitrust law AND PICs out of intra-state anticompetitive practices.

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Abandoning the substantial effects test and retracting the scope of the Sherman Act would reboot competitive federalism in the antitrust field. States would again be free to adopt unique antitrust doctrine applicable to restraints that occur within their borders and produce no external harm. States would reap the benefits of doctrinal innovations, with no prospect that federal courts applying the Sherman Act will undermine state-specific policies. 556 The resulting competition between the states acting as "laboratories of democracy"557 would presumably generate a wider variety of possible solutions-both substantive and institutional-to various antitrust problems, as states vie for producers and consumers by offering rival packages of antitrust doctrine and enforcement institutions. 558 This decentralized process of articulating antitrust doctrine and policy would generate both experience and data about the impact of various rules and institutions, thereby informing lawmakers and state courts considering possible reforms. Federal courts, too, could learn from these results, drawing upon the "accumulated experience" of various states when fashioning Sherman Act doctrine. 559

Retraction of the scope of the Sherman Act would also radically alter the prominence and role of the state action doctrine, first articulated in 1943 in Parker v. Brown.560 As noted earlier, the vast majority of cases where parties raise the state action defense involve police power regulations restraining local commerce without producing any interstate harm.51 No doubt the resulting framing of the legal question as a clash between the Sherman Act and historic police power regulation has deterred the Court from invoking the Act as a source of general authority to evaluate the "reasonableness" of garden variety state regulations, especially during the 1940s, when faith in the motives and capacity of regulators was at its apogee.5 2 Indeed, scholars and jurists have attributed Parker to just such an anti-Lochnerian impulse. 563

Restoration of the pre-1948 direct/indirect standard would place such local regulations beyond the reach of the Sherman Act altogether, eliminating the need for any state action analysis with respect to such restraints.564 The Supreme Court's state action docket would shrink accordingly. Moreover, state action cases that did reach the Court would differ significantly from those that have thus far informed the Court's treatment of state-imposed restraints. Instead of state regulations of local billboards, dentistry, and intrastate lawyer advertising, such cases would, like Parker, involve state restraints imposing substantial harm on out-of-state consumers. 565 This new framing could force the current Court, less friendly to regulation than the Parker Court, to reconsider its hands-off approach to state-approved restraints. Reducing the scope of the Sherman Act could ironically result in more robust preemption of state-approved restraints than ever accomplished under the post1948 regime.

#### Solves the case and restores competitive government---the plan and perm unduly expand the Commerce Clause.

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Scholars and jurists increasingly acknowledge that the U.S. Supreme Court's Commerce Clause jurisprudence desperately needs a new direction. Even Laurence Tribe, widely regarded as a liberal commentator, concedes that until very recently the Court's decisions in this area came dangerously close to foreclosing it from imposing any kind of principled constitutional limitation on the scope of Commerce Clause jurisdiction.3 Chief Justice Rehnquist has openly admitted that much of the case law in this area is less than a model of clarity.4 In what has been heralded by some as the Rehnquist Court's "celebrated project to re-establish structural constitutional principles on federalism,' ' and by others more prosaically as "the new federalism, ''6 recent Supreme Court cases have imposed Tenth Amendment constraints on federal commerce power,7 limited the local application of federal regulatory statutes to Congress's unmistakable intent," and most importantly found that local non-economic activities lie outside the constitutional scope of Commerce Clause jurisdiction.9 Yet, in spite of indications the Rehnquist Court is inclined to seek a new direction, it remains to be seen how it might do so in a way that minimizes troublesome conflicts with the existing body of constitutional precedent. This Article shows that the Court can look to the evolution of Sherman Acto jurisdiction to realign its approach to Commerce Clause jurisdiction to restore the balance of dual sovereignty while posing little immediate threat to constitutional precedent.

The first of two steps is for the Court to fully embrace competitive federalism as the long-run framework within which to gradually narrow the evolving contours of Commerce Clause jurisdiction." Competitive federalism has experienced growing appreciation among political scientists, economists, and constitutional scholars, 2 with some even suggesting it has been the driving force of sustained economic development in modern times.1 3 There is no doubt the U.S. Constitution establishes a federal system, but this says nothing about what determines the proper balance of dual sovereignty. Under competitive federalism, state and federal governments compete with one another to provide regulation to a mobile citizenry. State regulation under local "police powers" is justified when economic markets fail to allocate resources efficiently due to economic spillovers-so-called "externalities"-that separate the parties who benefit from those who bear costs of an activity. When confined to a single state, competition from other states ensures that the state's regulators have sufficient incentive to address economic spillovers. In the face of interstate spillovers, however, individual states will misallocate political resources by engaging in too little regulation of their internal economic markets. Federal regulation of economic markets under the Commerce Clause is justified only when competition between states leads to a political market failure.

This approach has been criticized as a prescription for how the Court should determine the limits of federal commerce power because those seeking regulation can always make a plausible claim that the activity in question generates an interstate economic spillover, while in fact they are motivated by private rent seeking. 4 Through out this Article we remain agnostic on this issue. Whether a federal regulation is driven by public interest or rent seeking, our sole concern is with how the Court can gradually identify and screen out applications of antitrust regulations that do not plausibly involve interstate economic spillovers. The Court can thereby move toward the proper balance of dual sovereignty, and political competition should increasingly limit the sum of economic rents the respective sovereigns are able to extract.15

Competitive federalism has clear implications for the evolution of Sherman Act jurisdiction. This evolution provides a useful roadmap to help the Court find the appropriate jurisdictional balance for its general Commerce Clause jurisprudence. It is both fitting and instructive that case law under one of the nation's first pieces of Commerce Clause legislation would provide such a roadmap,"6 for this is where judicial understanding of the relevant market failure can be expected to have evolved furthest to reduce legal uncertainty raised by the statutory shock. Passed in response to fears that the great trusts were beyond • • the power \* of 17 any state to effectively regulate owing to a political market failure, the Sherman Act prohibits only restraints of trade or commerce "among the several States."'8 For more than eighty years following passage of the Act, the Court struggled to identify the nature of the market failure resulting from various business practices alleged to restrain. This led to a patchwork of conflicting decisions, judicial confusion over the proper objective of the Act, and condemnation of business activities now widely recognized as pro-competitive. As economic theory progressed it gave the Court increasing insight into the nature and effect of various trade restraints. Driven largely by the Chicago School of economics,' 9 antitrust scholars began to develop and test hypotheses regarding a host of business practices that were argued to restrain trade.2 0 This process eventually generated a body of scientific knowledge sufficiently reliable to support expert testimony on the nature of the market failure associated with trade restraints, now widely regarded as the defendants' exercise of market power. The problem with market power is not that it allows firms to suppress competition or earn monopoly profits, but that it may lead them to misallocate resources by reducing output and raising prices to consumers. Courts and commentators now largely agree that the exclusive substantive objective of the Sherman Act is to promote consumer welfare.

Case law under the Sherman Act has since evolved toward a body of clear, workable substantive rules. But relying uncritically on the substantial effects test from its decisions on general Commerce Clause jurisdiction, the Court has routinely upheld applications of the Sherman Act to restraints that harm consumers only locally, if at all. The Court's most recent jurisdictional decision under the Act indicates that it has yet to recognize the consumer welfare standard's profound jurisdictional implications. In Summit Health, Ltd. v. Pin- 23 has, a narrow majority of the Court found that an alleged conspiracy by a chain of hospitals to exclude a single doctor from the Los Angeles market for eye surgery had a sufficient nexus to interstate commerce to support jurisdiction under the Act. The Court reasoned that the defendants' alleged restraint on the practice of ophthalmological services should be measured by its impact on other market participants not just by its impact on the respondent.24 Joined in dissent by three members of the Court, Justice Scalia noted that the majority's "analysis tells us nothing about the substantiality of the impact on interstate commerce generated by the particular conduct at issue here."25 He also argued that the Sherman Act does not "prohibit all conspiracies that have sufficient constitutional 'nexus' to interstate commerce to be regulated. It prohibits only those conspiracies that are 'in restraint of trade or commerce among the several States.' This language commands a judicial inquiry into the nature and potential effect of each particular restraint."26

Following Summit, federal courts have regularly entertained cases in which the interstate exercise of market power is so unlikely that the defendants' restraint should be presumed as a matter of law to be purely intrastate. 7 In the spirit of Justice Scalia's dissent, the second step the Court should take to realign its approach to Commerce Clause jurisdiction is to overturn Summit by formally recognizing the jurisdictional implications of the consumer welfare standard. If the market failure justifying federal regulation of trade restraints is the exercise of market power, and if the problem with market power is that it injures consumers by raising prices, then, according to competitive federalism, trade restraints that do not plausibly increase prices to consumers outside the home state should lie beyond federal reach.

#### Extinction---concentrated power makes prolif, terrorism, warming, and inequality inevitable.

Nasos Mihalakas 19. Global Professor of Practice in Law at the University of Arizona College of Law, and a Visiting Research Associate at the Athens Institute for Education & Research (ATINER). "The Need for Governance Reform – Symptoms vs. Cause". Federalism Project. 5-21-2019. https://the-federalism-project.org/2019/05/21/the-need-for-governance-reform-symptoms-vs-cause/

There is no doubt that we live in “challenging” times. We face ‘social challenges,’ from racial discrimination to gender inequality, women’s rights (reproductive or otherwise) that will have to be addressed, LGBTQ issues (recognition of gay marriage), a gun violence epidemic due to both inadequate gun control laws but also excessive violence in our society, etc. We also face ‘economic challenges,’ like stagnant salaries and low wages, job insecurity (due to automation or outsourcing), taxes that are too high for some and not high enough for others, mounting student debt, and yes massive income inequality. And, of course, we do face ‘external challenges’, from nuclear proliferation in the Korean peninsula, to ISIS and religiously motivated global terrorism, to global warming and climate change!

Yet, most of these issues are but symptoms of a greater cause. Their existence, or our inability to overcome them, is being caused by a much greater problem in our society that unless we address soon we risk permanent societal failures within the next 20 to 30 years.

This greater cause is our very own failing system of governance!!!

Though brilliant in its original construction by the founding fathers, our Federal system of governance (separation of powers, check and balances, separate Federal and State governments) is grossly off track and highly unbalanced. During the past 200 years, we witnessed a steady transfer of power away from the States and into the Federal government, and within the Federal government we saw a similar steady concentration of power in the hands of the Executive (the singular President), and to a certain extend the Supreme Court (due to Congressional acquiescence).

This did not happen due to some conspiracy by the ‘powerful elite’ or through interference by foreign powers. It happened gradually (almost naturally), as a response to major failures at the State level: in dealing with slavery and racial discrimination (see Civil War and Jim Crow laws in the south), in dealing with market failures and the need to regulate business and provide a safety net (see Great Depression, The New Deal and the Great Society), in fighting a Cold War with the Soviet Union (see expansion of military and intelligence services to advance US foreign policy).

Today, power and authority to deal with issues and solve problems is highly concentrated at the Federal level, away from ordinary people and their ability to monitor let alone influence elected politicians.

There is so much power concentrated at the Federal level, and in particular in the hands of one person (the President) that it makes Washington politicians constant targets of special interests and lobbying organizations, makes negotiations for compromise impossible because there is so much at stake, and it has created a highly unbalanced system (where “checks and balances” are not fully implemented and more often can’t work effectively).

Washington gridlock, dysfunction, polarization, and partisanship have led to the inability to pass a budget (balanced or otherwise), or address the need for immigration reform, or provide for adequate healthcare coverage and affordable prescription drugs, or even implement proper tax reform. Therefore, unless we address these ‘systemic’ failures of our system of governance, unless we implement institutional changes and fix the process, we will never get lasting solutions to our current and future societal challenges.

Unfortunately, there is no one thing we can do, no ‘magic bullet’ that can fix the dysfunction of our Federal system of governance (because it’s not just ‘the Federal government’ that needs reform, but also/primarily Congress and the Judiciary). Rather, there are several things (from specific process changes through laws/regulations to Constitutional amendments) that we will have to changes now, in order to see improvement in the function of our system of governance in the next 20 to 30 years.

There is a parallel example to this system of governance failures, and it’s that of ‘global warming.’ Global temperatures have been rising, due to greenhouse gases (caused by human activity – burning fossil fuels like coal and oil), presenting an existential threat to our planet and our way of life. However, fossil fuels are not inherently evil, used by certain people bent on the destruction of humanity! Energy from fossil fuels was instrumental in facilitating the industrial revolution, which brought progress and technological innovations during the past 150 years, that helped the whole world to advance, prosper, and better connect. It was not until recently that we realized that the constantly expanding use of fossil fuels by humans is contributing to rising temperatures, and if we don’t do something now to ‘bent the curve’, then in 20 to 30 years from now temperatures will rise to levels that can be devastating to the planets ecosystem, and by extension us humans.

Concentration of power at the Federal level, over the past 200 years, though not inherently evil (downright necessary and proper during some critical periods), has reached a point of pure dysfunction. The proof of the unsustainable nature of our current system (like rising temperatures are a proof of global warming) is income inequality. During the past 50 years, we have witnessed a steady concentration of wealth at the hands of the top 10% (and primarily the top 1%).

And although one can look at our society today statically and say: “things are still ok: there are rich people and poor people, and we are still the most powerful and wealthy nation in the world – so what’s the problem?”… the trend keeps going upwards: currently over 70% of our national wealth is concentrated at the hands for the top 10%. When do we need to do something to stop this trend? When it gets to 80%, or 90%?

Democrats and Republicans (now thanks to Donald Trump) both agree on the existence of a ‘powerful elite, in cahoots with the political establishment, bent on exploiting the middle class’… yet both party’s solution is the same: win political power and cut or raise taxes, regulate more or less, appoint some type of judges… in essence, deal with the symptoms and not the underlying cause!

If we want to address the underlying cause of income inequality (and outsourcing of jobs, health-care failures, racial tensions, education funding, women’s rights, public housing, etc.), then we need to reform our system of governance, before we can consider specific policy priorities. By fixing the legislative process, restoring proper checks, correcting the imbalance within the government branches and returning powers back to the States… we can get on a path where we see real results within the next 20 to 30 years.

Otherwise, gridlock and dysfunction at the Federal level will only get worse!

### FTC DA---1NC

#### Bedoya will be confirmed to the FTC now, but it’s narrow---his agenda is key to regulating facial-recognition tech.

Jessica Rich 11/18/21. Former director of the Federal Trade Commission’s (FTC) Bureau of Consumer Protection (BCP), Counsel at Kelley Drye LLP. “Some fireworks at Bedoya’s Senate confirmation hearing, but confirmation still seems likely.” Ad Law Access, 11-18-2021. https://www.adlawaccess.com/2021/11/articles/some-fireworks-at-bedoyas-senate-confirmation-hearing-but-confirmation-still-seems-likely/

On November 17, the Senate Commerce Committee held its eagerly-awaited hearing on the nomination of Alvaro Bedoya, a data privacy academic from Georgetown Law, to be FTC Commissioner. Bedoya is slated to replace Rohit Chopra, who departed the agency last month to become Director of the CFPB, and Bedoya’s appointment would once again give the Democrats a voting majority. In the run-up to his hearing, some have wondered – Can we expect Bedoya to provide Chair Khan with a reliable third vote for her agenda, or will he bring a more bipartisan approach to the agency? From his answers and demeanor at the hearing, the answer is probably…both.

First, a little table-setting: Bedoya’s nomination was considered along with three others – Jessica Rosenworcel for FCC Chair and two nominees for the Department of Commerce. The hearing was well-attended by Committee members, who directed the majority of their questions to Rosenworcel. (Yes, net neutrality, broadband access, and the “homework gap” all got more attention than privacy.) All four current FTC Commissioners attended the hearing in person, in a bipartisan show of support for Bedoya, though Bedoya attended remotely due to a recent exposure to COVID.

Here are some takeaways from Bedoya’s portion of the hearing.

He appears likely to be confirmed, even if largely along party lines. Although Senator Wicker made a reference to Bedoya’s “strident” views and Senators Lee, Cruz, and Sullivan slammed his “extremist” tweets (see below), most of the questions (from 18 Senators!) related to Bedoya’s area of expertise (privacy), where there is more alignment between the parties than in other areas. He handled the questions well, and repeatedly expressed support for collaboration and bipartisanship (e.g., specifically mentioning that he wants to work closely with Commissioner Wilson on privacy). Democrats have the votes (in the Committee and on the Senate floor), even if they ultimately have to call in V.P. Harris to break a tie.

He spoke about his nomination and the issues in personal and emotional terms. Bedoya highlighted that he and his family were welcomed into this country 34 years ago. He talked about his experience as a Senate staffer, learning about the terror and harm caused by stalking apps from a shelter for battered women. He realized then and believes now that “privacy is not just about data, it’s about people.” His goal as a Commissioner would be to make sure the FTC protects people, and to help both consumers and businesses manage the multiple crises facing the country – a COVID crisis, a privacy crisis, and a small business crisis.

He appears likely to vote with the majority on many (or most) issues. No big surprise here, but when asked his views about various issues, he consistently supported positions that Khan, Slaughter, and (his predecessor) Chopra have supported – federal privacy legislation, Magnuson-Moss privacy rulemaking if Congress doesn’t act, pushing back against the “unprecedented consolidation” that is forcing small businesses to close, streamlining the FTC’s rulemaking and subpoena processes, reducing the power of the platforms, and reining in tracking technologies like facial recognition. As to the latter, he said he would not support banning facial recognition technologies altogether, since some applications assist with benefits like public safety and healthcare. However, he would support banning facial recognition technologies that are hidden, that lack consent, or that collect, use, and share data without limits.

He’s a real-live privacy expert. He clearly has the credentials, starting with his work as a Senate staffer and continuing through his years at Georgetown Law as a professor and head of a privacy think tank. But he also quickly and confidently answered all questions related to privacy – from the need for privacy legislation generally, to his views on Senator Schatz’s “duty of loyalty” and Senator Markey’s proposal to amend COPPA, to the lines he would draw on facial recognition (see above).

He wrote some controversial tweets, and a number of Republicans seem poised to vote “no” on his confirmation. Senator Sullivan cited a tweet from Bedoya calling the 2016 Republican convention a “White Supremacist rally.” Cruz cited tweets about ICE as a “domestic surveillance agency” and a retweet involving critical race theory and white supremacy. He also called Bedoya a “left wing activist, bomb thrower, extremist, and provocateur.” Lee ran through a series of supposedly “yes or no” questions in rapid succession, and accused Bedoya of being evasive when he tried to qualify his responses. And Wicker referred to Bedoya’s “strident” views, as noted above. As to the tweets, Bedoya apologized, saying that it was “rhetoric” and that he would put aside any partisan views if he became Commissioner. However, these Senators (and perhaps other Republicans) seem poised to vote “no” on Bedoya’s confirmation, and some have said they plan to place a “hold” on the process, which could slow it down.

If confirmed, he could help reduce tensions at the Commission. With acrimony among the Commissioners currently at unprecedented levels (see our recent post here), adding Bedoya to the mix could help reduce the tensions (despite the tweets). He’s known to be collegial, he worked across the aisle as a Senate staffer, he repeatedly invoked bipartisanship at the hearing, and all of the sitting Commissioners (Democrats and Republicans) showed up at the hearing to support him. That augurs well for the dynamics at the Commission, even if the votes remain split along party lines.

We will continue to monitor progress on Bedoya’s nomination and post updates as they occur.

#### The plan triggers backlash to the FTC.

Alison Jones 20. Professor of Law at King's College London, with William E. Kovacic – George Washington University, March, “Antitrust’s Implementation Blind Side: Challenges to Major Expansion of U.S. Competition Policy.” The Antitrust Bulletin. https://journals.sagepub.com/doi/full/10.1177/0003603X20912884

D. Political Backlash

As we have already indicated, the government’s prosecution of high stakes antitrust cases often inspires defendants to lobby elected officials to rein in the enforcement agency. Targets of cases that seek to impose powerful remedies have several possible paths to encourage politicians to blunt enforcement measures. One path is to seek intervention from the President. The Assistant Attorney General of the Antitrust Division serves at the will of the President, making DOJ policy dependent on the President’s continuing support. The White House ordinarily does not guide the Antitrust Division’s selection of cases, but there have been instances in which the President pressured the Division to alter course on behalf of a defendant, and did so successfully.125

The second path is to lobby the Congress. The FTC is called an “independent” regulatory agency, but Congress interprets independence in an idiosyncratic way.126 Legislators believe independence means insulation from the executive branch, not from the legislature. The FTC is dependent on a good relationship with Congress, which controls its budget and can react with hostility, and forcefully, when it disapproves of FTC litigation—particularly where it adversely affects the interests of members’ constituents. Controversial and contested cases may consequently be derailed or muted if political support for them wanes and politicians become more sympathetic to commercial interests. The FTC’s sometimes tempestuous relationship with Congress demonstrates that political coalitions favoring bold enforcement can be volatile, unpredictable, and evanescent.127 If the FTC does not manage its relationship with Congress carefully, its litigation opponents may mobilize legislative intervention that causes ambitious enforcement measures to the founder.

Imagine, for a moment, that the DOJ and the FTC launch monopolization cases against each of the GAFA giants. Among other grounds, these cases might be premised on the theory that the firms used mergers to accumulate and protect positions of dominance. The GAFA firms have received unfavorable scrutiny from legislators from both political parties over the past few years, but the current wave of political opprobrium is unlikely to discourage the firms from bringing their formidable lobbying resources to bear upon the Congress. It would be hazardous for the enforcement agencies to assume that a sustained, well-financed lobbying campaign will be ineffective. At a minimum, the agencies would need to consider how many battles they can fight at one time, and how to foster a countervailing coalition of business interests to oppose the defendants.

#### That derails Bedoya’s nomination

Kathleen Murphy 21. Senior reporter at FTC Watch, 11/1/21. “Bedoya’s confirmation hearing draws closer,” FTC Watch. https://www.mlexwatch.com/articles/13940/print?section=ftcwatch

When Alvaro Bedoya, President Joe Biden’s nominee to the Federal Trade Commission, faces US senators, he will be asked about his scholarly views on privacy. But the hearing also gives senators a chance to assess the agenda of the last FTC nominee they confirmed, Chair Lina Khan.

The Senate Commerce, Science and Transportation Committee is set to consider Bedoya’s nomination, although no hearing date has been set. It’s most likely to occur the week of Nov. 15 or early December, based on the 2021 Senate calendar.

Serving on the FTC means Bedoya, a Georgetown University professor and former congressional lawyer, would end a 2-2 split and give Democrats a majority to implement the chair’s policies. Bedoya, founding director of the Center on Privacy & Technology at Georgetown Law, would replace former Commissioner Rohit Chopra who left Oct. 8 to serve as director of the Consumer Financial Protection Bureau.

Biden nominated Bedoya in mid-September. Khan, meanwhile, started serving as FTC chair in mid-June after an 83-day confirmation process. (See FTCWatch, No. 1002, March 29, 2021.)

‘99% about FTC Chair Lina Khan’

Michael Keeley, co-chair of the antitrust practice at Axinn, Veltrop & Harkrider, tweeted: “Bedoya confirmation is going to be 99% about FTC Chair Lina Khan, and 1% to do with Alvaro Bedoya. (And hopefully 0% about the Vertical Merger Guidelines.)”

Keeley said he expects the focus of the hearing to be assessing the wisdom of the policies being pursued by Khan.

“One area that might come up will be the number of steps the commission has been taking already to try to discourage mergers generally, which is consistent with the policies that were pursued and announced by the administration,” Keeley said in an interview. Confirmation hearings are useful for antitrust lawyers, Keeley said, because it’s “always good to understand the priorities that an enforcer believes in and to have them engage with senators on tough questions.”

Bedoya’s expertise

Bedoya, who is a naturalized US citizen born in Peru, has focused his work on the impact of surveillance and commercial data collection on immigrants and people of color. He has written about police use of facial recognition and oversaw the Center’s investigation that showed most American adults are enrolled in police face recognition databases that suffer from race and gender bias. Advocacy groups, such as anti-monopoly and civil rights organizations, urged the Senate to confirm Bedoya swiftly.

The antitrust views of Bedoya, a Yale Law School graduate, are less spelled out, offering another avenue of inquiry for senators. Republican senators are expected to examine how closely Bedoya will mirror the priorities Khan has established.

#### Bad facial-recognition tech causes democratic backsliding---proactive US regulation is key.

Andrea Kendall-Taylor et. al 20. Senior fellow and director of the Transatlantic Security Program at the Center for a New American Security, co-author of Democracies and Authoritarian Regimes, with Erica Frantz - Assistant Professor of Political Science at Michigan State University, and Joseph Wright - Professor of Political Science at Pennsylvania State University, March/April 2020. “The Digital Dictators,” Foreign Affairs. <https://www.foreignaffairs.com/articles/china/2020-02-06/digital-dictators>

THE CHINA MODEL

The advancement of AI-powered surveillance is the most significant evolution in digital authoritarianism. High-resolution cameras, facial recognition, spying malware, automated text analysis, and big-data processing have opened up a wide range of new methods of citizen control. These technologies allow governments to monitor citizens and identify dissidents in a timely—and sometimes even preemptive—manner.

No regime has exploited the repressive potential of AI quite as thoroughly as the one in China. The Chinese Communist Party collects an incredible amount of data on individuals and businesses: tax returns, bank statements, purchasing histories, and criminal and medical records. The regime then uses ai to analyze this information and compile “social credit scores,” which it seeks to use to set the parameters of acceptable behavior and improve citizen control. Individuals or companies deemed “untrustworthy” can find themselves excluded from state-sponsored benefits, such as deposit-free apartment rentals, or banned from air and rail travel. Although the ccp is still honing this system, advances in big-data analysis and decision-making technologies will only improve the regime’s capacity for predictive control, what the government calls “social management.”

China also demonstrates the way digital repression aids the physical variety—on a mass scale. In Xinjiang, the Chinese government has detained more than a million Uighurs in “reeducation” camps. Those not in camps are stuck in cities where neighborhoods are surrounded by gates equipped with facial recognition software. That software determines who may pass, who may not, and who will be detained on sight. China has collected a vast amount of data on its Uighur population, including cell phone information, genetic data, and information about religious practices, which it aggregates in an attempt to stave off actions deemed harmful to public order or national security.

New technologies also afford Chinese officials greater control over members of the government. Authoritarian regimes are always vulnerable to threats from within, including coups and high-level elite defections. With the new digital tools, leaders can keep tabs on government officials, gauging the extent to which they advance regime objectives and rooting out underperforming officials who over time can tarnish public perception of the regime. For example, research has shown that Beijing avoids censoring citizens’ posts about local corruption on Weibo (the Chinese equivalent of Twitter) because those posts give the regime a window into the performance of local officials.

In addition, the Chinese government deploys technology to perfect its systems of censorship. AI, for example, can sift through massive amounts of images and text, filtering and blocking content that is unfavorable to the regime. As a protest movement heated up in Hong Kong last summer, for example, the Chinese regime simply strengthened its “Great Firewall,” removing subversive content from the Internet in mainland China almost instantaneously. And even if censorship fails and dissent escalates, digital autocracies have an added line of defense: they can block all citizens’ access to the Internet (or large parts of it) to prevent members of the opposition from communicating, organizing, or broadcasting their messages. In Iran, for example, the government successfully shut down the Internet across the country amid widespread protests last November.

Although China is the leading player in digital repression, autocracies of all stripes are looking to follow suit. The Russian government, for example, is taking steps to rein in its citizens’ relative freedom online by incorporating elements of China’s Great Firewall, allowing the Kremlin to cut off the country’s Internet from the rest of the world. Likewise, Freedom House reported in 2018 that several countries were seeking to emulate the Chinese model of extensive censorship and automated surveillance, and numerous officials from autocracies across Africa have gone to China to participate in “cyberspace management” training sessions, where they learn Chinese methods of control.

THE VELVET GLOVE

Today’s technologies not only make it easier for governments to repress critics; they also make it easy to co-opt them. Tech-powered integration between government agencies allows the Chinese regime to more precisely control access to government services, so that it can calibrate the distribution—or denial—of everything from bus passes and passports to jobs and access to education. The nascent social credit system in China has the effect of punishing individuals critical of the regime and rewarding loyalty. Citizens with good social credit scores benefit from a range of perks, including expedited overseas travel applications, discounted energy bills, and less frequent audits. In this way, new technologies help authoritarian regimes fine-tune their use of reward and refusal, blurring the line between co-option and coercive control.

Dictatorships can also use new technologies to shape public perception of the regime and its legitimacy. Automated accounts (or “bots”) on social media can amplify influence campaigns and produce a flurry of distracting or misleading posts that crowd out opponents’ messaging. This is an area in which Russia has played a leading role. The Kremlin floods the Internet with pro-regime stories, distracting online users from negative news, and creates confusion and uncertainty through the spread of alternative narratives.

Maturing technologies such as so-called microtargeting and deepfakes—digital forgeries impossible to distinguish from authentic audio, video, or images—are likely to further boost the capacity of authoritarian regimes to manipulate their citizens’ perceptions. Microtargeting will eventually allow autocracies to tailor content for specific individuals or segments of society, just as the commercial world uses demographic and behavioral characteristics to customize advertisements. Ai-powered algorithms will allow autocracies to microtarget individuals with information that either reinforces their support for the regime or seeks to counteract specific sources of discontent. Likewise, the production of deepfakes will make it easier to discredit opposition leaders and will make it increasingly difficult for the public to know what is real, sowing doubt, confusion, and apathy.

Digital tools might even help regimes make themselves appear less repressive and more responsive to their citizens. In some cases, authoritarian regimes have deployed new technologies to mimic components of democracy, such as participation and deliberation. Some local Chinese officials, for example, are using the Internet and social media to allow citizens to voice their opinions in online polls or through other digitally based participatory channels. A 2014 study by the political scientist Rory Truex suggested that such online participation enhanced public perception of the ccp among less educated citizens. Consultative sites, such as the regime’s “You Propose My Opinion” portal, make citizens feel that their voices matter without the regime having to actually pursue genuine reform. By emulating elements of democracy dictatorships can improve their attractiveness to citizens and deflate the bottom-up pressure for change.

DURABLE DIGITAL AUTOCRACIES

As autocracies have learned to co-opt new technologies, they have become a more formidable threat to democracy. In particular, today’s dictatorships have grown more durable. Between 1946 and 2000—the year digital tools began to proliferate—the typical dictatorship ruled for around ten years. Since 2000, this number has more than doubled, to nearly 25 years.

Not only has the rising tide of technology seemingly benefited all dictatorships, but our own empirical analysis shows that those authoritarian regimes that rely more heavily on digital repression are among the most durable. Between 2000 and 2017, 37 of the 91 dictatorships that had lasted more than a year collapsed; those regimes that avoided collapse had significantly higher levels of digital repression, on average, than those that fell. Rather than succumb to what appeared to be a devastating challenge to their power—the emergence and spread of new technologies—many dictatorships leverage those tools in ways that bolster their rule.

Although autocracies have long relied on various degrees of repression to support their objectives, the ease with which today’s authoritarian regimes can acquire this repressive capacity marks a significant departure from the police states of the past. Building the effectiveness and pervasiveness of the East German Stasi, for example, was not something that could be achieved overnight. The regime had to cultivate the loyalty of thousands of cadres, training them and preparing them to engage in on-the-ground surveillance. Most dictatorships simply do not have the ability to create such a vast operation. There was, according to some accounts, one East German spy for every 66 citizens. The proportion in most contemporary dictatorships (for which there are data) pales in comparison. It is true that in North Korea, which ranks as possibly the most intense police state in power today, the ratio of internal security personnel and informants to citizens is 1 to 40—but it was 1 to 5,090 in Iraq under Saddam Hussein and 1 to 10,000 in Chad under Hissene Habre. In the digital age, however, dictatorships don’t need to summon immense manpower to effectively surveil and monitor their citizens.

Instead, aspiring dictatorships can purchase new technologies, train a small group of officials in how to use them—often with the support of external actors, such as China—and they are ready to go. For example, Huawei, a Chinese state-backed telecommunications firm, has deployed its digital surveillance technology in over a dozen authoritarian regimes. In 2019, reports surfaced that the Ugandan government was using it to hack the social media accounts and electronic communications of its political opponents. The vendors of such technologies don’t always reside in authoritarian countries. Israeli and Italian firms have also sold digital surveillance software to the Ugandan regime. Israeli companies have sold espionage and intelligence-gathering software to a number of authoritarian regimes across the world, including Angola, Bahrain, Kazakhstan, Mozambique, and Nicaragua. And U.S. firms have exported facial recognition technology to governments in Saudi Arabia and the United Arab Emirates.

A SLIPPERY SLOPE

As autocracies last longer, the number of such regimes in place at any point in time is likely to increase, as some countries backslide on democratic rule. Although the number of autocracies globally has not risen substantially in recent years, and more people than ever before live in countries that hold free and fair elections, the tide may be turning. Data collected by Freedom House show, for example, that between 2013 and 2018, although there were three countries that transitioned from “partly free” to “free” status (the Solomon Islands, Timor-Leste, and Tunisia), there were seven that experienced the reverse, moving from a status of “free” to one of “partly free” (the Dominican Republic, Hungary, Indonesia, Lesotho, Montenegro, Serbia, and Sierra Leone).

The risk that technology will usher in a wave of authoritarianism is all the more concerning because our own empirical research has indicated that beyond buttressing autocracies, digital tools are associated with an increased risk of democratic backsliding in fragile democracies. New technologies are particularly dangerous for weak democracies because many of these digital tools are dual use: technology can enhance government efficiency and provide the capacity to address challenges such as crime and terrorism, but no matter the intentions with which governments initially acquire such technology, they can also use these tools to muzzle and restrict the activities of their opponents.

Pushing back against the spread of digital authoritarianism will require addressing the detrimental effects of new technologies on governance in autocracies and democracies alike. As a first step, the United States should modernize and expand legislation to help ensure that U.S. entities are not enabling human rights abuses. A December 2019 report by the Center for a New American Security (where one of us is a senior fellow) highlights the need for Congress to restrict the export of hardware that incorporates AI-enabled biometric identification technologies, such as facial, voice, and gait recognition; impose further sanctions on businesses and entities that provide surveillance technology, training, or equipment to authoritarian regimes implicated in human rights abuses; and consider legislation to prevent U.S. entities from investing in companies that are building ai tools for repression, such as the Chinese ai company SenseTime.

The U.S. government should also use the Global Magnitsky Act, which allows the U.S. Treasury Department to sanction foreign individuals involved in human rights abuses, to punish foreigners who engage in or facilitate Ai-powered human rights abuses. Ccp officials responsible for atrocities in Xinjiang are clear candidates for such sanctions.

U.S. government agencies and civil society groups should also pursue actions to mitigate the potentially negative effects of the spread of surveillance technology, especially in fragile democracies. The focus of such engagement should be on strengthening the political and legal frameworks that govern how surveillance technologies are used and building the capacity of civil society and watchdog organizations to check government abuse.

What is perhaps most critical, the United States must make sure it leads in AI and helps shape global norms for its use in ways that are consistent with democratic values and respect for human rights. This means first and foremost that Americans must get this right at home, creating a model that people worldwide will want to emulate. The United States should also work in conjunction with like-minded democracies to develop a standard for digital surveillance that strikes the right balance between security and respect for privacy and human rights. The United States will also need to work closely with like-minded allies and partners to set and enforce the rules of the road, including by restoring U.S. leadership in multilateral institutions such as the United Nations.

AI and other technological innovations hold great promise for improving everyday lives, but they have indisputably strengthened the grip of authoritarian regimes. The intensifying digital repression in countries such as China offers a bleak vision of ever-expanding state control and ever-shrinking individual liberty.

But that need not be the only vision. In the near term, rapid technological change will likely produce a cat-and-mouse dynamic as citizens and governments race to gain the upper hand. If history is any guide, the creativity and responsiveness of open societies will in the long term allow democracies to more effectively navigate this era of technological transformation. Just as today’s autocracies have evolved to embrace new tools, so, too, must democracies develop new ideas, new approaches, and the leadership to ensure that the promise of technology in the twenty-first century doesn’t become a curse.

#### Democratic backsliding causes nuclear war

Dr. Larry Diamond 19. Professor of Political Science and Sociology at Stanford University, Senior Fellow at the Hoover Institution, Senior Fellow at the Freeman Spogli Institute for International Studies, PhD in Sociology from Stanford University, Ill Winds: Saving Democracy from Russian Rage, Chinese Ambition, and American Complacency, p. 199-202

The most obvious response to the ill winds blowing from the world’s autocracies is to help the winds of freedom blowing in the other direction. The democracies of the West cannot save themselves if they do not stand with democrats around the world.

This is truer now than ever, for several reasons. We live in a globalized world, one in which models, trends, and ideas cascade across borders. Any wind of change may gather quickly and blow with gale force. People everywhere form ideas about how to govern—or simply about which forms of government and sources of power may be irresistible—based on what they see happening elsewhere. We are now immersed in a fierce global contest of ideas, information, and norms. In the digital age, that contest is moving at lightning speed, shaping how people think about their political systems and the way the world runs. As doubts about and threats to democracy are mounting in the West, this is not a contest that the democracies can afford to lose.

Globalization, with its flows of trade and information, raises the stakes for us in another way. Authoritarian and badly governed regimes increasingly pose a direct threat to popular sovereignty and the rule of law in our own democracies. Covert flows of money and influence are subverting and corrupting our democratic processes and institutions. They will not stop just because Americans and others pretend that we have no stake in the future of freedom in the world. If we want to defend the core principles of self-government, transparency, and accountability in our own democracies, we have no choice but to promote them globally.

It is not enough to say that dictatorship is bad and that democracy, however flawed, is still better. Popular enthusiasm for a lesser evil cannot be sustained indefinitely. People need the inspiration of a positive vision. Democracy must demonstrate that it is a just and fair political system that advances humane values and the common good.

To make our republics more perfect, established democracies must not only adopt reforms to more fully include and empower their own citizens. They must also support people, groups, and institutions struggling to achieve democratic values elsewhere. The best way to counter Russian rage and Chinese ambition is to show that Moscow and Beijing are on the wrong side of history; that people everywhere yearn to be free; and that they can make freedom work to achieve a more just, sustainable, and prosperous society.

In our networked age, both idealism and the harder imperatives of global power and security argue for more democracy, not less. For one thing, if we do not worry about the quality of governance in lower-income countries, we will face more and more troubled and failing states. Famine and genocide are the curse of authoritarian states, not democratic ones. Outright state collapse is the ultimate, bitter fruit of tyranny. When countries like Syria, Libya, and Afghanistan descend into civil war; when poor states in Africa cannot generate jobs and improve their citizens’ lives due to rule by corrupt and callous strongmen; when Central American societies are held hostage by brutal gangs and kleptocratic rulers, people flee—and wash up on the shores of the democracies. Europe and the United States cannot withstand the rising pressures of immigration unless they work to support better, more stable and accountable government in troubled countries. The world has simply grown too small, too flat, and too fast to wall off rotten states and pretend they are on some other planet.

Hard security interests are at stake. As even the Trump administration’s 2017 National Security Strategy makes clear, the main threats to U.S. national security all stem from authoritarianism, whether in the form of tyrannies from Russia and China to Iran and North Korea or in the guise of antidemocratic terrorist movements such as ISIS.1 By supporting the development of democracy around the world, we can deny these authoritarian adversaries the geopolitical running room they seek. Just as Russia, China, and Iran are trying to undermine democracies to bend other countries to their will, so too can we contain these autocrats’ ambitions by helping other countries build effective, resilient democracies that can withstand the dictators’ malevolence.

Of course, democratically elected governments with open societies will not support the American line on every issue. But no free society wants to mortgage its future to another country. The American national interest would best be secured by a pluralistic world of free countries—one in which autocrats can no longer use corruption and coercion to gobble up resources, alliances, and territory.

If you look back over our history to see who has posed a threat to the United States and our allies, it has always been authoritarian regimes and empires. As political scientists have long noted, no two democracies have ever gone to war with each other—ever. It is not the democracies of the world that are supporting international terrorism, proliferating weapons of mass destruction, or threatening the territory of their neighbors.

For all these reasons, we need a new global campaign for freedom. Everything I am proposing in this book plays a role in that campaign, but in this chapter, I am concerned more narrowly with the ways that we can directly advance democracy, human rights, and the rule of law in the twenty-first-century world.

As with any policy area, many of the challenges can be somewhat technical, requiring smart design and the careful management of programs and institutions. Those operational debates I leave for another venue. Here, I make a more basic case for four imperatives. First, we must support the democrats of the world—the people and organizations struggling to create and improve free and accountable government. Second, we must support struggling and developing democracies, helping them to grow their economies and strengthen their institutions. Third, we must pressure authoritarian regimes to stop abusing the rights and stealing the resources of their citizens, including by imposing sanctions on dictators to make them think hard about their choices and separate them from both their supporters and the people at large. Finally, we need to reboot our public diplomacy—our global networks of information and ideas—for today’s fast-paced age of information and disinformation. For the sake of both our interests and our values, we need a foreign policy that puts a high priority on democracy, human rights, and the rule of law.

### Advantage CP---1NC

#### The United States federal government should

#### Increase disclosure requirements on the Food and Drug Administration regarding citizen petitions

#### Remove current conditions and require that 505(q) petitions be filed within one year of the petitioner learning of the safety or efficacy issue asserted in the petition

#### Amend section 505(q)(1)(H) to require a peti­tioner to certify that it filed its objection within one year of discovering the claim that is the basis of the petition

#### Regulate letters that use deceptive or false statements to intimidate recipients into purchasing a license, and enable the states to do so as well,

#### Determine that antitrust is immune from antitrust under the Noerr Pennington doctrine

#### CP solves citizen-petition abuse

Michael A. Carrier 18. Distinguished Professor of Law, Rutgers Law School. “FIVE ACTIONS TO STOP CITIZEN PETITION ABUSE.” CLR FORUM, Vol. 118, No. 3. https://columbialawreview.org/content/five-actions-to-stop-citizen-petition-abuse-2/

High drug prices are in the news. In some cases, such as AIDS-treating Daraprim1 and the life-saving EpiPen,2 the price increases dramati­cally. In other cases, which have received less attention, the price stays high longer than it should. Either way, anticompetitive behavior often lurks behind inflated prices.

By delaying price-reducing generic competition, this behavior forces consumers to spend billions of extra dollars each year. Brand drug companies have engaged in an array of conduct to delay generic entry. They have entered into agreements by which they pay generic manufacturers to settle patent litigation and delay entering the market.3 They have engaged in “product hopping,” switching from one version of a drug to another, often to delay generic entry.4 And they have restricted their distribution systems to prevent generics from obtaining needed sam­ples.5

Another one of these strategies, which has flown under the radar until recently, involves “citizen petitions” filed with the U.S. Food and Drug Administration (FDA). Although intended to serve the public interest by bringing safety concerns to the agency’s attention, nearly all petitions today that target generic drugs are denied.6 Despite the low suc­cess rate, petitions are still able to delay generic entry and hamstring the FDA. This Piece provides an overview of citizen petitions and the anti­competitive harm they threaten and offers five solutions to address the problem posed by abusive citizen petitions.

I. THE SETTING

Citizen petitions allow any party to raise safety or effectiveness con­cerns with drugs the FDA is considering for approval.7 The petitions, with a foundation in the First Amendment8 and Administrative Procedure Act,9 in theory play an important role in ensuring that drugs are safe and effective. In practice, however, brand firms have used peti­tions to delay generic approval, extending monopolies on their products at a potential cost to consumers of millions of dollars per day. In many cases, petitions offer little incremental value to the review process but require considera­ble time, with the FDA forced to address the merits of every petition, many of which contain “detailed analysis and precise scien­tific doc­umentation” and require review by “multiple disciplines” within the agency.10

One type of petition has caused particular concern. As part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress created Section 505(q),11 which applies to “certain petitions that request that the FDA take any form of action” related to a pending Abbreviated New Drug Application (ANDA or “generic application”).12 Congress intended to reduce delays13 by requiring petitioners to certify that they did not delay in filing the petition14 and mandating that the FDA take final action no later than 180 days15 (later shortened to 150 days) after the petition’s filing date, unless delay would be necessary to protect the public health.16

Brand firms have filed the vast majority of 505(q) petitions, seeking additional testing or questioning whether generics are bioequivalent— that is, able to be absorbed into the body at the same rate.17 The FDA denied 92% of 505(q) petitions filed between 2011 and 2015, with this figure rising to 98% for petitions filed within six months of the expiration of a patent or FDA exclusivity date.18 In addition to these general find­ings, particular examples demonstrate anticompetitive harm in the form of:

Multiple petitions (such as Teva’s eight petitions on MS-treating Copaxone and Shire ViroPharma’s twenty-four peti­tions on the medication treating a life-threatening gastroin­testinal infection);19

Late-filed petitions (such as Bayer Healthcare filing a peti­tion one day before the expiration of the patent on Mirena, a long-acting intrauterine device (IUD));20

The combination of citizen petitions and product hopping (as shown by acne-treating Doryx);21 and

The combination of petitions and entry-delaying settlements (as shown by Mylan’s allergic emergency–treating EpiPen).22

To pick one example, in February 2017, the FTC filed its first com­plaint challenging citizen petition conduct as an antitrust violation.23 The FTC alleged that ViroPharma “inundated the FDA” with twenty-four citizen petitions and twenty-two other filings, which was “by far the most filings that any firm has ever made to the FDA concerning a single drug product.”24 The agency alleged that “[t]hese repetitive, serial, and merit­less filings lacked any supporting clinical data” but that “ViroPharma’s campaign had succeeded in delaying generic entry at a cost of hundreds of millions of dollars.”25

Not only do petitions threaten the public but they also harm the FDA, which has lamented the deluge of petitions that has forced it to expend resources “at the expense of completing the other work of the Agency.”26 The FDA also bemoaned the “strain on Agency resources” from Congress’s reduction of the response period by 30 days to 150 days, which “affords [the] FDA even less time to evaluate the issues raised in the petitions and to provide a response that articulates the scientific and legal reasoning supporting the Agency’s decision.”27 In addition, the FDA has revealed frustration with “serial 505(q) petitions, frequently from the same petitioner, about the same specific drug or class of drugs” that require “several separate responses about different issues regarding the same product.”28

The FDA’s concerns are accompanied by the public’s difficulty in uncovering information about petitions, which obscures the prevalence of the conduct and the full extent of the delay. The government website regulations.gov is difficult to navigate,29 leading to dependence on the privately compiled collection at FDALawBlog.30 Moreover, the FDA does not provide a comprehensive account of delay from petitions targeting generics. In its annual reports to Congress, the FDA has found “delayed approvals” on only ten occasions between 2008 and 2015.31 The agency, however, does not specify these petitions, nor does it consider a petition delayed if it responds within the 150-day period.32 Relatedly, the FDA has failed to consider that it could be delaying generic approval by not approving the generic until it resolves the petition.33

Congress attempted to address concerns presented by citizen peti­tions in the FDAAA.34 It allowed the FDA to delay its approval of a ge­neric only if the delay was “necessary to protect the public health.”35 And it required that the agency provide certain types of information to Congress each year.36 But this legislation was not successful in its goal of “stop[ping] frivolous petitions from delaying generic entry,”37 as the num­ber of petitions increased after the law went into effect and has shown no signs of abating.38 This Piece picks up where the FDAAA left off, proposing five solutions to the citizen petition problem: (1) increasing transparency; (2) shedding light on simultaneous decisions on peti­tions and generic approval; (3) facilitating the FDA’s summary disposi­tions of petitions; (4) addressing resource waste; and (5) promoting timely filed petitions.

II. ENHANCE TRANSPARENCY

The first proposal would increase transparency. The FDA currently is required to provide annual reports to Congress that specify certain types of information:

“[T]he number of applications that were approved during the preceding 12-month period”;

“[T]he number of such applications whose effective dates were delayed by [the above-referenced] petitions”;

“[T]he number of days by which such applications were so delayed”; and

“[T]he number of such petitions that were submitted during such period.”39

Despite this information, the FDA never explains which petitions it believes have resulted in delay. And again, the agency considers a petition to be delayed only if it does not respond within the 150-day period.40 It is possible, however, that a petition leads to delayed entry even within the 150-day period. The FDA, for example, might approve a generic later than it would have if the petition had not been filed. For these reasons, Congress should require the FDA to specify additional categories of information, including:

Every 505(q) petition;

The timing of the petition in relation to the expiration date of patents listed in the Orange Book41 for the brand drug referenced by the generic application;

The time the FDA expended on the petition; and

The delay (if any) in generic approval caused by the petition and determination of how the delay is calculated.

The FDA can provide this information in its annual report to Congress or on its website (like it does for patents listed in the Orange Book, generic applications, and products requiring Risk Evaluation and Mitigation Strategies (REMS)42 ). Each of the categories would address certain current deficiencies. By providing a list of every 505(q) petition, the FDA would make it significantly easier to research and analyze peti­tions. Including information on when the petitions were filed would high­light late filings in relation to patents. The third category would, as discussed in more detail below,43 shed light on FDA resources expended on petitions. And the fourth category would provide more useful infor­mation than is currently available on delay from petitions.

In short, these additional categories would provide valuable infor­mation that is currently missing and would highlight the significant con­cerns presented by citizen petitions.

III. ELUCIDATE SIMULTANEOUS RESOLUTIONS

A second proposal targets a particular instance of transparency, which involves simultaneous determinations. On certain occasions, the FDA denies a citizen petition at the same time it grants generic approval. Some of these decisions occur within a short time (for example, one month) of each other while others occur on the same day. Although the FDA has never acknowledged doing so, industry observers have com­mented that the agency’s “practice for many years has been to simultane­ously announce both decisions.”44

The FDA’s control over the timing of decisions relating to petitions and generic approval has been criticized, with one court lamenting the “mess” that prevented “the opportunity to actually review the FDA’s actual decision and actual reasoning” on the citizen petition before the agency reached a decision on the generic application.45 An industry ex­pert concluded that “the current FDA system to announce . . . hotly con­tested decisions is broken,” with “whatever advantage” the agency “may think it is getting from hiding the ball from the world on the timing and substance of these decisions . . . more than overcome by the criticism the Agency has received from judges.”46

When the FDA issues simultaneous rulings, one concern is that the generic would have been approved earlier absent the petition. As dis­cussed above, petitions often require multiple divisions of the FDA to review detailed documentation, slowing down the approval process.47 But as long as the decision is reached within 150 days, the FDA does not count these as instances of delay in its annual report.48 For example, the FDA asserts that there is no delay when the 150-day period ends before the generic is “ready for approval,” without considering whether the peti­tion itself delayed approval.49

This position seems inconsistent with the agency’s guidance. In determining whether a petition would delay a generic application (which is allowed only to protect health),50 it applies a “but for” test to deter­mine delay that asks if the generic would be “ready for approval but for the issues raised by the petition.”51 Given the information currently available to the public, it is not possible for observers to determine this. Applying its “but for” analysis, the agency should make clear when it was likely to have approved the generic absent the petition.

A second concern is that the FDA delays announcing a petition deci­sion it has already reached until it formally approves the generic applica­tion. In this scenario, the petition does not delay the generic, but the FDA delays the announcement of the petition’s denial so that it is made simultaneously with the generic’s approval. The FDA may engage in this conduct to eliminate the possibility of judicial review of the petition decision.

The FDA has demonstrated concern that rulings on petitions “consti­tute final Agency action and are subject to immediate review by the courts.”52 As a result, petition rulings “carry with them none of the procedural rights . . . that attach to a decision to deny” generic approval.53 Rulings on petitions before decisions on generic approval thus “could interfere with the statutory and regulatory scheme governing the review of applications and related procedural rights of applicants.”54

More skeptically, the FDA may be delaying petition rulings so that it is less likely to be sued in court. A petition denied before generic approval may be appealed to the courts, but one announced simultane­ously with the approval decision is less likely to be challenged since in that case the generic has received approval and may be on the market shortly thereafter, which would dissuade a brand firm seeking to keep a generic off the market.

Shedding light on the timing of simultaneous decisions—including determinations of (1) when the generic would have received approval absent the petition and (2) when the FDA would have announced the petition decision absent the pending generic application—would help resolve these contentious issues.

IV. FACILITATE SUMMARY DISPOSITION

Third, Congress could make it easier for the FDA to quickly dispose of certain petitions. Because the legislature understood that some peti­tions raised significant concern, it allowed the FDA to summarily dispense with them. This authority, however, has never been used.55

The reason is that the standard is too high. Section 505(q)(1)(E) requires the FDA to conclude that a petition is “submitted with the pri­mary purpose of delaying” the generic application and that “the petition does not on its face raise valid scientific or regulatory issues.”56 But the provi­sion “has neither curbed the filing of petitions submitted with the primary purpose of delay” nor “permitted FDA to dispose of such peti­tions without expending substantial amounts of resources.”57

As the agency has explained, the standards for summary disposition are “extremely difficult to meet.”58 For starters, the FDA cannot deter­mine a petitioner’s primary purpose based on the petition itself. Merely reviewing such a document, which includes safety or effectiveness con­cerns, cannot reveal the filer’s purpose, let alone its primary purpose.

Moreover, even a petition that ultimately is denied will tend not to reveal “on its face” that it “does not . . . raise valid scientific or regulatory issues.”59 Petitions will include language and sometimes documentation challenging a drug’s safety or efficacy that at first glance may sound plausi­ble. The FDA would be hesitant to rule in a cursory review that the petition does not raise valid issues. Its concern is obvious: that errone­ously granted summary dispositions result in safety mishaps years down the road.

What can be done? First, remove the two conditions. The FDA can­not determine purpose from the petition itself, nor can it dismiss peti­tions raising safety or effectiveness concerns based on a document’s “face.”

In place of these requirements, the agency could focus on timing. Legitimate petitions should be filed within a reasonably short time of dis­covering the safety or efficacy concern. Late-filed petitions raise the con­cern that the petitioner is gaming the system, often by waiting until a generic is about to enter the market to file even though it was long aware of the information forming the basis of the petition.

As one example, Mylan received widespread notoriety for its price in­creases on the life-saving epinephrine-autoinjector EpiPen device.60 Not receiving as much attention was Mylan’s filing of a petition challeng­ing Teva’s EpiPen alternative at least five years after it most likely was aware of the generic product specifications.61

Congress could consider replacing Section 505(q)(1)(E) with lan­guage emphasizing the filing of petitions within a reasonable time, with one year providing sufficient time to prepare a petition. One poten­tial statutory amendment (which includes a waiver for unusual circum­stances62 ) could provide:

505(q) petitions must be filed within one year of the petitioner learning of the safety or efficacy issue asserted in the petition. FDA may grant a waiver to allow later filing.

Such an amendment would make it more difficult to file questiona­ble petitions. And by focusing on the delay in filing, the analysis would pinpoint concerns based on timing, which raise red flags and can be dis­cerned, rather than the filer’s purpose or problems on the peti­tion’s face, which cannot readily be determined.63

V. ADDRESS RESOURCE WASTE

A fourth proposal would require the FDA to disclose the money and time it expends resolving 505(q) petitions. In its Eighth Report to Congress, the FDA was “concerned about the resources required to respond to 505(q) petitions within the 150-day deadline at the expense of completing [its] other work.”64 And in its Seventh Report, it explained that the reduction from 180 to 150 days “increased the strain on Agency resources,” which required it “to direct resources away from other important initiatives to attempt to comply with the new shorter deadline.”65

Putting dollar and time figures on the resource drain from petition responses could offer important benefits. It would make the problems posed by citizen petitions more concrete and provide greater impetus for changes. As it stands now, the theoretical arguments based on freedom of expression and the possibility of raising legitimate concerns with the FDA, combined with inertia and the difficulty of limiting existing proce­dures, make it more difficult to impose limits on the process. Concrete figures depicting the resources expended on petitions, when considered in the setting of the overwhelming incidence of denials,66 could pave the way for changes.

VI. PROMOTE TIMELINESS

Fifth, Congress could amend section 505(q)(1)(H) to require a peti­tioner to certify that it filed its objection within a reasonable time—say, one year—of discovering the claim that is the basis of the petition. Currently, the section requires the petitioner to certify that the petition includes “all information and views upon which the petition relies” and “representative data and/or information known to the petitioner which are unfavorable to the petition,” and that it took “reasonable steps to ensure that any representative data and/or information which are unfavor­able to the petition were disclosed.”67 The petitioner is also re­quired to “certify that the information upon which” the action requested is based “first became known” on a date the party specifies.”68

Although it would appear that these requirements would result in peti­tions that are timely filed, that is not always the case. Petitioners sometimes file long after becoming aware of the basis for the petition. One example appears with Mylan’s citizen petition against Teva’s Epi-Pen alternative, filed on January 16, 2015.69 In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008.70 And court documents show that Teva produced its ANDA filing in the course of litigation on September 17, 2010.71 This material included “detailed product descriptions, drawings, and instructions for use” for Teva’s proposed generic.72

At the time (and to this day), Mylan (as distributor and marketer) was working hand-in-hand with Meridian/King (manufacturer), with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.73 It thus seems exceedingly likely that Mylan would have been aware of Teva’s ANDA in 2008 and aware of documents explaining Teva’s product in 2010. In fact, it was Mylan that announced the settlement of the litigation, confirming its close connection to the case.74 This connection raises significant con­cerns that Mylan waited more than four years to file its citizen petition in 2015.

An amendment to section 505(q)(1)(H) to require a petitioner to certify that it filed its objection within one year of discovering the claim underlying the petition would help address the situation. The end of the section could include the following language:

The petitioner must certify that it became aware of the infor­mation upon which the action requested is based within one year of the petition.

Putting a timeframe on the obligation could make it more concrete and more difficult to evade. At the same time, one year should be enough time to research potential concerns with the generic drug. A certi­fication requiring filing within one year would make clear that peti­tions cannot be used to delay generic entry.75

CONCLUSION

Citizen petitions have recently received attention as a tool by which brand firms have delayed generic entry, allowing them to maintain their monopolies and preventing consumers from enjoying lower prices. The FDA has revealed concern with the resources it expends on petitions and has recently denied nearly all petitions targeting generic entry.

The five proposals offered in this Piece would address the most egre­gious aspects of the process. They would increase transparency, allow the dismissal of frivolous petitions, and prevent some of the most flagrant instances of delayed generic entry. Given high drug prices, the five pro­posals are worth attention.

### Civil RICO CP---1NC

#### The United States federal government should rule that the constitutional right to petition immunizes anticompetitive petitioning from the antitrust laws, explicitly irrespective of statutory interpretation principles, including when petitioning is a “sham,” and subject anticompetitive petitioning by the private sector to scrutiny under the civil RICO prohibition on racketeering activity.

#### The CP expands AND constitutionalizes the Noerr-Pennington exemption through a mutually exclusive ruling that shrinks the antitrust laws. Instead, it applies Civil RICO to petitioning---that solves the case.

Blair Silver 9. J.D., Georgetown University Law Center, 2008, “Controlling Patent Trolling with Civil RICO,” 11 Yale J.L. & Tech. 70 (2009), https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1046&context=yjolt

V. CONCLUSION

The modern patent system is incapable of policing extensive fraud. This inability to control fraudulent activity has created a system susceptible for abuse. The current remedies offered by the courts to counterbalance fraudulent conduct and trolling have not proved a sufficient disincentive to curb this behavior. Specifically, the remedies for fraud have not proven capable of deterring repetitive abusers.

Other areas of law outside patent law have tried to curb repetitive abuse, especially under antitrust. Walker Process opened up violators to the treble damages under the Sherman Act. However, Walker Process proved so unworkable as to be almost dead letter. Other attempts to control abusive behavior under the patent laws using antitrust have been attempted such as the questionably legal reverse payment settlement where the plaintiff patentee pays the alleged infringer to stay out of the market, the Noerr-Pennington doctrine's sham litigation exception, and the patent misuse doctrine. All of these have proven ineffective or unworkable. Simply, there is no effective deterrent to extensive fraud and abuse.

Civil RICO may be that solution. The incentive for using civil RICO is too high to permit its use as a common counterclaim, and the limitations on civil RICO, like the number of victims and the length of activity, help keep civil RICO from overtaking ordinary fraud. While civil RICO should not apply to where the Patent Office's standard remedies of unenforceability for inequitable conduct compensate for individual instances of fraud, civil RICO can be used to limit repeated abuses of the system where these ordinary penalties do not work. Fraud that extends beyond just filing to include Lemelson litigation schemes, should be recognized to lead to civil liability under RICO.

Recognizing civil RICO in the patent context may disproportionately affect brand name pharmaceutical companies. Any concerns of the cost to brand name manufacturers are overwhelmingly counterbalanced by the incentive for companies to seek the strongest patents possible. The immediate cost to the brand name companies may be high, but the overall public good demands patents with integrity. The public benefits by confidence in the fortitude of its patents. The judicial system benefits when patents stand firm against invalidity. Civil RICO will promote honesty and fair dealing throughout the patent process, from when the brand name companies acquire their patent through when they litigate their patents.

The modern abuses of the patent system need to be addressed. Congress is attempting to remedy these problems in modern patent reform. However, effective, pre-existing law should not be ignored. As the courts have previously attempted to control patent abuse using the antitrust laws, courts should not overlook the ability of civil RICO to apply in patent litigations. Although violations may be rare and should only be found for extreme abuses, the result could be a reduction in extensive fraud on the Patent Office, a reduction in the misuse of the court systems, and a higher quality of issued patents. Patent holding companies may then think twice about using such dubious tactics in acquisition, challenging existing patentees, and enforcement.

#### The precedent set by Noerr constitutionalization spills over.

Michael Pemstein 14. Attorney, Quinn Emanuel Urquhart & Sullivan, LLP, “The Basis for Noerr-Pennington Immunity: An Argument That Federal Antitrust Law, Not The First Amendment, Defines the Boundaries of Noerr-Pennington,” 40 T. Marshall L. Rev. 79, Lexis.

III. HARMONIZING SUPREME COURT PETITIONING IMMUNITY JURISPRUDENCE

As was discussed in the introduction, many lower courts have assumed that the primary basis for the Noerr-Pennington doctrine is the First Amendment right to petition. 40 This Part argues, however, that the Supreme Court's petitioning immunity decisions are best explained if the Noerr-Pennington doctrine is understood as being based on an interpretation of federal antitrust laws, not an interpretation of the First Amendment right to petition. Section A of this Part analyzes three cases from the Court's petitioning immunity jurisprudence in the context of antitrust law, E. R. R. Presidents [\*89] Conference v. Noerr Motor Freight, Inc., Allied Tube & Conduit Corp. v. Indian Head, Inc., and FTC v. Superior Court Trial Lawyers Ass'n. In the first of these cases, Noerr, the Court granted the defendants petitioning immunity 41, but it declined to do so in the other two cases. 42 Therefore, if Noerr-Pennington is based primarily on constitutional principles, then Allied Tube and Trial Lawyers must be distinguishable from Noerr on constitutional grounds. A close analysis reveals, however, that the best reading of these cases is that they are not distinguishable on constitutional grounds, but are distinguishable if they are based on an interpretation of antitrust laws.

Section B analyzes two cases from the Court's petitioning immunity jurisprudence decided outside the context of antitrust laws, McDonald v. Smith 43 and BE & K Const. Co. v. N.L.R.B. 44 In McDonald, the Court declined to extend petitioning immunity to a defendant in a defamation suit. If Noerr-Pennington were based on constitutional principles and therefore should be applicable regardless of the statutory context, then McDonald must be distinguishable on constitutional grounds from other Noerr-Pennington cases where the Court extended immunity. Again, however, a close analysis of the reasoning and result in McDonald shows that it can be best explained if Noerr-Pennington is not based primarily on the First Amendment right to petition, but instead extends a greater level of protection than the Constitution requires based on non-constitutional considerations.

In BE & K Const. Co., a case addressing the scope of petitioning immunity in the labor law context, the Court expressly left open the possibility that an unsuccessful but objectively based suit may be deemed a violation of the National Labor Relations Act if it would not have been brought but for a retaliatory purpose. 45 Such a possibility, however, was expressly rejected in the antitrust context by the Court in PRE. 46 Therefore, if Noerr-Pennington were based on constitutional principles, BE & K Const. Co. would represent a partial overruling of PRE. Once again, however, a close analysis of [\*90] the text and reasoning in BE & K Const. Co., as well as the opinions of the concurring justices, shows that the better reading of BE & K Const. Co. is that it did not overrule PRE. Instead, it implicitly recognized that because Noerr-Pennington is based primarily on an interpretation of federal antitrust laws, the scope of its protections might not necessarily apply to the same extent outside of the antitrust context.

Finally, Section C refutes a common critique of this reading of Noerr-Pennington: that California Motor Transport Co. v. Trucking Unlimited "constitutionalized" the holdings from Noerr. 47

A. Petitioning immunity in antitrust: Noerr, Allied Tube, and Trial Lawyers

This Section examines the Court's holdings and supporting reasoning in Noerr, a case where the Court extended antitrust petitioning immunity, and two subsequent cases where the court declined to provide antitrust petitioning immunity, Allied Tube, and Trial Lawyers. If Noerr provides constitutionally mandated minimum levels of protection, only constitutional considerations would allow the Court to provide a lower level of protection in Allied Tube and Trial Lawyers. An analysis of these three cases shows that the sole shared distinguishing characteristic between them is the form of the petitioning activity. Therefore, in order for Noerr to be primarily based on constitutional principles, the Constitution must provide a lower level of protection for the types of petitioning activity in Allied Tube and Trial Lawyers than the type of petitioning activity in Noerr. There is, however, no adequate constitutional justification for providing the form of petitioning in Noerr with a greater level of protection than the form of petitioning in Allied Tube and Trial Lawyers. In fact, the different treatment of the petitioning activity in these cases can best be explained if Noerr is understood as being based primarily on an interpretation of federal antitrust laws.

1. Comparing Noerr, Allied Tube and Trial Lawyers

In Noerr, a coalition of trucking companies sued a coalition of rail companies under the Sherman Act alleging that the rail [\*91] companies had conducted a publicity campaign to "foster the adoption and retention of laws and law enforcement practices destructive of the trucking business." 48 The harm underlying the action stemmed from two sources. First, the truckers claimed injury from the government action for which the rail companies had lobbied, i.e. the passage of weight limit laws. 49 Second, the truckers claimed that the publicity campaign painted the truckers in a negative light thereby causing them to lose business and goodwill with their customers. 50 The truckers argued that the rail companies could be held liable because their purpose in conducting the campaign was to cause anticompetitive harm to the trucking companies. 51 The truckers also argued that the rail companies could be held liable because the rail companies had engaged in unethical behavior in their publicity campaign by using the "third party technique." 52

The Court explicitly held that the anticompetitive motivation of the rail companies and the unethical manner of the petition were insufficient to impose antitrust liability. 53 First, the Court addressed the anticompetitive motivations. 54 It determined that a petitioner could not be held liable under the Sherman Act simply because he was subjectively motivated to bring the petition by a desire to cause harm to a competitor. 55 Speaking for a unanimous court, Justice Black reasoned that the Sherman Act was meant to regulate business, not political activity, and to interpret the Sherman act as sustaining this cause of action would raise serious constitutional questions regarding the First Amendment right to petition. 56 "A construction of the Sherman Act that would disqualify people from taking a public position on matters in which they are financially interested would thus deprive the government of a valuable source of information and, at the same time, deprive the people of their right to petition in the [\*92] very instances in which that right may be of the most importance to them." 57

The Court also found unpersuasive the suggestion that the unethical means of petitioning should lead to a different result. 58 It reasoned that unethical behavior in the political realm is not meant to be addressed by the Sherman Act. 59 Historically, Congress had been cautious in regulating political activity, and if the Court were to impute this purpose to the Sherman Act it would negate this caution. 60

If these holdings from Noerr are rooted in the First Amendment, then they are constitutionally mandated minimum levels of protection. Therefore, the Court should apply the same levels of protection in analogous situations, or in cases that have the same considerations that were present in Noerr, unless other constitutional principles dictate a different result. A close analysis of two subsequent petitioning immunity cases, Allied Tube, and Trial Lawyers, however, shows that the Court did not apply the same levels of protection in these cases, though they presented analogous situations and considerations as those present in Noerr.

In Allied Tube, the plaintiff, a manufacturer of polyvinyl chloride electrical conduits, brought an antitrust action against a manufacturer of steel electrical conduits. 61 The plaintiff claimed that the defendant conspired to prevent the inclusion of polyvinyl conduits in the industry safety standards. 62 Specifically, the plaintiff claimed that the defendant along with the top steel manufacturing companies in the country recruited and paid for over 200 people to join the National Fire Protection Association with instructions that they were to vote against the inclusion of polyvinyl conduits in the industry code. 63 The defendants claimed they were entitled to Noerr-Pennington immunity because the code was commonly adopted into state safety codes by numerous state legislatures and therefore their actions were [\*93] a means of petitioning state legislatures to exclude polyvinyl conduit from their state safety codes. 64

It may not be apparent on its face, but Allied Tube actually has a factual situation very close to the one presented in Noerr. In both cases, the suit was brought under the Sherman Act for antitrust violations. 65 Also, in both cases the petitioning was not objectively baseless, as both the rail companies and the defendant in Allied Tube succeeded in obtaining their sought after government action: the passage of anti-trucking legislation and the exclusion of polyvinyl conduits from state safety codes. 66 In both cases the defendants engaged in the petitioning activity specifically because it would cause harm to their competitors. 67 Also in both cases, the harm underlying the suit resulted from both a government decision and the petitioning activity that led to that government decision. In Allied Tube, the harm that formed the basis of the suit derived both from the adoption of the association's safety code by state legislatures (the petitioned for government action), and from being excluded from the association's safety code (the petitioning activity itself). 68 In Noerr, the harm resulted from both the harmful trucking legislation (the petitioned for government action), and the negative publicity campaign (the petitioning activity itself). 69 Finally, the petitioning activity in Allied Tube was unethical, but did not violate any of the rules of the National Fire Protection Association, 70 just as in Noerr where the publicity campaign was misleading and unethical, but not necessarily illegal. 71

There are a few notable differences, which distinguish Noerr from Allied Tube. First, the conduit used by the defendants to influence to the government decision maker differed in these two cases. In Allied Tube, the government decision maker whom the petitioning activity was ultimately intended to affect was a legislative body, as it was in Noerr. But unlike Noerr, the conduit to the legislature was not the public at large (to whom the Noerr publicity [\*94] campaign was aimed), but the members of a private standards setting association. Second, the form of the petitioning activity differed in these two cases. In Allied Tube, the petition took the form of packing the ranks of a private standards setting association, whereas in Noerr it was in the form of a publicity campaign. 72

Ultimately, the Court in Allied Tube found these differences to be dispositive, concluding that the defendant was not entitled to petitioning immunity. 73 The Court noted that the "petitioner's actions took place within the context of the standard-setting process of a private association" whereas "the publicity campaign in Noerr… [took] place in the open political arena." 74 It also noted that "[t]he essential character of the Noerr publicity campaign was … political" a type of activity which "has been regulated with extreme caution," whereas the petitioner's activity in Allied Tube was "the type of commercial activity that has traditionally had its validity determined by the antitrust laws themselves." 75 "[T]he activity at issue here … cannot, as in Noerr, be characterized as an activity that has traditionally been regulated with extreme caution, or as an activity that 'bear[s] little if any resemblance to the combinations normally held violative of the Sherman Act." 76 Petitioning immunity in this instance, therefore was not appropriate.

In Trial Lawyers, private practice attorney's that worked as court-appointed counsel for indigent criminal defendants in the District of Columbia organized a boycott in order to coerce the District of Columbia to increase their compensation. 77 The boycott was ultimately successful, but the Federal Trade Commission brought antitrust charges under the Sherman Act against the trial lawyers. 78 The trial lawyers argued, in part, that their activities were protected as a means of petitioning the government and so were immune from liability under the Noerr-Pennington doctrine. 79

Trial Lawyers, like Allied Tube, presents a situation very similar to the one in Noerr. While the attorney's were able to convince the [\*95] government to raise their compensation, the harm that formed the basis of the Trial Lawyers suit actually resulted from the petitioning activity itself. As the court pointed out: "[t]he restraint of trade that was implemented while the boycott lasted would have had precisely the same anticompetitive consequences during that period even if no legislation had been enacted." 80 The suit, like in Noerr, was brought under the Sherman Act. 81 The petitioning activity was not objectively baseless, indeed it was ultimately successful, and was engaged in specifically because it would have an anticompetitive effect, i.e., it created a supply shortage in the market for public defenders. Even the "audience" was the same in Trial Lawyers as it was in Noerr, as the boycott was directed not only toward the legislature, but also to the public at large as a conduit to the legislature.

The sole distinguishing characteristic in Trial Lawyers from Noerr is the form of the petitioning activity. In Noerr, it was a publicity campaign, but in Trial Lawyers it was by means of a boycott. 82 Like in Allied Tube, this distinguishing characteristic led the court to a different result than in Noerr. Deciding that the attorney's were not entitled to petitioning immunity, the Court, quoting Allied Tube, reasoned that "the Noerr doctrine does not extend to 'every concerted effort that is genuinely intended to influence governmental action.'" 83 If it did, the Court reasoned that the Noerr-Pennington doctrine would immunize a whole host of anticompetitive activity simply because its purpose in doing so was to influence a government decision maker. 84

2. Constitutional Considerations Cannot Harmonize Allied Tube, Trial Lawyers and Noerr

Both Trial Lawyers and Allied Tube presented situations that were very close to the one in Noerr. The only difference with Noerr that was shared by Allied Tube and Trial Lawyers was the form of the petitioning activity. Yet the Court provided a lower level of [\*96] protection for the activity in both Allied Tube and Trial Lawyers than it afforded the activity in Noerr.

As was discussed in the introduction, the Constitution sets a mandated minimum level of protection for petitioning activity. This means that there are only two possible explanations for the differing treatment in Allied Tube, Trial Lawyers, and Noerr. Either Noerr is a constitutional decision and the Constitution requires a greater level of protection for the form of petitioning activity in Noerr than in Allied Tube and Trial Lawyers, or Noerr is not a constitutional decision and the level of protection the Court provided the petitioning activity in Noerr went beyond what the Constitution requires based on nonconstitutional considerations. In order for Noerr to be a constitutional decision there must be some constitutional justification for providing publicity campaigns with greater protection than boycotts or packing private standard setting associations with supporters.

Looking first to the reasoning in Noerr, the Court in coming to its decision specifically focused on the concern that imposing liability would inhibit people's ability to "make their wishes known" to the government. 85 If the constitutional concern in Noerr was that imposing liability would deprive the government of information, and deprive the people of their ability to provide that information, then this concern should not be present in Allied Tube or Trial Lawyers, since unlike Noerr, they were decidedly adversely to the petitioning party. This is not the case however. Depriving boycotts or the petitioning activity in Allied Tube of constitutional protection would likely inhibit people's ability to "make their wishes known" to the government to the same degree as depriving publicity campaigns of constitutional protection. In fact, the Court in Allied Tube specifically noted that the petitioners' activity might have been "the most effective means of influencing legislation." 86 Thus, the Allied Tube decision may in fact raise this concern to a greater extent than the situation in Noerr did. 87 Similarly, boycotting is a classic form of political protest, one that the Court provided with constitutional [\*94] protection in NAACP v. Claiborne Hardware. 88 In that case the Court specifically acknowledged that "a major purpose of the boycott … was to influence governmental action." 89 In extending the boycott in Claiborne Hardware constitutional protection the Court stated: "[t]he right of the States to regulate economic activity could not justify a complete prohibition against a nonviolent, politically motivated boycott designed to force governmental and economic change and to effectuate rights guaranteed by the Constitution itself." 90

One might argue then that the form of the petitioning in Noerr is afforded greater constitutional protection than the forms in Allied Tube and Trial Lawyers because the forms of the petitions in Allied Tube and Trial Lawyers were illegal. 91 There are three problems with this argument however. First, it is circular, essentially stating that this form of petitioning activity is not protected by the First Amendment because Congress has prohibited it and Congress cannot prohibit constitutionally protected behavior. The result presumes the premise.

Second, it is premised on a definition of the right to petition that completely eviscerates that right. If petitioning activity can be moved outside the protection of the Constitution by an act of Congress or an order from the executive branch, then the Constitution would provide no protection for petitioning activity whatsoever. And while the Court does not interpret the First Amendment prohibition "Congress shall make no law" literally, this definition completely contradicts this prohibition, making the right to petition entirely dependent on laws "ma[d]e" by Congress.

Finally, other cases in the Court's petitioning immunity jurisprudence refute this argument. In Noerr itself, the defendant was alleged to have "deliberately deceived the public and public officials," 92 a potentially illegal act for which the Court nonetheless [\*98] provided protection. Similarly in City of Columbia v. Omni Outdoor Advertising, 93 the Court extended petitioning immunity to a defendant who was alleged to have, as part of his lobbying strategy, conspired with and bribed public officials. 94 The Court reasoned that to allow liability under the Sherman act in such circumstances "would produce precisely that conversion of antitrust law into regulation of the political process that we have sought to avoid." 95 Therefore, as Omni and Noerr itself demonstrate, the fact that the form of the petitioning activity is illegal is not sufficient to explain the differences in treatment between Trial Lawyers, Allied Tube, and Noerr, if Noerr were interpreted as a constitutional decision.

One final argument for why the Constitution may provide greater protection for the form of petitioning in Noerr than for the form in Allied Tube and Trial Lawyers, could be that the Constitution protects certain traditional forms of petitioning, such as the publicity campaign in Noerr, but does not protect untraditional forms of petitioning such as the boycott in Trial Lawyers, or the actions of the defendant in Allied Tube. This argument is unpersuasive for two reasons. First, nothing in the language of the Court's Noerr- Pennington line of opinions indicates that it made any such distinction. Rather, to the extent that Noerr addresses the relevance of the historical character of the petitioning activity, it does so by analyzing whether the form of the petitioning activity is the kind of activity "traditionally condemned" by antitrust laws, not the Constitution. 96

Second, this interpretation of the First Amendment right to petition does not fit with the Court's other petitioning immunity cases. For example in NAACP v. Claiborne Hardware, the Court extended petitioning immunity protection to a boycott of segregated businesses, the same form of petitioning which was denied protection in Trial Lawyers. 97 Also, in California Motor Transport Co. v. Trucking Unlimited, the Court refused to provide protection to what [\*99] would probably be considered a very traditional form of petitioning activity: filing lawsuits in courts and grievances with administrative agencies. 98

3. Allied Tube, Trial Lawyers and Noerr Can Be Harmonized as Statutory Interpretation Decisions

While the results in these cases cannot be persuasively explained if Noerr were regarded as a constitutional holding, they can be explained if Noerr was a holding based on statutory interpretation principles. First, the reasoning in Noerr fits with this interpretation. Recall that the Court in Noerr stated that it must provide petitioning immunity to the defendant because interpreting the Sherman Act to sustain the cause of action "would raise important constitutional questions." 99 By applying the doctrine of constitutional avoidance, the Court was able to avoid these questions because the Sherman Act was susceptible to another interpretation that did not raise them, specifically that the Sherman Act was not meant to regulate political activity: "[t]he proscriptions of the Act, tailored as they are for the business world, are not at all appropriate for application in the political arena." 100 Similarly, the Court reasoned that because Congress had been historically hesitant to regulate political activity, it would be imprudent to interpret the Sherman act to do so. 101

In Allied Tube and Trial Lawyers, however, the form of the petitioning at issue precluded the Court from taking such a cautious approach. This is because the form of the petitioning activity in these cases was the type of conduct the Sherman Act specifically meant to prohibit. Boycotts are one of the per se violations of the Sherman Act. 102 Similarly, in Allied Tube, the Court pointed out that the petitioner's activity was "the type of commercial activity that has traditionally had its validity determined by the antitrust laws themselves." 103

[\*100] Unable to avoid the difficult constitutional questions posed by the Sherman Act, the Court was forced to address them. In Allied Tube, the Court specifically noted that it is "difficult to draw the precise lines separating anticompetitive political activity that is immunized despite its commercial impact from anticompetitive commercial activity that is unprotected despite its political impact, and this is itself a case close to the line." 104 The Court concluded, however, that the defendant's activity in this case fell in the latter category, and therefore was not entitled to petitioning immunity.

In Trial Lawyers, the Court was also forced to answer difficult constitutional questions because in NAACP v. Claiborne Hardware, the Court had held that the participants in the NAACP's boycott of white merchants were protected from suit under antitrust and common law claims. 105 Therefore, in order to hold the defendants in Trial Lawyers liable the Court needed to distinguish Claiborne Hardware. It did so based on the fact the boycotters in Trial Lawyers were "at least partially motivated by the desire to lessen competition, and… stood to reap substantial economic benefits from [the anticompetitive activity]," 106 whereas the petitioners in Claiborne did not seek to destroy their competitors in the market, but "sought only the equal respect and equal treatment to which they were constitutionally entitled." 107 In Noerr, the Sherman Act and its purposes allowed the Court to avoid making such bold First Amendment pronouncements, but in Allied Tube and Trial Lawyers the Act clearly applied and the Court had no choice but to determine whether the First Amendment allowed the imposition of liability for these petitioning activities, which the Court held it did.

[\*101] B. Petitioning immunity outside of antitrust: McDonald and BE & K Const.

If Noerr-Pennington were based on constitutional considerations and not an interpretation of antitrust laws, then its principles should be equally applicable outside the realm of antitrust laws. An analysis of two such Supreme Court petitioning cases McDonald v. Smith, 108 a libel case, and BE & K Const. Co. v. N.L.R.B., 109 a labor law case, shows that this has not been the case.

In McDonald, the defendant made knowingly false statements in order to convince the President not to appoint the plaintiff as a United States Attorney. The plaintiff brought a libel suit and the defendant claimed that he was immune from liability because his activities were protected by the First Amendment. 110 The Court declined to extend petitioning immunity to the defendant, reasoning that while the First Amendment protects the right to petition, it does not protect all petitioning activity. 111 Providing an absolute immunity for petitioning activity "would elevate the Petition Clause to special First Amendment status." 112 It concluded therefore that the state common law standard of allowing libel liability upon a showing of "actual malice," would not violate the First Amendment right to petition. 113

This ruling would seem to at least partially overrule Noerr if Noerr were a constitutional decision. Recall that in Noerr, the Court provided the defendant with petitioning immunity despite the fact that the defendant's publicity campaign had "deliberately deceived the public and public officials." 114 In McDonald, however, the Court came to the exact opposite conclusion. It specifically held that the First Amendment did not protect a petition that entailed deliberate falsehoods.

This result cannot be explained away by arguing that the petitioning activity in McDonald fell under the "sham" exception recognized in Noerr. 115 First, the defendant's petition was ultimately [\*102] successful: he was able to convince the President not to appoint the plaintiff as a US attorney. Therefore it cannot be considered "objectively baseless." 116 Second, the harm in McDonald did not stem solely from the petitioning process itself, as the "sham" exception requires, but also from the government action the petitioning party sought, specifically the President's decision not to appoint the plaintiff as a US attorney. 117

If Noerr were a constitutional decision, McDonald would at the very least seem to create a new "malicious" false statement exception to Noerr. In subsequent cases, however, the Court has not treated McDonald as establishing such an exception, instead the Court has expressly declined to "decide … whether and, if so, to what extent Noerr permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations." 118 Even those jurisdictions that have recognized a fraud exception to the Noerr-Pennington doctrine limit it to petitions before adjudicative bodies. 119 Therefore, even if the Court had implicitly recognized an analogous fraud exception, the petition in McDonald, which was directed to a non-adjudicative part of the executive branch, would not fall within it.

If, however, Noerr-Pennington does not delineate constitutionally mandated minimum levels of protection, but provides a higher level of protection for petitioning activity based on an interpretation of antitrust laws, these problems do not arise. In fact, this explanation seems to fit with the language and reasoning of other [\*103] cases in the Court's Noerr-Pennington jurisprudence. For example, in City of Columbia v. Omni Outdoor Advertising, the Court held that illegal lobbying activities, such as bribery and conspiracy with elected officials "can be of no consequence so far as the Sherman Act is concerned." 120 In McDonald, however, the petitioner's knowingly false statements were exactly the type of activity the tort of libel is concerned with. Therefore, the Court was forced to delve into the question of how much petitioning activity the First Amendment protects in that particular instance.

BE & K Const., a Supreme Court case addressing the subject of petitioning immunity in the context of Labor law, provides further support for this interpretation of the Noerr-Pennington doctrine. 121 In that case, the petitioner, a general contractor, filed a lawsuit against a group of unions alleging that the unions had attempted to delay one of the petitioner's projects through lobbying, litigation, and other concerted activities because the petitioner used non-union employees. 122 After the petitioner's lawsuit failed, the National Labor Review Board's ("NLRB") general counsel filed an administrative complaint against the petitioner claiming its lawsuit violated the National Labor Relations Act ("NLRA"). 123 The Board ruled in the general counsel's favor finding the petitioner's lawsuit violated the NLRA because it was unsuccessful and was brought with a retaliatory purpose. 124 The case subsequently came before the Supreme Court which certified the specific question of whether the NLRB "may declare that an unsuccessful retaliatory lawsuit violates the NLRA even if reasonably based." 125

If the protections afforded by Noerr-Pennington were constitutionally based and so were mandated even outside the context of antitrust, then this question would be easy. The Court had already determined in PRE that a reasonably based lawsuit, even if unsuccessful and brought with an improper motive, was entitled to petitioning immunity. 126 The PRE Court held that this is the case [\*104] even if the suit would not have been brought but for its anticompetitive effects. 127

The Court in BE & K Const. ultimately followed PRE and the Noerr-Pennington cases, but only to a certain extent. First, it took a similar tact as in Noerr and held that an interpretation of the NLRA, which allowed it to punish all reasonably based but unsuccessful retaliatory suits would raise serious constitutional questions. 128 Turning to the statutory text, the Court found that "while [the NLRA] might be read to reach the entire class of suits the Board has deemed retaliatory, it need not be read so broadly." 129 Therefore the Court held that "[b]ecause there is nothing in the statutory text indicating that [the NRLA] must be read to reach all reasonably based but unsuccessful suits filed with retaliatory purpose, we decline to do so." 130

Up to this point the BE & K Const. Court is entirely in line with the Noerr-Pennington doctrine. In the closing paragraph of the opinion, however, the Court expressly left open the possibility "that the board may declare unlawful any unsuccessful but reasonably based suits that would not have been filed but for a motive to impose the costs of the litigation process, regardless of the outcome, in retaliation for NLRA protected activity." 131 As was just discussed, however, such a possibility was expressly rejected in the antitrust context by the Court in PRE. 132

If Noerr-Pennington provides constitutionally mandated levels of protection (and therefore is equally applicable regardless of the statutory context), then by leaving this possibility open BE & K Const. would partially overrule this aspect of PRE. But there is no indication in the text of BE & K Const. that the Court intended such a result. In fact, the Court expressly relies on the reasoning and result [\*105] in PRE in its opinion. 133 If, however, Noerr-Pennington and PRE do not dictate constitutionally mandated minimum levels of protection, but instead provide a greater level of protection based an interpretation of federal antitrust laws, then BE & K Const. need not be read as overruling PRE. Under such an interpretation the Court in BE & K Const. simply left open the possibility that a lower level of protection for petitioning activity may be warranted in the labor law context than in the antitrust context due to the differences between these laws.

In fact, the debate of whether such differences justify differing treatment for petitioning activity is acknowledged in the Courts' opinion in BE & K Const. 134 and actually plays out in the concurring opinions of Scalia and Breyer. Breyer argues that the "Court's antitrust precedent [should not] determine[] the outcome here" because of the differences between antitrust and labor law "in respect to their consequences, administration, scope, history and purposes." 135 Scalia disagrees and argues that the scope of protection for petitioning activity should be equal in these two areas of law. 136 In fact, he argues that if anything, petitioning activity should be afforded greater protection in the labor law context because the burdens imposed on petitioning activity in that context are imposed by an executive agency, the NLRB, whereas in the antitrust context the burdens are imposed by an Article III court. 137

The answer to this debate, however, does not dictate the result here. The mere fact that such a debate exists demonstrates that Noerr-Pennington does not provide constitutionally mandated levels of protection because if it did then the question debated would already have been answered by PRE.

[\*106] C. Rebutting the Argument that California Motor Transport Co. "constitutionalized" Noerr-Pennington.

Some commentators have argued that while the Court did not initially base its holdings in Noerr on the First Amendment, a subsequent case, California Motor Transport Co. v. Trucking Unlimited, 138 later interpreted Noerr's holdings as being based on the Constitution and thus "constitutionalized" them. 139 The following language from California Motor is frequently cited in support of this proposition: "We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-à-vis their competitors." 140 This "constitutionalization" interpretation, however, is not a necessary or even the best reading of California Motor.

Even were this language read in isolation from the rest of the Court's reasoning in California Motor, it would not support the conclusion that California Motor "constitutionalized" the holdings in Noerr. Simply because imposing liability would "be destructive of rights of association and of petition" does not mean that it would violate the First Amendment. As the Court stated in Claiborne Hardware: "[t]he presence of protected activity … does not end the relevant constitutional inquiry." 141 The Court regularly upholds government regulation even if it incidentally infringes on a constitutionally protected right. 142

When read in context, though, it is even clearer that this language is not "constitutionalizing" the holdings of Noerr, but only extending the Noerr holdings to apply to petitioning activity before courts and administrative bodies. Prior to this statement, the Court in California Motor noted that in Noerr and Pennington it had provided petitioning immunity to parties who attempted to "influence the [\*107] Legislative Branch for the passage of laws or the Executive Branch for their enforcement." 143 The California Motor Court then adopted two justifications from Noerr to support the extension of petitioning immunity beyond the realms of the Legislative and Executive branches and into the realm of the Judicial branch. The first was the people's ability to communicate their concerns to the government, and the government's ability to receive this information. 144 The second was the Court's presumption that it should not "lightly impute to congress an intent to invade [freedoms protected by the Bill of Rights]." 145 The California Motor Court, finding these justifications equally applicable to "administrative agencies (which are both creatures of the legislature, and arms of the executive) and to courts, the third branch of Government," held that the protections recognized in Noerr and Pennington should therefore be applicable in these realms as well. 146 Because this extension of Noerr-Pennington protection was explicitly based on these two justifications from Noerr, the same principles on which these justifications rest should also underlie this extension. But, as was demonstrated supra Part II.A.2., neither of these justifications provides a basis to conclude that the Noerr-Pennington doctrine defines constitutional levels of protection.

A further analysis of California Motor demonstrates that its holdings and supporting reasoning are not based on constitutional considerations, but like Noerr are based on an interpretation of antitrust laws. In California Motor, the plaintiff highway carrier brought a suit against a coalition of its competitors claiming these competitors violated federal antitrust laws by opposing every one of the plaintiff's applications to acquire operating rights in California regardless of the merits of the opposition. 147 The Court, using an analogous line of reasoning as it would subsequently use in Trial Lawyers and Allied Tube, noted that while in Noerr the Court had recognized that Congress's caution in regulating unethical political activity prevented them from imputing such a purpose to the Sherman act, Congress had not been similarly cautious in regulating unethical [\*108] activity before adjudicatory bodies. 148 The Court continued: "First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." 149 Therefore, while the defendant may have a right to oppose the plaintiff's applications, this right does not entitle him to "to eliminate an applicant as a competitor by denying him free and meaningful access to the agencies and courts." 150 The Court held, therefore, that the defendant was not entitled to petitioning immunity.

Note that one of the first moves the Court makes in California Motor is distinguishing Noerr by noting that this petitioning activity comes before an adjudicative body. The Court does not argue that this distinction is critical to a First Amendment analysis, but rather, it is important for interpreting the Sherman act. Specifically, the Court argues that because Congress is not similarly cautious when legislating in the adjudicative sphere as it is when legislating in the political sphere, it may interpret the Sherman act to reach more activity in the adjudicative sphere than it may in the political sphere. 151 This reasoning is explicitly based on an interpretation of the Sherman act, not the First Amendment.

Furthermore, the Court's holding in California Motor is too narrow to have the expansive effect of "constitutionalizing" Noerr. The Court only concludes that imposing liability on the defendants in this particular instance would not violate the First Amendment. It does not follow from this conclusion, however, that it would have violated the First Amendment had the Court refused to extend immunity to the defendants in Noerr.

Even if such an expansive reading of California Motor were possible, this particular issue was not before the Court and was not necessary to the Court's holding. Therefore, at most it would be dictum. Importantly, California Motor predates every case in the Court's petitioning immunity jurisprudence except for Noerr and Pennington, including Allied Tube, McDonald, and Trial Lawyers. And, as was argued in the preceding sections, the results and reasoning of these subsequent cases cannot cohere with this reading of California Motor, as "constitutionalizing" Noerr. Therefore, even [\*109] if California Motor read Noerr as being based on constitutional principles, these subsequent cases implicitly rejected this reading and declined to follow this dictum. 152

IV. RETURNING TO THE MISTAKE AND CONSEQUENCES OF THEME PROMOTIONS

With the understanding that Noerr-Pennington is primarily a doctrine based on an interpretation of Federal Antitrust law, it is now possible to see how courts may be extending constitutional protections for petitioning activity outside the context of antitrust law based on a misinterpretation of Supreme Court precedent. Returning to the example from the introduction of this Article, recall that in Theme Promotions, Inc. v. News Am. Mktg. FSI 153 the Ninth Circuit was presented with a novel question of law: to what extent should defendants in common law tort suits be afforded petitioning immunity? 154 The court somewhat summarily determined that the Noerr-Pennington doctrine should apply to the exact same extent as in the antitrust context where it was developed: "'There is simply no reason that a common-law tort doctrine can any more permissibly abridge or chill the constitutional right of petition than can a statutory claim such as antitrust.' … [W]e hold that the Noerr-Pennington doctrine applies to Theme's state law tortious interference with prospective economic advantage claims." 155

Under a statutory interpretation reading of Noerr, this reasoning is mistaken. While it may be the case that a common-law tort doctrine may "abridge or chill the constitutional right of petition" to the same extent as an antitrust claim, the Noerr-Pennington doctrine is not a statement by the Supreme Court as to the level of protection the First Amendment right to petition mandates in antitrust law, but rather is a doctrine which delineates a greater level of protection for [\*110] petitioning activity in the context of antitrust claims based on an interpretation of federal antitrust law. In fact, the closest the Court has come to making a statement regarding the scope of protection afforded by the First Amendment was in three cases which held that Noerr was inapplicable or distinguishable: NAACP. v. Claiborne Hardware Co., 156 F.T.C. v. Superior Court Trial Lawyers Ass'n., 157 and Allied Tube & Conduit Corp. v. Indian Head, Inc. 158 Therefore, even if petitioning activity should be afforded the same level of constitutional protection from a common-law tort suit as an antitrust cause of action, the Noerr-Pennington doctrine does not determine that level of protection.

Mistakes like the one made by the court in Theme Promotions can result in a number of errors. First, the court may provide too much protection for petitioning activity. As a result of this type of error plaintiffs who are harmed by a defendant's petitioning activities may be wrongfully denied redress for those harms. In cases where the plaintiff would have ultimately been successful, this means the plaintiff will have to unjustly bear the cost of the defendant's petitioning activity, which can entail very high damages. The tort claims dismissed by the Theme Promotions court on appeal, for example, had received an $ 833,345 award for actual damages and a $ 2,500,000 award for punitive damages from a jury. 159 Even in cases where the plaintiff would not have ultimately prevailed, simply having the case resolved before an impartial tribunal has its own inherent benefits. 160

Also, because Noerr-Pennington provides such a high level of protection for petitioning activity, some petitioning activity that may be socially undesirable will go unpunished. In our representative system of government, which requires government officials to heavily rely on information it receives from interested parties, there is [\*111] a strong incentive for those parties to do whatever it takes to convince the government that their desired course of action is the best course of action. The problem presented by such an incentive can be seen, for example, in jurisdictions that do not recognize a "misrepresentation" exception to the Noerr-Pennington doctrine. 161 In these jurisdictions parties have a huge incentive to deliberately mislead government bodies, knowing that their deceitful petitioning activities will receive full immunity.

The second type of error that may occur is not an error in result, but an error in reasoning. If the "proper" level of protection for petitioning activity in a non-antitrust cause of action happens to be the same level that would be required by the Noerr-Pennington doctrine, then while courts may reach the correct outcome by transposing the Noerr-Pennington doctrine outside the context of antitrust law, these courts will base this result on an improper analysis. Even though this is a mistake in reasoning and not in result, there still may be consequences. For example, courts which make this mistake may be avoiding constitutional questions concerning the proper scope and application of the First Amendment right to petition when they should be addressing them. This can occur because the Noerr-Pennington doctrine is primarily based on an interpretation of federal antitrust statutes and therefore it is imbued with statutory interpretation principles. These principles require courts to take a cautious approach and to be hesitant to attribute an intent to infringe or chill constitutionally protected freedoms to the legislature. For example, in Noerr, the Court avoided "difficult constitutional questions" by refusing to interpret the Sherman Act as imposing antitrust liability for political activities, noting that Congress had traditionally been hesitant to regulate such activities. 162

These statutory interpretation principles, however, are not applicable in petitioning immunity cases based on common law causes of action. The common law is the sole province of the judicial branch. By imputing these statutory interpretation principles into the realm of common law, courts, like the one in Theme Promotions, are [\*112] shirking their institutional responsibility to address the "difficult constitutional questions" posed by petitioning immunity suits that are based on common law causes of action. 163 As a result, the right to petition, an already underdeveloped area of law, will continue to be neglected, potentially compounding these problems in future petitioning immunity cases.

Another consequence to this error in reasoning is that it attributes constitutional status to levels of protection which were primarily based on non-constitutional considerations. As a result it entirely precludes Congress from changing the levels of protection afforded to petitioning activity in areas of law governed by statute. Any changes to those levels of protection would have to come by way of constitutional amendment or court decision.

V. CONCLUSION

While the Supreme Court has not explicitly stated whether the Noerr-Pennington doctrine is a constitutional doctrine or a statutory interpretation doctrine, what it has done demonstrates that Noerr-Pennington falls into the latter category. Noerr-Pennington is difficult to conflate with the Court's own petitioning immunity jurisprudence if it is read as a doctrine defining the contours of the First Amendment right to petition. A statutory interpretation reading of the Noerr-Pennington doctrine, however, ameliorates the contradictions and problems that would otherwise result from a constitutional reading. A statutory interpretation reading also fits with, and helps explain, other decisions in the Court's petitioning immunity jurisprudence. Thus, lower courts that interpret Noerr-Pennington as mandating a constitutional level of protection may potentially be shielding petitioning activities from liability that may constitutionally be imposed. These courts are also giving [\*113] constitutional status to levels of protection determined by nonconstitutional considerations and are failing to engage in the analysis needed to determine the scope of petitioning immunity in causes of action that are not based on antitrust law.

#### Specifically to the ATS

Aaron P. Brecher 15. Attorney at Lane Powell PC, Seattle, Washington. Disclosure, “Noerr-Pennington Immunity and the Alien Tort Statute,” New York University Law Review, Vol. 90, pp 25-35.

II THE NOERR-PENNINGTON DOCTRINE CAN EXCLUDE EVIDENCE OF PETITIONING

The Supreme Court has ruled that efforts to petition the government, even if undertaken for anticompetitive purposes and with anticompetitive effects, lie beyond the reach of the antitrust laws.20 The Noerr-Pennington doctrine, named for the cases that first described it, has been used to reject “attempt[s] to base a Sherman Act conspiracy on evidence consisting entirely of activities of competitors seeking to influence public officials”21 and avoids transgressing First Amendment petitioning rights by extending immunity from antitrust liability to genuine efforts to influence any branch of government.22

So far, so good.

But here’s where things get a bit tricky for my theory. Pennington itself says that evidence of petitioning activities, “which . . . are barred from forming the basis for a suit, may nevertheless be introduced if it tends reasonably to show the purpose and character of the particular transactions under scrutiny.”23 Moreover, the Supreme Court ruled in Wisconsin v. Mitchell that the First Amendment “does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.”24

Where, however, there is little evidence of an antitrust violation other than efforts to petition some branch of government, lower courts have sometimes concluded such evidence should be excluded.25 For example, in a class action alleging price-fixing of credit card interest rates among banks, the only evidence of a conspiracy other than the parallel interest rates was that the defendants had hired a lobbyist who had successfully pushed for legislation approving increased interest rates.26 The Seventh Circuit upheld the district court’s grant of summary judgment to the defendants and its refusal to consider the lobbying evidence, reasoning that the evidence was far more suggestive of petitioning immune from liability than conspiratorial intent.27 The Tenth Circuit also upheld summary judgment for an ambulance service accused of monopolizing the county ambulance market.28 There, the only evidence of market power was the company’s market share, yet most of the company’s business came from a city-granted franchise.29 The court held that evidence of market share derived from the defendant’s lobbying to acquire and maintain the franchise with the city could not therefore be considered.30 In addition, a district court concluded that “the exclusion of ‘purpose and character’ evidence consisting of conduct clearly embraced by Noerr-Pennington should be the rule rather than the exception in an antitrust case.”31 It’s this use of Noerr-Pennington to exclude evidence that most interests me.

III NOERR-PENNINGTON SHOULD BE EXTENDED TO ATS CLAIMS

Other legal areas have already incorporated First Amendment avoidance doctrines, whether Noerr-Pennington or something similar. Extending Noerr-Pennington immunity as an evidentiary bar to ATS claims serves two major functions: (1) it supports the Supreme Court’s requirements—narrow construction and imposing liability only for conduct that touches and concerns U.S. territory—for ATS claims; and (2) it guards against chilling First Amendment freedoms.

Noerr-Pennington has already been extended beyond the antitrust context. Other areas in which the doctrine has been held to preclude liability for petitioning activity include civil RICO32 and tortious interference with business relations.33 And at least one scholar has suggested that it might apply to ATS claims.34 NoerrPennington’s restrictions on certain uses of evidence, which lower courts have recognized, can be applied to ATS claims as well.

But just because courts can expand the doctrine, should they? For starters, a narrow, cautious approach to recognizing those federal common law claims for which the ATS provides jurisdiction is consistent with the Supreme Court’s rulings in Sosa v. AlvarezMachain and Kiobel. For violations of customary international norms, federal common law creates the substantive underlying claim brought under the ATS.35 The Court is increasingly skeptical of judicial creativity in expanding rights of action through federal common law, even in the foreign affairs realm, once an area where federal common law had flourished.36 Indeed, antitrust law is itself governed largely by federal common law,37 and Noerr-Pennington is a judge-made constitutional avoidance doctrine limiting its reach. Specifically, applying Noerr-Pennington to ATS claims is consistent with Sosa v. Alvarez-Machain’s instruction that courts be cautious in recognizing claims under the ATS, an instruction rooted in concerns about judgemade law and especially in apprehension about interfering with foreign relations without guidance from the elected branches.38 In ruling that the presumption against extraterritoriality applies to ATS claims, Kiobel similarly expressed concern about clashes with other countries’ interests absent a clear command from Congress.39 Expanding the Noerr-Pennington doctrine, which would preclude liability for certain conduct and prevent the introduction of evidence about similar conduct, would advance the interests in narrowing the recognition of ATS claims that the Supreme Court emphasized.

Second, expanding Noerr-Pennington immunity to ATS claims will guard against chilling activity protected by the First Amendment. An otherwise unobjectionable regulation may impermissibly deter expression protected under the First Amendment.40 Chilling effect reasoning cuts across several procedural and substantive aspects of First Amendment doctrine. Procedurally, the chilling effect doctrine loosens normal standing rules by allowing claims to sometimes move forward based only on a fear of future government speech restriction, rather than the concrete injury usually required for federal courts to hear cases.41 Substantively, courts are “tolerant of a certain degree of imprecision in legislative line drawing . . . [and] normally [accepting of] some overdeterrence as the inevitable result of lawmaking” outside the First Amendment context.42 But where the First Amendment is concerned, overdeterrence becomes more problematic. Where some categories of speech are not entitled to any—or receive little—constitutional protection, “courts have used chilling effect-based reasoning to insist that such categorical distinctions be bounded by bright lines in order to prevent spillover effects on protected speech.”43 Because expression of political views, including asking government officials to enact policies consistent with the speaker or petitioner’s preferences, is critical to democratic government,44 extending a judicial doctrine cognizant of this to limit the ATS is appropriate. Noerr-Pennington evidence, “which by its very nature chills the exercise of First Amendment rights, is properly viewed as presumptively prejudicial.”45

The Doe plaintiffs allege that by purchasing cocoa from the Ivorian plantations that use child slaves, giving training and equipment to plantation owners, and lobbying against federal childslavery labeling legislation—all with knowledge of child slavery in the Ivory Coast—the defendant companies aided and abetted child slavery.46 The decisions to take those actions may have been made in the United States, but because the slavery and the defendants’ training for the cocoa farmers occurred abroad, and the equipment was used abroad, the plaintiffs face an uphill battle to overcome Kiobel’s presumption against extraterritoriality. The Ninth Circuit let the plaintiffs replead their claims to show that the defendants gave the slavers substantial assistance in the commission of a crime, but it is unclear what, if any, additional conduct might be alleged.47 Regardless of what the plaintiffs allege in their amended complaint to prove the defendants’ intent, or to show that the defendants’ actions touch and concern U.S. territory, the evidence of the defendants’ lobbying should not be considered. The defendants’ lobbying against proposed slavery-labeling legislation was used to show the plausibility of alleging that the defendants acted purposely, rather than as proof of substantive wrongdoing.48 While using evidence of lobbying to show intent does not violate the First Amendment under Mitchell, it may nevertheless discourage protected activity and threatens to confuse the issues. The optics of opposing child-slavery labeling requirements are less than stellar, and that evidence is much more likely to inflame a factfinder than to shed light on whether the defendants violated a well-established international legal norm.

As for Sexual Minorities Uganda, it’s possible that the defendant’s conduct in writing homophobic books and giving similarly-themed speeches will be held protected from liability under the First Amendment itself in a later stage of the proceedings. In terms of lobbying the Ugandan government, the result under my theory would depend on how completely courts import NoerrPennington from the antitrust context: While some courts have extended Noerr-Pennington immunity to petitioning aimed at foreign governments,49 the First Amendment’s Petition Clause does not protect petitioning foreign governments.50 On the one hand, immunizing all lobbying activities from liability under ATS claims is consistent with First Amendment values, including its protections for speech generally. On the other hand, because such an extension is not strictly necessary to avoid constitutional concerns about the Petition Clause, there may be good reasons for confining Noerr-Pennington’s protections for foreign lobbying to the realm of antitrust law.51

I don’t necessarily agree with everything the Supreme Court has said in interpreting the ATS. The Court’s ruling in Kiobel risks turning the United States into “a safe harbor (free of civil as well as criminal liability) for a torturer or other common enemy of mankind.”52 And I readily acknowledge that there are serious human costs to further restricting an already narrow avenue of relief for human rights abuses.53 But lobbying Congress for an expanded right of action or persuading the Supreme Court that its view in Kiobel was mistaken are preferable to circumventing Kiobel by relying on activity that lies at the First Amendment’s core and is likely to confuse a factfinder about what a case is really about: whether defendants have actually violated customary international law, or merely advocated for government policies the factfinder thinks unseemly.

CONCLUSION

There will continue to be questions about which claims based on customary international law may go forward under the ATS. This Essay suggests that evidence of petitioning the government should typically be barred from consideration in such claims under an extension of Noerr-Pennington immunity. This will help limit the scope of common law claims cognizable under the ATS, and help ensure that the territoriality requirement is not circumvented. It will also prevent the undue chilling of constitutionally protected activity.

#### That prevents litigation from crushing developing economies.

R. Reeves Anderson et al. 20. Arnold & Porter Kaye Scholer LLP; John P. Elwood, John B. Bellinger, III, Kaitlin Konkel, Sean A. Mirski, Arnold & Porter, Kaye Scholer LLP; Steven P. Lehotsky, Jonathan D. Urick, U.S. Chamber Litigation Center, Patrick Hedren, Erica Klenicki, Manufactures' Center for Legal Action, “Brief of Amici Curiae the Chamber of Commerce of the United States of America, the National Association of Manufacturers, the National Foreign Trade Council, Global Business Alliance, and United State Council for International Business in Support of Petitioners,” NESTLE USA, INC., Petitioner, v. John DOE I, et al., CARGILL, INC., Petitioner, v. John DOE I, et al., 2020 WL 5501204, WestLaw

III. Clear Limitations On ATS Liability Will Blunt The Sprawling Litigation That Continues To Burden Courts And Litigants

Amici's concerns are not abstract. In the past 25 years, plaintiffs have filed more than 150 ATS lawsuits against U.S. and foreign corporations for business activities in a wide range of industry sectors and more than sixty countries. John B. Bellinger, III & R. Reeves Anderson, Whither to “Touch and Concern”: The Battle to Construe the Supreme Court's Holding in Kiobel v. Royal Dutch Petroleum, in Federal Cases from Foreign Places 22 (U.S. Chamber Inst. for Legal Reform 2014); see also Donald E. Childress III, The Alien Tort Statute, Federalism, and the Next Wave of Transnational Litigation, 100 Geo. L.J. 709, 713 (2012). Dozens of major U.S. corporations have been targeted, particularly with respect to their activities in developing and post-conflict countries.

Courts have struggled to decide these cases, and even threshold questions can often take a decade or more to resolve. This case, which has been pending at the pleading stage for 15 years, is typical of practice under the Ninth Circuit's amorphous standard. The Bauman case against Daimler was pending for 10 years before this Court finally reversed the Ninth Circuit's expansive jurisdictional holding; Chevron and Rio Tinto each defended themselves in independent ATS cases for 13 years before securing dismissal; and a case against Cisco has been pending for nine years and is now awaiting this Court's disposition here. The Ninth Circuit is not the only court that has adopted an open-ended jurisdictional rule that can take a decade or more to resolve. ATS claims filed against Exxon in the \*25 D.C. District Court in June 2001 were not fully dismissed until June 2019-18 years later.

All the while, ATS suits threaten substantial reputational harm and require considerable resources to defend. See Cheryl Holzmeyer, Human Rights in an Era of Neoliberal Globalization: The Alien Tort Claims Act and Grassroots Mobilization in Doe v. Unocal, 43 Law & Soc'y Rev. 271,290-291 (2009). That, in turn, imposes unjustified settlement pressure on companies. Indeed, imposing pressure is often the point. See, e.g., Peiqing Cong v. ConocoPhillips Co., 250 F. Supp. 3d 229,235 (S.D. Tex. 2016) (describing an ATS case based on “factually-devoid pleadings and untenable legal theories,” having “nothing to do with the United States,” as “a strike suit”); Khu-lumani v. Barclay Nat'l Bank Ltd., 504 F.3d 254,295 (2d Cir. 2007) (Korman, J., concurring in part and dissenting in part) (describing the South Africa apartheid litigation as “a vehicle to coerce a settlement”). One court observed critically how “hyperactive lawyers” sometimes search for sympathetic plaintiffs and then, with barely any client involvement, file ATS suits in the hopes of coercing a quick settlement. Peiqing Cong, 250 F. Supp. 3d at 231. Such in terrorem tactics are easy to employ when courts do not properly apply the touch-and-concern test and allow ATS suits to proceed against U.S. corporations.

If the Court does not articulate clear limits on the touch-and-concern test and bar suits against U.S. corpo-rations, the decision below could affect U.S. businesses operating around the globe. See Sosa, 542 U.S. at 732-733 (requiring courts to consider the “practical consequences” of expanding ATS jurisdiction). Here, the panel's holding that routine U.S.-based business decisions clear the touch-and-concern hurdle leaves no room for U.S. defend-ants to safely invoke the extraterritorial bar. According to the panel below, even allegations of corporate oversight measures such as inspections of overseas operations could \*26 plead sufficient domestic conduct to survive a motion to dismiss. Nestle Pet. App. 43a (citing allegations that “De-fendants also had employees from their United States headquarters regularly inspect operations in the Ivory Coast and report back to the United States offices”). That is a counterproductive message to send to the U.S. busi-ness community.

Among other consequences, allowing ATS claims to proceed in cases like this one “could establish a precedent that discourages American corporations from investing abroad, including in developing economies where the host government might have a history of alleged human-rights violations, or where judicial systems might lack the safe-guards of United States courts.” Jesner, 138 S. Ct. at 1406 (plurality op.). The political branches, not the courts, are responsible for regulating the foreign commerce of U.S. corporations. Congress has chosen to regulate only certain foreign activities of U.S. companies - for example, by enacting the Foreign Corrupt Practices Act. See 15 U.S.C. § 78dd-1 et seq. And the State Department has encouraged commercial interaction with still-developing nations, in the hope of promoting economic development, the rule of law, and change from within the system.4

#### Extinction

UNSC 17. United Nations Security Council, “Prevention, Development Must Be at Centre of All Efforts Tackling Emerging Complex Threats to International Peace, Secretary-General Tells Security Council,” 12/20/17, https://www.un.org/press/en/2017/sc13131.doc.htm

Prevention and development must be at the centre of all efforts to address both the quantitative and qualitative changes that were emerging in threats around the world, the Secretary‑General of the United Nations told the Security Council today, as some 60 Member States participated in an all‑day debate tackling complex contemporary challenges to international peace and security.

António Guterres said the perils of nuclear weapons were once again front and centre, with tensions higher than those during the Cold War. Climate change was a threat multiplier and technology advances had made it easier for extremists to communicate. Conflicts were longer, with some lasting 20 years on average, and were more complex, with armed and extremist groups linked with each other and with the worldwide threat of terrorism. Transnational drug smugglers and human traffickers were perpetuating the chaos and preying on refugees and migrants.

The changing nature of conflict meant rethinking approaches that included integrated action, he said, stressing that prevention must be at the centre of all efforts. Development was one of the best instruments of prevention. The 2030 Agenda for Sustainable Development would help build peaceful societies. Respect for human rights was also essential and there was a need to invest in social cohesion so that all felt they had a stake in society.

He also emphasized that women’s participation was crucial to success, from conflict prevention to peacemaking and sustaining peace. Where women were in power, societies flourished, he pointed out. Sexual violence against women, therefore, must be addressed and justice pursued for perpetrators.

Prevention also included preventive diplomacy, he said, noting that the newly established High-level Advisory Board on Mediation had met for the first time. The concept of human security was a useful frame of reference for that work, as it was people‑centred and holistic and emphasized the need to act early and prioritize the most vulnerable.

“Let us work together to enhance the Council’s focus on emerging situations, expand the toolbox, increase resources for prevention, and be more systematic in avoiding conflict and sustaining peace,” he said, emphasizing the need for Council unity. Without it, he said, the parties to conflict might take more inflexible and intransigent positions, and the drivers of conflict might push situations to the point of no return.

Japan’s representative, Council President for December, spoke in his national capacity, noting that in the 25 years since the end of the Cold War, there had been a rise in complex contemporary challenges to international peace and security. That included the proliferation of weapons of mass destruction, the expansion of terrorism, and non‑traditional challenges such as non‑State actors and inter‑State criminal organizations.

## Citizen Petitioning

### Wrong---1NC

#### The thesis of the advantage is wrong.

Scott Lassman 17. Partner with Goodwin LLP in Washington, D.C., 11/20/17. “Criticism Of FDA Citizen Petitions Is Often Misguided.” https://www.goodwinlaw.com/-/media/files/publications/law360-criticism-of-fda-citizen-petitions-is-often.pdf?la=en

First, and most significantly, the critics fail to acknowledge that, as a legal matter, the filing of a citizen petition cannot delay the approval of a competing product. The law was amended in 2007 to prohibit the FDA from delaying approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application during its review of a citizen petition (the law recently was amended to afford this same protection to biosimilar applications).[7] The only exception is if the FDA determines that a delay “is necessary to protect the public health.”[8] Accordingly, except in very limited circumstances, the FDA’s review of a citizen petition and its review of a generic drug application are required to be completely separate processes that proceed down separate tracks with distinct requirements and timelines.

Critics, however, either ignore or do not understand this critical aspect of the law. For example, some have argued that Congress should address alleged delays caused by petitions by creating a “parallel timing track for ANDA approval and citizen petition review.”[9] But the law already does this and has done so since 2007.

Second, critics overlook or ignore the FDA’s own data, which demonstrates that the 2007 changes to the law are working as intended and that the FDA almost never delays approval of an ANDA or 505(b)(2) application simply because of the filing of a citizen petition. According to the FDA’s latest annual report on drug-related citizen petitions, of the 537 ANDAs and 505(b)(2) applications approved in fiscal year 2015, less than 1 percent were delayed because of a citizen petition (2/537).[10] This is consistent with other fiscal years going back to fiscal year 2008 (10/4008). Moreover, for the eight years spanning fiscal years 2008 through 2015, only 9 of the 175 drug-related petitions — 5 percent — resulted in the delay of a generic drug approval.

Although delays are rare, they do occur. Such delays, however, typically are short and, as required by the law, are justified by public health concerns. Under the 2007 law, the FDA can delay the approval of an ANDA or 505(b)(2) application because of a petition only if it determines that a delay is “necessary to protect the public health.”[11] This exception recognizes that the FDA should not approve a competing drug if there are outstanding scientific or medical issues that implicate patient welfare and safety. Since fiscal year 2008, the FDA has delayed the approval of only 10 applications because of a petition, and in every instance, the agency determined that the delay was necessary to protect the public health. Accordingly, it appears that the system is working as intended and that the FDA is striking the proper balance between expediting approvals for competing drug products and protecting the public health.

Despite the above evidence, critics nevertheless contend that the petition process is subject to abuse because “FDA denies the requested action for approximately 80 percent of citizen petitions filed by competitors against drug companies.”[12] But these statistics are presented out of context. In fact, the success rate of petitions filed by pharmaceutical companies is well in line with — and by some measures significantly higher than — the success rate for petitions filed by other stakeholders. For example, according to one recent study, only 12.7 percent of petitions filed by individuals or nonmanufacturer organizations (e.g., nonprofits, state governments) between 2001 and 2013 resulted in a favorable outcome.[13] This is significantly lower than the 20 percent success rate for pharmaceutical company petitions filed during a similar time period (2001-2010) and generally in line with success rates from more recent years (8 percent). The fact is that administrative agency inertia is strong, and the FDA rarely reverses course based on a citizen petition — any citizen petition. The FDA, however, appears to grant petitions filed by pharmaceutical companies more often than petitions filed by other entities.

Moreover, there are good reasons to believe that academic researchers are reporting denial rates for pharmaceutical company petitions that are artificially inflated. First, the critics often count “non- substantive denials” as true denials. In recent years, the FDA has adopted a practice of issuing nonsubstantive denials in which the agency “denies” the petition without indicating whether or not it agrees with the substance of the petition.[14] The agency typically does this when it is not ready to make a decision on a pending ANDA or 505(b)(2) application but the 150-day deadline for answering the petition is about to expire. A nonsubstantive denial is thus a way for the FDA to meet its statutory deadline without actually making a substantive decision. In essence, the FDA just kicks the can down the road. In order to obtain a substantive decision, a company thus may need to resubmit its citizen petition, sometimes multiple times. By counting these nonsubstantive denials as true denials, however, the critics artificially inflate the rejection rate and artificially depress the success rate.

Critics also fail to recognize that the FDA is not always the last word on issues raised in citizen petitions. Citizen petitions serve the critical function of assuring the opportunity for meaningful judicial review of the FDA’s policies and decisions. Consequently, citizen petitions often are filed by pharmaceutical companies to exhaust administrative remedies and to define and create an administrative record for purposes of judicial review. In many cases, the FDA’s denial of a petition is reversed when reviewed by a federal court. For example, in 2016, a United States district court reversed the FDA’s decision that a combination drug product was not eligible for new chemical entity (NCE) exclusivity.[15] Critics of the citizen petition process, however, never look beyond the FDA’s decision to account for judicial reversal of the FDA decisions on petitions.

Finally, the various criticisms of the citizen petition process often overlook or downplay the importance of petitions to the drug approval process. Both branded and generic companies utilize citizen petitions to raise a wide variety of important medical, scientific and legal issues relating to the approval of new drug products through the NDA, ANDA and 505(b)(2) approval pathways. The issues raised in petitions by pharmaceutical companies often relate to significant public health and safety concerns, such as active ingredient sameness or bioequivalence requirements or application of the FDA’s combination drug rule.

### Drug Prices Down---1NC

#### Drug prices are down.

Joel Zinberg 12/26/21. Snior fellow at the Competitive Enterprise Institute, director of Paragon Health Institute’s Public Health and American Well-being Initiative, and associate clinical professor of surgery at the Icahn Mount Sinai School of Medicine. “Drug Prices Haven’t Been Going Up.” https://www.wsj.com/articles/drug-prices-havent-been-going-up-generics-inflation-caps-biden-costs-innovation-11640533671

President Biden insists such controls are needed because pharmaceutical companies are “jacking up prices on a range of medicines.” He promises “to end the days when drug companies could increase their prices with no oversight and no accountability.” Yet while inflation has skyrocketed under Mr. Biden, drug prices are lower than when he took office. As the consumer-price index over the past year rose 6.8%, the largest increase in 39 years, prescription-drug prices fell 0.3%.

Mr. Biden and other pharmaceutical critics have mistakenly focused on increases in the list prices set by companies. But the actual prices consumers pay, after various discounts and rebates, are considerably lower than list prices, and changes in the two measures differ substantially. Insulin, with large increases in list prices over the past few decades, has become the poster child for unreasonable price increases. Yet net prices have increased much more slowly or not at all.

The best measure is the consumer-price index for prescription drugs, or CPI-Rx, which measures price changes in a large basket of drugs over time, accounting for discounts and most rebates. Another strength of the CPI-Rx is that it accounts for price declines that occur when consumers substitute cheaper generic versions for brand-name drugs. Too often, Mr. Biden and others focus on a few high-priced drugs and fail to consider the entire market.

Prices for brand-name prescription drugs are higher in the U.S. than in other countries. But U.S. regulatory, legal and incentive structures encourage aggressive price competition and switching from branded drugs to generics. As a result, Americans use more generics (accounting for 9 out of 10 prescriptions) and pay less for them (16% lower on average) than in other developed countries. Nearly all European countries impose price controls on generics, which results in delayed market entry and availability, less competition and higher prices.

CPI-Rx has been negative for much of the past three years. The decline stems largely from increased drug approvals by the Food and Drug Administration since 2017. When new brand-name drugs enter the market, they compete with other drugs that treat the same condition. When generic versions are approved, prices fall rapidly as patients switch, especially as multiple generic versions enter the market.

#### There’s no impact.

Peter Coffey 22. Wall Street Journal, 1/2/22. “Drug Prices Are High and Low.” https://www.wsj.com/articles/drug-prices-generic-pharmaceutical-advertising-11640908082

Joel Zinberg points out that while list prices for some drugs have increased, average drug costs have risen more slowly, or even fallen (“Drug Prices Haven’t Been Going Up,” op-ed, Dec. 27). These two trends are intimately connected.

Before widespread use of generic drugs, pharmaceutical companies could count on a long run of moderate prices to earn back their investments in drug research and development. But with the acceptance of generics, prescription drugs must earn virtually all their returns on new drugs before they go off patent and prices plummet amid generic competition. This also explains why drug makers advertise new products so heavily.

Wide use of generics keeps average drug prices lower, even as list prices for new, patented drugs rise when faced with a shorter period to earn a return on high-risk innovation. The combination benefits consumers: It preserves the incentive for new drug development while moderating the long-term trend in drug costs overall.

### No Disease Impact---1NC/2AC

#### Burnout and geographic dispersion check disease.

Sebastian Farquhar 17. \*\*Project Manager at FHI responsible for external relations, M.A in Physics and Philosophy, Oxford. \*\*John Halstead, Global Priorities Project. \*\*Owen Cotton-Barratt, Research Associate in the FHI at Oxford, Lecturer in Mathematics at St. Hugh’s College. \*\*Stefan Schubert, PhD in philosophy, Researcher at the Centre for Effective Altruism. \*\*Haydn Belfield, Academic Project Manager, Centre for the Study of Existential Risk, Cambridge. \*\*Andrew Snyder-Beattie, Director of Research at FHI. “Existential Risk: Diplomacy and Governance.” *Future of Humanity Institute*. Oxford, Global Priorities Project. <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>.

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Drug resistance doesn’t overcome burnout.

Ed Cara 17, science writer for The Atlantic, Newsweek, and Vocativ, 1/27/17, “The Attack Of The Superbugs,” http://www.vocativ.com/394419/attack-of-the-superbugs/

Antibiotic-resistant infections kill at least 700,000 people worldwide a year right now, according to an exhaustive report commissioned by the UK in 2014, and without any substantial medical breakthroughs or policy changes that slow down resistance, they may claim some 10 million deaths annually by 2050 — eclipsing cancer in general as a leading cause. These deaths largely won’t come from pan-resistant infections, just tougher ones. A preventable death there, a preventable death here. Leaving that aside, antibiotics, along with proper sanitation and nutrition, gird our entire way of living. Most every invasive surgery, pregnancy, organ transplant and chemotherapy session we go through will become riskier. Other diseases like HIV, malaria or influenza will become deadlier, since bacteria often exploit the opening in our immune system they leave behind. And already precarious populations like those living with cystic fibrosis, prisoners, and the poor will lose years off their lives. For all the warranted gloom, though, Farewell does think there are reasons to be hopeful. “I don’t think we are doing enough, but the scientific community along with many governmental and private foundations are very actively involved in finding not only new antibiotics, but new solutions to this problem,” she said. There’s been a noticeable change in attitude and increased urgency surrounding antibiotic resistance, she said, one that she hadn’t seen even five years ago, let alone twenty. Until recently, that attitude change could be seen from places as high up as the U.S. federal government. In 2014, former President Obama issued an executive order aimed at addressing antibiotic resistance, the first real acknowledgement of the problem from an administration, devoting funding and outlining a national action for combatting resistance. Through its federal agencies, the administration pushed to reduce antibiotic use on farms and encouraged doctors to stop using them in excess. “There has been a lot of work done the last couple of years, much of it spurned by [Obama’s] National Action Plan,” said Dr. David Hyun, a senior officer for Pew Charitable Trusts’ Antibiotic Resistance Project. The CDC, in particular, has used its funding to open up regional labs that allow them to better detect and respond to antibiotic-resistant outbreaks like the Nevada case, he said. They ultimately hope to create an expansive surveillance system that can easily keep track of resistance rates on a national, state and regional level. A parallel system also exists for monitoring resistance in the food chain, shepherded by the CDC and the U.S. Department of Agriculture. In fact, it was this sort of cooperation between national and local health agencies that enabled Nevada doctors to stop the worst from happening, said Dr. Lei Chen. The swift identification of a possible CRE strain by the hospital, coupled with the woman’s medical history, led to a precautionary quarantine, while also prompting Chen’s public health department and eventually the CDC into action. And it may help prevent future cases from spilling into the public. According to Chen, the CDC has allocated funding this year to all of Nevada’s state public health departments so they can better detect CRE and other dangerous resistant strains. Under the Trump administration, there’s no telling how these small victories will hold up or whether they will advance. All references to antibiotics once found on the Whitehouse.gov site have been removed, including a link to the Obama administration’s national action plan, and the fact that they’re already tried to bar USDA scientists from discussing their work with the public while stripping funding from other public health agencies isn’t encouraging. Even with the best public policy, however, there’s no clear light at the end of the tunnel. Antibiotic resistance has gradually been worsening, even within the last 15 to 20 years, when superbugs like methicillin-resistant Staphylococcus aureus (MRSA) first became widely known, said Hyun. The effort needed to develop new drugs has been in short supply, hamstrung by pharmaceutical companies’ inability to recoup the costs of bringing new antibiotics to market. That’s because, unlike the latest heart medication, any new antibiotics will have to be treated like the last drops of water during a drought, used as little as possible — the exact opposite way to make money off a new product. Yet, much like climate change, the financial toll of not doing anything will total in the trillions years down the road. And it already numbers in the billions now, according to the CDC. Of course, we need bacteria to survive. And most need or pay no mind to us in return. Even pan-resistant bacteria don’t really mean harm. Some have been found in perfectly healthy people, a fact that’ll either comfort you or keep you awake at night, only causing problems when our immune system wavers. There’s no army of sentient E. coli that will rise up and someday overthrow the human race. But barring the calvary showing up, a new fear of ours will learn to settle in, almost unnoticed. It’ll creep in when we pick our heads up from a nasty fall that scrapes our skin open or breaks our bones; when we wave goodbye to our loved ones before they enter an operating room, or when we cradle our newborns into a world teeming with the living infinitesimal, wishing there was still a way to shield them from it as our parents once could for us. A fear of naked vulnerability. The antibiotic apocalypse will be gentle, if it fully arrives, but it won’t be any less devastating to the human spirit.

## New Advantage

### Wrong---1NC

#### Doesn’t solve a good faith standard---the plan is vague and merely restricts Noerr---that doesn’t develop a new standard to guide the Courts or the states.

#### Doesn’t solve IP innovation---Ford says the Patent Office grants invalid patents---restricting Noerr doesn’t solve.

### AT: Ag---1NC

#### Food prices don’t cause conflict–reject their bad studies.

Demarest 15—PhD Researcher at the Centre for Research on Peace and Development [Leila, “Food price rises and political instability: Problematizing a complex relationship,” *The European Journal of Development Research*, Vol. 27, No. 5, p. 650-671, Emory Libraries]

6. Conclusions and Way Forward

While some progress has been made in improving our understanding of the linkages between rising food prices and conflict, several important gaps remain. Firstly, notions of conflict and political instability are often used interchangeably, while these concepts and the relationships between them remain to some extent vague. The ‘food riot’ concept in particular leads to confusion. Although it is popularly seen as a violent rise of the masses, in reality, many peaceful events are gathered under this term, while violence is often committed by the state rather than by hungry consumers. The term also presupposes that food is the central issue at hand, which does not necessarily have to be the case. Many misunderstanding arise from the second gap identified in this paper: the uncritical data gathering based on international news reports. Not only are these remarkably inconsistent, they also make use of classifications which are not scientifically investigated. Finally, causal mechanisms in the relationship between rising food prices and conflict often remain assumptions in the literature and lack empirical foundation. Three crosscutting avenues for improvement therefore exist: better concept definitions, better data gathering, and more focus on contexts.

Clearly defined concepts and categorizations of conflict and instability are a necessary foundation for research on the linkages between rising food prices and conflict. For (food) protests in particular, purposeful categorizations require an enhanced insight in the events that took place on the ground. Local news sources for data gathering can prove to be more reliable than Western (English) media to accomplish this. Event descriptions are also likely to be more detailed in local sources, which allows for a first-hand qualitative analysis of causes and context.

As international food prices are likely to remain high, improving our understanding of the causal mechanisms which can lead to conflict remains crucial. We can draw important lessons from the literature on poverty and conflict, resource scarcity and conflict, and regime transition in Africa. The causal role of economic factors alone has continuously been questioned, and ‘context’ or prevailing political, economic, and social factors play a crucial role in the conflict outcome. The argument that adverse economic shocks seem more of a trigger to conflict rather than an important cause is not particularly remarkable in itself. Yet while many authors acknowledge this, the focus often remains on the trigger. Resource scarcity, climate change, population growth, or food insecurity often remain the starting point of analyses, with researchers consequently tracing the divergent (theoretical) possibilities for conflict. In the end, most admit that these factors do not automatically lead to conflict everywhere, and stress the importance of context. Because the theoretical possibilities for conflict are so large, however, the context factor remains rather understudied with as most agreed upon notions that elements of ‘grievance’ and ‘collective action’ are required.

It is hence important to focus more on the ‘contexts’ that can lead to conflict and, in doing so, to make the distinction between different forms of conflict. This also implies a data collection exercise. Contextual data are currently collected at the aggregate, national level, and only on a yearly basis, which can lead to spurious relations. While the use of these variables is increasingly questioned in civil war studies, we can also doubt their strength in the study of highly localized, one-time events such as riots. I particularly make the case for ‘bringing politics back in’. The policies taken by the government are crucial in the violent escalation of social conflict (e.g. accommodation versus repression), but the only variable currently in use to explain state behaviour seems to be the country-level regime type variable (Polity IV or Freedom House), which is also used with regards to highly localized conflicts. Other ways in which politics matter, can be the strength of the political opposition. The Muslim Brotherhood in Egypt, for example, was probably better organized than other opposition groups to make use of economic unrest.

### AT: Water---1NC

#### No water wars – states cooperate.

Patrice C. MCMAHON 17. Associate professor of political science, University of Nebraska. “Cooperation Rules: Insights on Water and Conflict from International Relations” in Jean Axelrad Cahan ed. *Water Security in the Middle East: Essays in Scientific and Social Cooperation*. Anthem Water Diplomacy Series. 19-37.

At least implicitly, many disciplines recognize that a changing climate with higher temperatures and altered precipitation patterns will require adaptive water- management strategies. Climate change necessitates a collective and coordinated response to water shortage, and states must yield to this reality. If these processes are not carefully calibrated to respond both to physical characteristics and to cultural norms, the path ahead will have grave implications for future generations who will experience human suffering, social and political discord and an impoverished environment. An important question for political scientists is this: will water insecurity—whether it is caused by access, allocation, degradation or scarcity—necessarily result in violent conflict between states?

The answer may depend on whom you ask and the region in question. Although research on water politics and international conflict has led to separate substantial literatures, this chapter considers them together and presents a tentative answer. I argue that, although literature in international relations (IR) is historically predisposed to focusing on war and interstate violent conflict, when it comes to arguments and research on water there is a decisive, if largely overlooked, consensus that it is cooperation rather than violent conflict that dictates interstate water relationships. The past is not always the best predictor of the future, but research on war and conflict thus far indicates that water insecurity is unlikely to result in violent conflict between states. As Aaron Wolf puts it, water may be a tool, target or victim of warfare, but up until this point it has not been the cause (2007, 4).

Nonetheless, a significant amount of scholarship in IR assumes, and sometimes asserts, that problems with access to freshwater and water insecurity will not only lead to violence within states but also result in interstate war (Setter et al. 2011 ). Especially for scholars who focus on certain regions where water scarcity is severe, where political tensions are significant and where there are no international institutions in place to promote cooperation, violent conflict is overdetermined. The Middle East is usually considered one of the likely hot zones where the quest for water is seen as a catalyst for future conflict either within states or between states (Dinar 2002). This volume’s focus on the Middle East and peace building demonstrates clearly that conflict over water is not inevitable and that many institutions, mechanisms and ideas exist to encourage states, local authorities and members of civil society to use water as a conduit for cooperation and peaceful interactions. Employing literature from IR and security studies, this chapter provides several explanations for cooperation and many examples of cooperative water management, even in the Middle East.

# Block

## 2NC

### States CP---2NC

#### 2. Literature---proposes that the States and Fed will both act.

Bruce Johnson and Moin A. Yahya 04. D. Bruce Johnsen, Professor of Law, George Mason University School of Law. J.D., Emory University, 1985; Ph.D., University of Washington, 1987. Moin A. Yahya, Visiting Assistant Professor of Law, University of Alberta School of Law. J.D., George Mason University School of Law, 2003. Ph.D., University of Toronto, 2000. The Evolution of Sherman Act Jurisdiction: A Roadmap for Competitive Federalism, 7 U. Pa. J. Const. L. 403 (2004). https://scholarship.law.upenn.edu/jcl/vol7/iss2/2

The alternative view is that antitrust regulation is subject to such dramatic scale economies that unlimited federal authority is overwhelmingly efficient. This view could apply either to legal administration or to the stock of legal precedents itself. The geographic market power test in no way hinders the realization of scale economies in lawmaking. Because law is a public good, under the geographic market power test states can easily capture any scale economies attributable to federal lawmaking at no cost to the federal system simply by adopting federal rules to cover their purely internal activity if they so choose. Conversely, federal courts are free to rely on state court decisions covering novel questions of law or fact purely internal to the state. The geographic market power test in no way inhibits the inter-jurisdictional sharing of legal rules. Any state that chooses to adopt novel rules is either acting foolishly, in which case it will suffer from competition by other states, or it is acting properly in the interest of its own citizens as local consumers of law.

#### 4. Real world---fed and states coordinate all the time.

American Stewards of Liberty (ASL) No Date. Non-profit organization working to protect private property rights and the liberties they secure. "Coordination". https://americanstewards.us/coordination/

Coordination is a process that requires Federal agencies to resolve policy conflicts with State and local plans, policies and programs for the purpose of reaching consistency. This direction is found in many of our nation’s Federal laws as well as many State laws. It recognizes that the responsibilities of State and local governments, to protect the health, safety and welfare of the people, must be harmonized with the Federal position in order to ensure effective governance.

#### 2. Counterplan’s competitive federalism model ensures race to the top.

Bruce Johnson and Moin A. Yahya 04. D. Bruce Johnsen, Professor of Law, George Mason University School of Law. J.D., Emory University, 1985; Ph.D., University of Washington, 1987. Moin A. Yahya, Visiting Assistant Professor of Law, University of Alberta School of Law. J.D., George Mason University School of Law, 2003. Ph.D., University of Toronto, 2000. The Evolution of Sherman Act Jurisdiction: A Roadmap for Competitive Federalism, 7 U. Pa. J. Const. L. 403 (2004). https://scholarship.law.upenn.edu/jcl/vol7/iss2/2

A. Competitive Federalism

The theoretical foundation for competitive federalism derives from Charles Tiebout's pioneering 1956 essay, A Pure Theory of Local Expenditures.'8 Tiebout was concerned with analyzing the municipal supply of local public goods, such as roads, schools, and police and fire services. 89 In the face of literature concluding that the only mechanism for the provision of public goods was the ballot box, Tiebout demonstrated that a quasi-market mechanism could also work.' 90 As long as consumers of local public goods have a large number of municipalities in which they can locate and are mobile and fully aware of the different patterns of taxation, expenditures, and levels of services provided by each municipality, then they can "vote with their feet" by exiting one municipality and relocating in a more hospitable one. Thus, while voting may dictate what level of services a municipality provides, competition among municipalities ensures that consumers will migrate to the municipality whose services match their preferences for public good provision and taxation. The normative implication is that to ensure all consumers receive the services they desire at the lowest cost, the size and scope of government should be kept small to promote political competition.'9'

The Tiebout model has been extended to analyze the government's provision of a host of public goods, 19 ' 2 including law itself. Laws are a form of public good because once a court has established a given precedent, one person's reliance on it does not diminish others' ability to so rely. As with the provision of other public goods, the citizenry is best served if the provision of law is subject to political or inter-jurisdictional competition between local providers, at least to the extent that the effects of the law are confined to the jurisdiction. While the effects of some laws are strictly local and the effects of other laws national, Tiebout's vision for the provision of public goods can be achieved through a federal system in which the states and the federal government have credible legislative and judicial powers, and healthy political competition maintains the balance of sovereignty.

The geographic market power test applies the framework of competitive federalism to the specific context of antitrust. The sole concern for Sherman Act jurisdiction under this test is whether the defendants' conduct in one state creates market power that spills across state lines in the form of higher prices. For those trade restraints whose price effects are confined to the defendants' home state, that state's antitrust regulators have sufficient incentive and resources to adequately address the problem. Political competition between states will result in optimal, though not necessarily uniform, antitrust policy with due regard for experimentation to address novel business practices tailored to local conditions.

When firms restrain trade in their home state unchallenged by home-state antitrust regulators and the price effects of market power spill across state lines, the citizens of neighboring states bear a portion of the losses. If the restraining firms are careful to keep their capital out of the neighboring state, there is little that the neighboring state's antitrust regulators can do to address the problem. With citizens of the home state bearing less than the full cost of the restraint, while receiving one hundred percent of the benefits (assuming the owners of the restraining firms are citizens of the home state), the state's antitrust regulators are unlikely to pursue antitrust policy with the same zeal as in the absence of a spillover. Federal antitrust regulation is warranted only in these cases.

#### Solves their offense AND the case

D. Bruce Johnsen and Moin A. Yahya 14. “9 A Geographic Market Power Test for Sherman Act Jurisdiction”. https://www.aei.org/wp-content/uploads/2014/07/-competition-laws-in-conflict\_101545313195.pdf?x91208

Second, within the framework of competitive federalism, Summit undermines political competition among the states to resolve purely internal market failures. If price effects resulting from market power are strictly local and confined to a single state, that states regulators have adequate incentives to address the problem, and there is no justification for federal regulation. The economic circumstances facing the citizens of the several states vary tremendously and can surely benefit from regulatory policies tailored specifically to those circumstances. The geographiC market power test for Sherman Act jurisdiction thus identifies a substantively reasoned balance between state and federal antitrust enforcement. In our view, the Court should overturn Summit at the next available opportunity and establish the geographic market power test as the basis for Sherman Act jurisdiction.

#### 3. It’s a comparative disad to the aff---federal courts fail.

Bruce Johnson and Moin A. Yahya 04. D. Bruce Johnsen, Professor of Law, George Mason University School of Law. J.D., Emory University, 1985; Ph.D., University of Washington, 1987. Moin A. Yahya, Visiting Assistant Professor of Law, University of Alberta School of Law. J.D., George Mason University School of Law, 2003. Ph.D., University of Toronto, 2000. The Evolution of Sherman Act Jurisdiction: A Roadmap for Competitive Federalism, 7 U. Pa. J. Const. L. 403 (2004). https://scholarship.law.upenn.edu/jcl/vol7/iss2/2

A virtual scientific revolution in economics over the past forty years has shown that competition leads private parties to choose the form of organization that internalizes, as "1 far 226 as possible, what would otherwise be economic market spillovers. By allowing political competition between states to resolve any remaining internal spillovers according to local circumstances, the geographic market power test promises to hasten the rate at which substantive antitrust law evolves toward the optimal treatment of novel business practices alleged to restrain trade. The weight of federal antitrust case law and commentary makes it abundantly clear that considerable disagreement exists about the nature or effect of novel business practices. Federal courts have often failed to correctly assess many such practices, with a decidedly negative effect on consumer welfare during the interim. Examples include the Court's recent reversal of the per se 227 rule against vertically imposed maximum prices, its earlier reversal 228 of the per se rule against vertically imposed exclusive territories, and the advent of the characterization question to parse horizontal restraints that are unreasonable per se from those subject to a full reasonableness inquiry. 29 Even now, federal courts are struggling with the proper application of the Sherman Act to horizontal aggregations in so-called "network industries," for which the optimal tradeoff between allocative and productive efficiency is far from clear.23° This is not to criticize our federal courts out of hand; it is simply to say that they have failed to preserve a federal system in which competitive state lawmaking could be mobilized to provide a more rapid information feedback mechanism as to the effect on consumer welfare of novel business practices.

#### 2. It’s textually competitive---“interstate” excludes the “intrastate” components present in the aff.

Conrad J. Weiler, Jr. 19. Associate Professor Emeritus, Department of Political Science, Temple University. Summer 2019 34 Const. Comment. 329 "How "Commerce Among the Several States" Became "Interstate Commerce," and Why it Matters – Constitutional Commentary". https://constitutionalcommentary.lib.umn.edu/article/how-commerce-among-the-several-states-became-interstate-commerce-and-why-it-matters/

But again, our point is that many commercial activities that are inside a state —”intrastate”— and that are thus textually not “interstate commerce” might nonetheless actually still be “commerce among the several states,” i.e., inside more states than one.[179] Consequently, as a textual matter, some “intrastate” commerce might not qualify as the commerce that can be regulated without the assistance of the necessary and proper clause, or perhaps at all, yet it might readily be regulated as a textual and original matter as commerce “among the several states” with no or little further assistance needed.

This difference in language is important also because even if the necessary and proper clause can and clearly has extended the reach of the power over commerce, the Court also can and has set limits on it. In his majority opinion in the Obamacare case,[180] Chief Justice Roberts specifically noted that the “proper” part of the necessary and proper clause sets limits on the use of the power.[181] Other cases and commentators have also noted that there are limits on the necessary and proper clause, including those described in McCulloch.[182] Thus if the “affecting interstate commerce” test is based upon the necessary and proper clause, in general it could be cut back again, as it was in Lopez, for exceeding the limits of that clause, much more readily than if the power over commerce among the states were construed as we argue the Framers and Marshall understood it. In the latter case, in general the same activity could possibly be regulated without resort to the necessary and proper clause at all, simply as commerce among the several states, and thus not suffer the risk of exceeding the Court’s limitations on the necessary and proper clause, or at least be exercised with a more modest use of the necessary and proper clause less subject to constitutional criticism.

#### 3. The counterplan is plan minus---“interstate” is a restrictive modifier---the counterplan is only a specific subclass and the perm severs the application to all others.

Practice Makes Perfect: Advanced English Grammar for ESL Learners 11. “12 Restrictive and nonrestrictive adjective clauses”. https://schoolbag.info/language/esl/12.html

Adjective clauses play two very different roles. One role, called restrictive, significantly affects the meaning of the noun it modifies by limiting or narrowing the meaning of that noun. (All of the examples that we examined in the previous chapter, “The structure of adjective clauses,” were restrictive.) Here is a clear-cut example of a restrictive adjective clause (underlined):

All students who fail the final exam will fail the course.

The restrictive adjective clause *who fail the final exam* significantly narrows the meaning of student from all students to a specific subclass of students, namely, those students who fail the final exam. If we delete the restrictive adjective clause, it completely changes the meaning of the original sentence:

All students will fail the course.

#### 4. It’s the principle of all-inclusiveness---when the plan says “anticompetitive practices” it must mean all “anticompetitive practices.”

Simon Desjardins No Date. Director of Christ is the Answer – Spain, Evangelistic Ministry. “Divorce and Remarriage”. https://simondesjardinsblog.com/divorce-and-remarriage/

To understand Section Three the reader will have to comprehend first of all the semantic principle of all-inclusiveness. The principle can be stated as follows: If a word is used without a restrictive clause the word is all-inclusive.

To understand the principle let us look to an example. If I write: “The windows of my house are blue”, it should not be interpreted to mean: Most windows of my house are blue, or some windows of my house are blue. If I have expressed myself clearly, my statement can only mean one thing, namely, all the windows of my house are blue. It must be so because in this statement the word ‘windows’ is all-inclusive, at least as far as the house is concerned. If one or more windows had been of another color, I would have had to add a restrictive clause to express myself clearly, or make use of a quantitative word such as ‘most’ or ‘some’.

Now if we would have a statement written in Greek which would read: “The windows of my house are πυρρός”, and there would be some disagreement in regard to the meaning of the Greek word πυρρός—a party maintaining that πυρρός means purple, and another party maintaining that πυρρός means red—how could the problem be solved? Obviously, if someone would demonstrate that one of the windows is red, then we could conclude with certainty that πυρρός cannot possibly mean purple, and that all the windows of the house are red, because “windows” is here all-inclusive, at least as far as the house is concerned. In other words, all the windows of the house will have to have the same color.

The same principle is to be applied to the Scriptures. For instance, in Romans 6:23 we read:

“For the wages of sin is death.”

Since there is no restrictive clause following the word ‘sin’, the word must be understood to be all-inclusive. Therefore it would be inadmissible for anyone to say: “This scripture doesn’t imply stealing”. No one has the authority to put exceptions where God puts none, or to restrict the meaning of a word God leaves unrestricted. Therefore if a word is used without a restrictive clause the word is all-inclusive. This is one of the most basic rules of semantics, a rule that can be useful to draw incontrovertible conclusions.

#### 8. Substantial---“interstate” is a material qualification

Don Dyke 06, Chief of Legal Services “TO: Representative Mark Gundrum RE: 2005 Assembly Joint Resolution 67 (Marriage Amendment) DATE: February 24, 2006”. https://news.wisc.edu/archive/domesticPartnerBenefits/images/LegCouncil\_0206.pdf

“Similar” is defined as “having characteristics in common, very much alike, comparable,” “alike in substance or essentials,” or “one that resembles another, counterpart” [Webster’s Third New International Dictionary], or “nearly corresponding, resembling in many respects, somewhat like, having a general likeness, although allowing for some degree of difference.” [Black’s Law Dictionary.] “Substantially” is defined as meaning “essentially; without material qualification.” [Black’s Law Dictionary.] Thus, something can be said to be “substantially similar” if it is essentially alike something else.

#### 10. “Scope”---the counterplan and perm are anti-topical because they retract part of Sherman.

Alan J. Meese 20. Ball Professor of Law and Co-Director, Center for the Study of Law and Markets, William and Mary Law School. Antitrust Regulation and the Federal-State Balance: Restoring the Original Design, 70 AM. U. L. REV. 75 (2020).

Abandoning the substantial effects test and retracting the scope of the Sherman Act would reboot competitive federalism in the antitrust field. The resulting competition between state "laboratories of democracy" would presumably generate a variety of substantive and institutional solutions to various antitrust problems, as states vie for producers and consumers by offering rival packages of antitrust doctrine and enforcement institutions.

Restoring the pre-1948 regime would also radically shrink the category of state-approved restraints potentially subject to the Act. Instead of state regulation of local billboards and the like, state action cases reaching the Court would involve restraints imposing substantial interstate harm. This new framing could force the current Court, less friendly to regulation than its post-New Deal predecessors, to reconsider its hands-off approach to state-approved restraints. Narrowing the Sherman Act's reach could ironically encourage more robust preemption of state-approved restraints.

Finally, the history recounted here would alter the question posed in state action cases. The Court's state action decisions emphasize that Congress did not anticipate Sherman Act preemption of stateapproved restraints. However, the Court is answering an anachronistic question. The 1890 Congress would have assumed that state-approved direct restraints of interstate commerce would fall prey to the Court's regime of implied preemption, a regime later eclipsed by the Court's more permissive dormant Commerce Clause jurisprudence. Thus, the real question for a Court reconsidering the Act's treatment of stateapproved restraints is how Congress would have treated such restraints absent implied preemption, and this question could produce a quite different answer.

Part I of this Article reviews the Court's pre-1948 jurisprudence regarding the scope of the Sherman Act, particularly the articulation of the direct/indirect standard and its application to intrastate restraints. Part II recounts the Supreme Court's post-New Deal expansion of the Act to reach intrastate restraints that induce substantial but fortuitous effects on interstate commerce. Part III details the three rationales the Court has offered tojustify rejection of the direct/indirect standard in favor of the substantial effects test. Part IV reviews the content of the Court's Commerce Clause jurisprudence when Congress debated and passed the Sherman Act. Part V draws upon the lessons of this review and assesses the original meaning of the phrase "restraint of . .. commerce among the several States," employing several accepted canons of construction. This Part also evaluates the contentions that the scope of the Sherman Act properly expands with the scope of the commerce power and that changed circumstances justify replacing the direct/indirect standard with the substantial effects test. Part VI reviews the legislative history of the Act. Finally, Part VII explores selected implications of the finding that the Court's adoption of the substantial effects test was unwarranted.

#### 11. That means the plan doesn’t fiat an “increase” in prohibitions and is not topical OR the perm is severance.

Dictionary.com. "Definition of increase". dictionary. xx-xx-xxxx. https://www.dictionary.com/browse/increase

What does increase mean?

To increase is to become greater or more in number, amount, size, or in some other way, as in Our profits will increase as demand increases.

As a verb, increase is also used in an active way in which someone or something is doing the increasing, as in I’m going to increase my hours at work or These sunglasses increase visibility.

Increase can also be used as a noun referring to a rise or growth in something, as in We are experiencing an increase in applicants.

It can also refer to the amount by which something has increased, as in The increase was $5,000 per year.

The words increased and increasing can both be used as adjectives, as in an increased appetite or increasing sales.

The opposite of increase as both a verb and a noun is decrease.

Example: My boss increased my workload, which led to an increase in stress.

#### 12. Perm doesn’t “expand” the scope.

Kanstantsin Dzehtsiarou\* and Conor O'Mahony\*\* 13 – \*MA (University of Sussex), PhD (University College Dublin); Lecturer in Law, University of Surrey, and \*\* BCL, LLM (National University of Ireland), PhD (University of Wales, Aberystwyth); Lecturer in Constitutional Law, University College Cork. “ARTICLE: EVOLUTIVE INTERPRETATION OF RIGHTS PROVISIONS: A COMPARISON OF THE EUROPEAN COURT OF HUMAN RIGHTS AND THE U.S. SUPREME COURT,” 44 Colum. Human Rights L. Rev. 309, 335-336. Lexis.

2. Consensus on Restriction of Rights

In all of the cases discussed so far, consensus was relied on to expand the scope of protection provided by a particular provision. Conversely, the opposite scenario may also arise, where consensus may be claimed to be in favor of a more restrictive interpretation of a rights provision. However, for two reasons, consensus analysis tends not to be used by either the ECtHR or the U.S. Supreme Court as a means of narrowing the scope of human rights protection. First, consensus is used in conjunction with other relevant considerations, [\*336] and it is sometimes called a rebuttable presumption. Therefore, courts can disregard consensus under certain circumstances. Second, since the laws in all states cannot be changed overnight, restrictive laws will inevitably find themselves in the minority, at least for a certain period of time during which those laws may well be challenged and found to be in violation of the ECHR or the U.S. Constitution.

#### 13. The addition of “interstate” is narrower than the plan.

Conrad J. Weiler, Jr. 19. Associate Professor Emeritus, Department of Political Science, Temple University. Summer 2019 34 Const. Comment. 329 "How "Commerce Among the Several States" Became "Interstate Commerce," and Why it Matters – Constitutional Commentary". https://constitutionalcommentary.lib.umn.edu/article/how-commerce-among-the-several-states-became-interstate-commerce-and-why-it-matters/

First, to be sure, the Court had developed commerce power narrowing doctrines well before it adopted “interstate commerce.” However, especially when paired with “intrastate,” “interstate commerce” became its own self-limiting text and doctrine, because the words themselves so clearly and strongly conveyed the narrow meaning of only crossing state boundaries. If “interstate commerce” is the language and meaning of the Constitution, nothing more is needed to define federal power as limited to crossing state boundaries, at least without assistance from the necessary and proper clause. In contrast, while “among the several states” is not as self-evidently clear in its meaning, it is also not on its face literally or clearly limited to crossing state lines, and arguably extends inside more states than one. Thus, to the considerable extent that “interstate” and “intrastate commerce” have replaced the actual words of the Constitution on the Court and in the public mind, these neologisms facially privilege a narrow understanding of the power in the Constitution in a way that earlier or other limiting doctrines did not. The general acceptance and unquestioning use of such language not just as doctrine but as if it were the literal words of the Constitution cements a narrow view of the power in the public mind far more effectively than if the Court had to struggle with elaborate and obscure explanations of how “among” in the Constitution really meant “between,” especially in the face of its rejection by Marshall in Gibbons,[168] or with Tenth Amendment arguments about how principles of federalism prohibit regulating activity inside states even if it is of national economic importance.[169] In sum, the originalist and linguistic case that “among” really means “between” is neither self-evident nor as facially strong as the argument that “interstate” means “between.” And though obviously this is and will be disputed, that is exactly the point-the meaning of the actual constitutional language is readily arguable to be much broader than its anachronistic gloss.

#### 2. That firmly imbeds new Commerce Clause jurisprudence---spills over to other regulation but the plan and perm break consistent case law and certainty.

Bruce Johnson and Moin A. Yahya 04. D. Bruce Johnsen, Professor of Law, George Mason University School of Law. J.D., Emory University, 1985; Ph.D., University of Washington, 1987. Moin A. Yahya, Visiting Assistant Professor of Law, University of Alberta School of Law. J.D., George Mason University School of Law, 2003. Ph.D., University of Toronto, 2000. The Evolution of Sherman Act Jurisdiction: A Roadmap for Competitive Federalism, 7 U. Pa. J. Const. L. 403 (2004). https://scholarship.law.upenn.edu/jcl/vol7/iss2/2

The evolutionary approach we outline in this Article is by no means perfect. It will require the Court to firmly imbed competitive federalism in its case law as a long-run evolutionary framework for redirecting Commerce Clause jurisdiction. We believe the Court's adoption of the geographic market power test for Sherman Act jurisdiction would be a powerful force in this regard. Its inevitable success in resolving the limits of Sherman Act jurisdiction would dramatically reduce legal uncertainty in applying competitive federalism to other regulatory statutes. It would also spark a sustained increase in scholarly attention to the nature and scope of market failures behind a host of federal statutes by those otherwise accustomed to thinking such projects are fruitless because federal commerce power has no limits.

#### 3. Generates a guide for general Commerce Clause jurisdiction.

Bruce Johnson and Moin A. Yahya 04. D. Bruce Johnsen, Professor of Law, George Mason University School of Law. J.D., Emory University, 1985; Ph.D., University of Washington, 1987. Moin A. Yahya, Visiting Assistant Professor of Law, University of Alberta School of Law. J.D., George Mason University School of Law, 2003. Ph.D., University of Toronto, 2000. The Evolution of Sherman Act Jurisdiction: A Roadmap for Competitive Federalism, 7 U. Pa. J. Const. L. 403 (2004). https://scholarship.law.upenn.edu/jcl/vol7/iss2/2

The remainder of this Article builds the normative case in favor of competitive federalism and shows how its implications for Sherman Act jurisdiction can be used to guide the evolution of general Commerce Clause jurisdiction. Part I reviews the relevant case law. It begins with a brief look at a selection of notable cases on general Commerce Clause jurisdiction and then turns specifically to the case law on Sherman Actjurisdiction. Our intent in reviewing this body of law is merely to lay a foundation to show that the geographic market power test is broadly consistent with Commerce Clause case law as it has evolved over the past 180 years.

Part II describes the simple economics of market power and illustrates the practical approach antitrust regulators have developed under the 1992 Horizontal Merger Guidelines ("Merger Guidelines") to define the relevant product and geographic markets.3 ' This approach uses the geographic antitrust market to assess the likely effect of horizontal mergers on market power and consumer welfare, but we show it can easily be adapted to assess the interstate effects of any category of trade restraints.

Part III describes what we characterize as the geographic market power test for Sherman Actjurisdicton. According to this test, to establish federal jurisdiction under the Act the complainant must allege and ultimately prove that the defendant has a sufficiently large share of the geographic antitrust market that it can plausibly exercise market power "in more States than one."33 Although straightforward, this jurisdictional test is novel, substantively reasoned, and completely consistent with the methodology antitrust regulators use under the Merger Guidelines to evaluate the substantive merits of horizontal 34 mergers. The geographic market power test resolves a number of troubling inconsistencies in the Court's case law on federal antitrust jurisdiction.

Part IV demonstrates the analytical force of the geographic market power test. We show that it is consistent with the statutory intent behind the Sherman Act, and that within the framework of competitive federalism it is the only economically sensible approach to setting appropriate limits on federal antitrust jurisdiction. Moreover, the geographic market power test will resolve the current turmoil over Sherman Act jurisdiction in the federal circuits and hasten the rate at which the Court's understanding of novel business practices evolves.

Part V concludes by sketching a model of how case law evolves in response to the judicial uncertainty created by statutory shocks. We show that the geographic market power test is a compelling step in the evolution of Sherman Act jurisdiction and that it provides the Court with a useful roadmap to realign its approach to general Commerce Clause jurisdiction. The legal uncertainty that attends most regulatory statutes prevents the Court from acting too quickly, but as the Court gradually accumulates the stock of knowledge necessary to identify the geographic scope of the underlying market failure, it can and should require an increasingly clear nexus between the proscribed conduct and an interstate spillover. This will allow the Court to achieve a balance of dual sovereignty consistent with competitive federalism while posing little immediate threat to constitutional precedent.

#### 4. The courts will follow once a new test for Sherman is set.

Bruce Johnson and Moin A. Yahya 04. D. Bruce Johnsen, Professor of Law, George Mason University School of Law. J.D., Emory University, 1985; Ph.D., University of Washington, 1987. Moin A. Yahya, Visiting Assistant Professor of Law, University of Alberta School of Law. J.D., George Mason University School of Law, 2003. Ph.D., University of Toronto, 2000. The Evolution of Sherman Act Jurisdiction: A Roadmap for Competitive Federalism, 7 U. Pa. J. Const. L. 403 (2004). https://scholarship.law.upenn.edu/jcl/vol7/iss2/2

The Court's decisions in Lopez and Morrison suggest a majority of the Justices would like to establish a clear and substantively reasoned basis for limiting federal Commerce Clause jurisdiction in a way that is consistent with competitive federalism. In part, this appears to reflect the Court's discomfort over its inability to establish bounds for the substantial effects test. As Justice Thomas stated in his Lopez concurrence, "[i] n an appropriate case, I believe that we must further reconsider our 'substantial effects' test with an eye toward constructing a standard that reflects the text and history of the Commerce Clause without totally rejecting our more recent Commerce Clause jurisprudence., 241 The question is how. The Court can begin by overturning Summit and adopting the geographic market power test as the basis for Sherman Act jurisdiction. This would set the bounds of the substantial effects test in the antitrust context by requiring the party asserting jurisdiction to allege a substantial interstate spillover of market power.

In what follows, we sketch a model that shows how a common law judicial system evolves to reduce legal uncertainty in the face of positive administrative costs. We then show that the geographic market power test represents a compelling step in the evolution of Sherman Act jurisdiction that promises to dramatically reduce legal uncertainty. By adopting the geographic market power test for Sherman Act jurisdiction, the Court can redirect the evolution of general Commerce Clause jurisdiction while posing little immediate threat to the existing stock of constitutional precedents.

### Advantage CP---2NC

#### 1. FDA guidance.

Eric Sagonowsky 18. Senior editor with Fierce Pharma, 10/4/18. “One way to thwart generics delays? Look skeptically at citizen petitions, FDA says.” https://www.fiercepharma.com/pharma/fda-revamps-citizen-petition-reviews-to-streamline-generic-approval-process

One tool drugmakers have used to delay generic versions of their blockbuster drugs is a seemingly humble, yet often effective one: the FDA citizen petition. But thanks to new agency guidance, that tool may not be so effective anymore.

FDA Commissioner Scott Gottlieb said Tuesday that the agency would be taking a harder look at each citizen petition to determine whether it was filed primarily to delay a generic. If so? The agency would simply reject it.

That approach might have stopped some high-profile citizen petitions in their tracks—and, in some cases, thwart some last-minute legal drama. And though the FDA has already raised the bar for citizen petitions once, the new guidance, now open for public comment, could raise it higher.

Under draft guidance proposed this week, if the FDA finds a petition was filed “with the primary purpose of delaying the approval of a generic drug application," the agency can forego investigating the petition's claims, which in some cases are complicated and technical. Those rejections would be publicized in an annual report to Congress and the agency would refer the cases to the Federal Trade Commission, which enforces antitrust law.

The move is the latest in a series of FDA changes designed to step up generics competition and speed copycat drugs to market. “We will not shy away from calling out instances where we believe brand firms may be leveraging tools intended to serve a useful purpose to instead thwart competition that can drive down prices for patients,” Gottlieb said in a statement announcing the guidance.

Market watchers might remember, for instance, AstraZeneca's attempt to delay Crestor generics with an FDA petition; that review then triggered a last-ditch lawsuit that, in the end, delayed all but one authorized generic by several months. Mylan tried to hold off Teva's EpiPen generic with a petition claiming the copycat wasn’t equivalent because its cap was different. Novo Nordisk has asked the agency to force companies seeking to market Victoza copies to conduct their own clinical trials. Takeda cited multiple reasons in asking the agency to hold off on approving Velcade generics.

Such attempts to block copycat launches rarely work, Gottlieb said, but the petitions add another hurdle for generics companies seeking to reach the market with cheap copies.

PhRMA, the branded drug industry's trade group, said it's reviewing the draft guidance. Petitions "provide an important avenue for raising critical scientific, policy and legal issues to the U.S Food and Drug Administration," a spokesman told FiercePharma in a statement.

"These petitions promote the transparent exchange of information and ideas about scientific, legal and regulatory matters, which is critical to achieving the FDA’s public health mission," he added. "Through petitions, the FDA receives valuable input reflecting various perspectives, and, through comments on pending petitions, the public may engage in the agency’s deliberative process." PhRMA is reviewing the draft guidance and looks "forward to engaging in the public comment process as appropriate," he added.

Aside from the agency's efforts with citizen petitions, the FDA has started to highlight cases where generics companies are claiming that branded drugmakers are thwarting their attempts to obtain samples for bioequivalence testing. The agency has also put out a "hit list" of drugs with little competition and put new versions of generics now available from single sources on a faster track to approval.

The changes at the FDA come as the Trump administration works to get a handle on drug prices, notably in May with the release of its pricing blueprint. The administration aims to bring more negotiation and transparency to the industry, plus create incentives to lower list prices and lower out-of-pocket costs for patients. In addition, the administration has been reviewing potential changes to drug rebates that could bring widespread changes to drug pricing.

#### 2. Already denies sham petitions.

Michael A. Carrier 20. Distinguished Professor, Rutgers Law School. "Three Challenges for Pharmaceutical Antitrust," Santa Clara Law Review 59, no. 3 (2020): 615-640. HeinOnline.

Many citizen petitions are questionable. Even though they are meant to raise legitimate safety concerns with the FDA, my empirical research found that the FDA has denied nearly all of the petitions. In particular, I found that the FDA denied 92% of petitions targeting generic entry, with that figure rising to 98% for petitions filed at the "last minute," within six months of the expiration of a patent or FDA exclusivity period.76

In addition to these general findings, particular examples demonstrate concern in the form of   
\* Multiple petitions (such as Teva's 8 petitions on MS-treating Copaxone and Shire Viropharma's 24 petitions on a life-threatening gastrointestinal infection)77;

\*Late-filed petitions (such as Bayer Healthcare filing a petition one day before the expiration of the patent on Mirena, a long-acting intrauterine device (IUD))78;

\* The combination of citizen petitions and product hopping (as shown by acne-treating Doryx)79; and   
\* The combination of petitions and entry-delaying settlements (as shown by Mylan's allergic-emergency-treating EpiPen). °

The FDA has also voiced unease with this conduct. In seeking to invigorate its ability to summarily deny petitions submitted "with the primary purpose of delaying" generic approval, the agency introduced a draft guidance articulating relevant factors, which included long-delayed petitions, repetitive petitions, submissions immediately before generic approval, petitions without support, and a history of concerning petitions. \* 81

In short, any attempted defense based on petitioning immunity runs headlong into the sham nature of petitions that are almost always denied and that often raise significant concerns of delayed generic competition, which directly harms consumers by increasing price.

#### 3. FDA’s rejecting baseless citizen petitions now

Brenda Sandburg 12/17/21. “FDA Slams Citizen Petition: Harsh Language, FTC Referral Suggest Tougher Stance On ANDA Delay Tactics.” <https://pink.pharmaintelligence.informa.com/PS145418/FDA-Slams-Citizen-Petition-Harsh-Language-FTC-Referral-Suggest-Tougher-Stance-On-ANDA-Delay-Tactics>

\*ANDA = Abbreviated New Drug Application, submitted for approval of a generic drug

The US Food and Drug Administration took an unusually harsh tone in denying Par Sterile Products LLC’s citizen petition asking the agency not to approve generic versions of Vasostrict (vasopressin injection) until certain conditions are met.

The agency routinely receives such requests from brand manufacturers, but it took particular umbrage with the submission by Par, a subsidiary of Endo International plc. In a 15 December letter to Par attorney Chad Landmon, a partner at Axinn, Veltrop & Harkrider, the FDA said it would have grounds to deny the petition “because it appears to have been submitted with the primary purpose of delaying approval of Eagle Pharmaceuticals, Inc.’s ANDA and fails to raise valid scientific or regulatory issues.”

While the agency has the authority to reject petitions on the basis of intent to delay, it apparently has never done so.

“My jaw was on the floor,” Kurt Karst, a director at Hyman, Phelps & McNamara, said. “I’ve never, never seen that.”

The letter was signed by Douglas Throckmorton, deputy center director for regulatory programs in the Center for Drug Evaluation and Research, and CDER Director Patrizia Cavazzoni. They said FDA intends to refer the matter to the Federal Trade Commission, noting that the FTC has the tools and expertise to investigate anticompetitive business practices. Karst said such referrals are rare but have occurred.

The agency approved Eagle’s ANDA the same day it issued the letter denying Par’s petition. Vasostrict is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

Policy Shifts Ahead?

Generic approvals are supposed to be the low-hanging fruit of the drug pricing debate, with Democrats and Republicans alike saying they should be abundant, but the fact that the FDA continues to reach new rhetorical heights to swat away petitions suggests the problem isn’t exactly going away.

Still, there are some indications that pro-approval policies could be gaining steam that, while unlikely to eliminate all the roadblocks, could make ANDA approval smoother.

As part of President Biden’s drug pricing plan, acting FDA Commission Janet Woodcock wrote to the Patent and Trademark Office seeking to collaborate on "possible misuse of the patent system." (Also see "US FDA’s Patent ‘Concerns’ Include Thickets, Product Hopping, And Evergreening" - Pink Sheet, 10 Sep, 2021.)

It seems quite possible that reforms to speed generic approvals could be included in the user fee renewal legislation next year. Bipartisan support for the concept, if not specific policy provisions, was shown during the 14 December confirmation hearing for Robert Califf to become FDA commissioner.

Sen. Bill Cassidy, (R-La.) asked Califf to “come back to this committee with recommendations as to how we’re going to address those legal tricks.” Cassidy was asking specifically about the impediments to complex generics, but seemed amenable to broader reforms.

One FTC Action On Citizen Petition

The mechanism that FDA used to deny Par’s petition was itself created through user fee renewal legislation. A provision of the FDA Amendments Act of 2007, Section 505(q), requires the agency to respond to petitions within a specified time frame and permits it to summarily deny a petition if it determines the petition was submitted with the primary purpose of delaying the approval of an application and does not on its face raise valid scientific or regulatory issues.

The FDA issued revised draft guidance on citizen petitions in 2018 saying if it determines a petition has been submitted with the primary purpose of delaying an application it would refer the matter to the FTC for possible enforcement action. ( (Also see "US FDA Amps Up "Name And Shame" Approach To Thwart Anti-Generic Tactics" - Pink Sheet, 2 Oct, 2018.) The final guidance was issued in September 2019.

The FTC has taken enforcement action against a company for allegedly abusing the citizen petition process in one instance.

#### 4. Comprehensive new rules.

Rachel Sachs 22. JD, MPH, associate professor of Law at Washington University in St. Louis, where her work explores the interaction of intellectual property law, food and drug regulation, and health law, 1/7/22. “Prescription Drug Policy, 2021 And 2022: The Year In Review, And The Year Ahead.” https://www.healthaffairs.org/do/10.1377/forefront.20220106.210890

In the absence of legislative changes, the Biden Administration has begun to signal potential administrative moves, but has yet to take significant action. In early September, the Biden Administration released its Comprehensive Plan for Addressing High Drug Prices, a report that centered the role that a lack of competition plays in establishing—and maintaining—high drug prices. The FDA itself has begun to take additional actions to assert its role in ensuring that pharmaceutical companies are not seeking to unduly delay generic or biosimilar competition. A letter from the FDA to the Patent and Trademark Office (PTO) lays out the agency’s concerns that certain pharmaceutical company patent practices may be creating obstacles to timely competition; the letter expresses the FDA’s desire to work with the PTO to address these challenges. And the FDA took the notable step of responding to a citizen petition filed by a branded pharmaceutical company by noting that the petition “appears to have been submitted with the primary purpose of delaying [generic] approval.” The FDA referred the petition to the Federal Trade Commission for investigation.

#### 5. FDA and FTC are on the case

Zachary Brennan 12/16/21. Senior Editor, Endpoints News. “FDA seeks FTC action after rejecting petition to block first generics for decades-old vasopressin.” https://endpts.com/fda-seeks-ftc-action-after-rejecting-petition-to-block-first-generics-for-decades-old-vasopressin/

The FDA on Wednesday not only approved the first generic versions of the decades-old diabetes insipidus treatment vasopressin, but also simultaneously offered a particularly damning rebuke of a citizen petition attempting to block the generic, while promising to pass along the matter to the Federal Trade Commission.

The response could prove troublesome for the sponsor of the brand name version of the drug, Endo’s Par Sterile Products, which brought in more than $780 million in 2020 for its brand name version of the drug Vasostrict.

Last month, Par’s lawyers at Axinn called on the FDA to refrain from approving any generics for Vasostrict due to the potential for certain stability and other specifications that could cause concerns with impurities or other safety issues.

But FDA points out at the top of its response that vasopressin has been marketed as a therapeutic agent for nearly a century.

“Pitressin, a natural vasopressin product developed as an extract of the bovine posterior pituitary, was first introduced in 1928,” the agency said.

What’s more is that Par only won FDA approval for vasopressin in the first place, in 2014, because of the FDA’s drug safety initiative at the time to encourage manufacturers to obtain the agency’s approval for old, unapproved drugs.

In addition to the denying the petition, FDA said that it “does not on its face raise valid scientific or regulatory issues” and “it appears to have been submitted with the primary purpose of delaying approval of Eagle’s ANDA and fails to raise valid scientific or regulatory issues. The Agency intends to refer this matter to the Federal Trade Commission (FTC), which has the administrative tools and the expertise to investigate and address anticompetitive business practices.”

This kind of action from the FDA is rare to see, as lawyer Kurt Karst at Hyman, Phelps & McNamara noted on Twitter, and it may be part of a wider collaboration between the FDA and FTC to put companies on notice over attempts to block future generics.

#### 6. They’re committed to solving the advantage

Philip Chen et al. 22. Associate in the Boston office of Fish & Richardson P.C., Casey Kraning, Ph.D., Kayleigh McGlynn, Jenny Shmuel, Ph.D.,

In February 2020, FDA and the Federal Trade Commission (FTC) issued a joint statement stating that “anti-competitive practices, such as making false or misleading statements comparing biological reference products and biosimilars, may be slowing progress and hampering uptake of these important therapies.” The agencies committed to “take appropriate steps to address companies making false or misleading communications about biologics, including biosimilars and interchangeable products, which will help deter anti-competitive behavior in the biologics market and can help lead to the use of all available biological products.” Citing this joint statement in a July 2021 press release, FDA announced that it had issued an untitled letter to Amgen citing issues with a banner advertisement of its biological product, Neulasta® (pegfilgrastim). In particular, FDA flagged as false or misleading Amgen’s claims in the advertisement that “In a Real-World Study with nearly 11,000 patients Pegfilgrastim PFS resulted in a significantly higher risk of FN [(febrile neutropenia)] vs Onpro®.” According to FDA, Amgen’s violations were “concerning from a public health perspective” because the claims in the advertisement “could cause healthcare providers to conclude that Neulasta delivered via the Onpro on-body injector (OBI) is more effective than Neulasta delivered via prefilled syringe (PFS) or that it is more effective than FDA-licensed biosimilar pegfilgrastim products, which are only delivered via PFS.”

#### 7. There’s no impact.

Caitlin Owens 1/20/22. Health care reporter for Axios, “The drugs pushing prescription prices down for Medicare patients.” https://www.axios.com/prescription-drug-prices-generic-medicare-medicaid-837bcc06-3185-4881-9384-77f497f969b4.html

Although net prices of brand-name drugs have increased significantly over the last decade, the savings produced by generics have actually driven average prescription prices down in Medicare's pharmacy benefit and Medicaid, according to a new analysis by the Congressional Budget Office.

Why it matters: The analysis reiterates that the generic market is largely working as intended.

By the numbers: The average net price of a prescription fell from $57 in 2009 to $50 in 2018 in Medicare Part D, and from $63 to $48 in Medicaid.

The drop is largely attributable to the growing use of generics, which jumped from 75% to 90% of all prescriptions nationally during that time frame. The average price for a generic prescription also fell in both programs.

But the average net brand-name prescription price more than doubled in Part D and increased by 50% in Medicaid, per the analysis. These increases were driven by higher launch prices for new drugs and price increases of drugs already on the market.

Higher launch prices are due in part to more specialty drugs entering the market.

#### 8. So many alt causes!

Robin Feldman 21. Visiting Professor at UCLA School of Law, and the Arthur J. Goldberg Distinguished Professor of Law, and Director of the Center for Innovation at the University of California Hastings, 7/22/21. “Captive Generics: The Wolf in Sheep’s Clothing.” UC Hastings Research Paper Forthcoming. https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3868436

Prior academic literature has identified a number of obstacles to realization of the goals of Hatch-Waxman. In particular, generics cannot reduce costs if they are prevented from entering the market. Various strategic behaviors that drug companies employ to delay or deter competitive entry play an important role in undermining the Act. From pay-for-delay12 to citizen petitions13 to product hopping,14 drug-makers throw everything but the kitchen sink in their efforts to keep generic competitors out of their yard as long as possible. These anticompetitive practices, as prior literature describes, have caused more than their fair share of lost savings.15 The grab bag alone, however, cannot fully answer the question of why the storied Hatch-Waxrnan Act is failing to deliver on its promise.

#### 3. That enacts meaningful procedural blocks that ensure that citizen petitions don’t delay generic entry

Robin Feldman et al. 17. Harry and Lillian Hastings Professor and Director of the Institute for Innovation Law, University of California, Hastings College of the Law, with Evan Frondorf, Andrew K. Cordova, and Connie Wang, “EMPIRICAL EVIDENCE OF DRUG PRICING GAMES—A CITIZEN’S PATHWAY GONE ASTRAY.” 20 STAN. TECH. L. REV. 39 (2017). https://law.stanford.edu/wp-content/uploads/2017/10/Empirical-Evidence-of-Drug-Pricing-Games%E2%80%94A-Citizens-Pathway-Gone-Astray-.pdf

An alternative approach would involve enacting procedural blocks to channel the behavior into positive, rather than suboptimal, results. In other words, one might wish to preserve the citizen petition process for all—including competitors—and yet ensure that citizen petitions ﬁled by competitors do not delay generic entry.

For example, one might direct that citizen petitions ﬁled by competitors must be ﬁled within a year of when the generic company ﬁles for approval. 145 Given that the average length of time for a generic application is approximately four years, citizen petitions ﬁled within a year are less likely to delay ﬁnal approval.

Similarly, when competitors raise an issue related to the drug in general, the rule could be that the generic application goes forward on a timeline unrelated to the citizen petition. In other words, the generic can receive approval, and whatever issue is raised can be resolved after that approval, if necessary. After all, the branded drug remains on the market under the current requirements for the drug, which suggests that the issues raised in the citizen petition are not of such magnitude that the drug cannot be offered to the public. Thus, whatever issues must be resolved would be resolved as to all forms of the drug—generic and brand-name—on a timeline unrelated to the generic’s approval. One could refer to this as the “band plays on” rule. Even for issues related to whether the generic is bioequivalent or satisﬁes the FDA’s requirements, one could once again conclude that the Agency is generally the best judge of that—at least with issues so serious that approval must be denied.

One concern is that, although most citizen petitions are denied, some are granted. This suggests that occasionally, legitimate issues are at stake, and safety must remain the FDA’s primary focus. Looking at concerns from the other direction, a “band plays on rule” still may squander some societal resources. The FDA must spend time responding to each concern raised. Similarly, branded companies could still use the tactic of ﬁling citizen petitions to raise their rivals’ costs.146 In other words, generic competitors conceivably could be forced to spend time and money responding to spurious issues raised. Nevertheless, with the prospect of delayed entry off the table, such a procedural block could substantially decrease a brand-name company’s incentives to engage in this behavior. Of the choices discussed here, this may, indeed, be the most effective.

#### 1. The Friedman evidence describes a broad scope existing now about a DIFFERENT policy proposal!

**EMORY GK = YELLOW**

**Friedman 13** (Ana Jemec Friedman, An Antidote to Efforts by Drug Manufacturers to Delay the Entry of Generic Competition via Sham Petitioning\*, 92 N.C.L. Rev. 277)

One scholar has addressed the first factor, suspect timing, as follows:

The FDA could make an additional regulatory improvement by imposing a **time frame** for citizen petition submissions. Similar to the predefined comment period for citizens to respond to a proposed FDA rule, citizens should be given a defined forty- five day comment period to raise health and safety concerns in response to ANDA applications. This would avoid eleventh-hour petitions and enable the FDA to rule in time for an approved generic to go to market without an unjust delay. These regulatory reforms would decrease the incentives for brand-name companies to submit sham petitions and help to safeguard the citizen petition process. 224

While this approach does address the concern of suspect timing, **its scope is overly broad**, reaching many parties **beyond the brand-name manufacturers** who are almost exclusively the parties accused of filing sham citizen petitions. This broad scope consequently reduces **the public health benefit** that can result from including as many citizen petitions in the ANDA approval process as possible.

#### 2. The CP’s the most promising approach to abusive citizen petitions

Beth Wang 17. Managing Editor at InsideHealthPolicy, 3/17/17. “Health Law Expert: Transparency, Limits Needed To Stop Petition Abuse.” InsideHealthPolicy.com's FDA Week , March 17, 2017, Vol. 23, No. 11 (March 17, 2017), pp. 4-6. JSTOR.

FDA needs to be more transparent about its citizen petition process and there should be more stringent restrictions around petitioning because regulatory and congressional attempts to reduce abuses of petitioning to keep competing drugs off the market are not working, a health law expert told Inside Health Policy. The call for greater transparency came days after a new study authored by the expert shows that nearly half of all delay-related citizen petitions filed in a 12-year period were filed within a year and a half of generic competition approval.

The use of citizen petitions by brand-name drug manufacturers to delay or halt generic drug approval has garnered attention as the Federal Trade Commission (FTC) “made history,” one academic says, in February by taking enforcement action against a company for abuse of FDA’s petition process. Reports show this method has increased during the past decade, despite implementation of legislation and agency rules intended to help reduce it.

Robin Feldman, law professor at UC Hastings College of the Law San Francisco, told IHP she would like to see more disclosure from FDA showing the impact that citizen petitions have, beyond the annual reports the agency submits to Congress.

“It’s extraordinarily difficult to get information and track down behaviors. It’s difficult for academics, for regulators, for competitors and for legislators. You can’t fix the problem if you can’t see it. We need disclosure. And the FDA is the best agency for disclosure,” Feldman told IHP.“The reports (FDA submits to Congress) are aggregate data, which is not tremendously useful. FDA should be publishing much more detailed data about, for example, when applications are filed and what drug they might relate to... Generally, legislators, regulators and researchers need much more information to identify and head off the inappropriate behavior. Right now it’s impossible to find.”

Michael Carrier, professor of law at Rutgers University, also said that FDA should make clear “what we’re dealing with here.” Like Feldman, Carrier argued FDA should provide information that goes beyond what’s in the agency’s annual reports to Congress.

“FDA provides a report to Congress each year. It’s not a big deal to make FDA list all the petitions it’s addressing each year — which ones lead to delay, how much time is spent on this. It’s certainly something Congress can do,” Carrier told IHP.

Suggestions from Feldman and Carrier to increase transparency included: disclosing when petitions are filed, which drug they might relate to, how much time was spent on the petition and which ones lead to delays.

A new study from Feldman, published in the New England Journal of Medicine, found that nearly half of all delay-related citizen petitions filed between 2000 and 2012 were filed within the year and a half before FDA approved the generic, and about 40 percent were filed a year or less before generic approval. The report also showed that the number of delay-related petitions filed has increased since 2003 when there were 12 delay-related petitions filed. In 2004 that number more than doubled to 26. The number did go back down to 15 in 2005, but then jumped to 24 in 2006. Since then, the number has remained mostly in the 20 to 30 range, with occasional spikes in the 30 to 35 range. The highest count during this 12-year time period was 32 petitions filed in 2009, accounting for 18.7 percent of all petitions filed during that year.

Feldman says generic companies also use the petition process to delay competition. “Generics play these games sometimes, too,” she told IHP. “We saw citizen petitions filed by generics to keep other generics out because there is an initial price drop when one generic enters the market, but the largest price drop is when multiple generics enter the market.”

While both Congress and FDA have taken action to attempt to reduce this kind of petitioning, Feldman said it hasn’t worked well. In 2007, Congress required FDA to respond to citizen petitions related to generics within 180 days. Then in 2012, they shortened the timeframe even further to 150 days.

In her NEJM article, Feldman wrote that the most promising approach to preventing manipulation of the citizen petition process would be to create stronger procedural blocks, “such as requiring that drug companies file their citizen petitions within a year after the generic company files its application, or establishing that issues raised by petitions will be resolved on a separate timeline from the generic’s approval process.”

Even with regulatory and legislative action to reduce the number of allegedly anti-competitive citizen petitions filed, Feldman told IHP the process structure remains largely unchanged.

“I am always happy to see FDA attempt to curb questionable behavior. I am skeptical that these changes will help ... because the incentive structure remains the same and the lack of enforcement measures remain the same,” she said.

FTC recently took strong action against an alleged citizen petition abuser. In February, FTC filed a complaint against Shire ViroPharma, which the agency says violated “antitrust laws by abusing government processes to delay generic competition to its branded prescription drug, Vancocin HCI Capsules.” According to the FTC, ViroPharma submitted 43 petitions to FDA and filed three lawsuits against the agency from 2006 to 2012.

“The number and frequency of ViroPharma’s petitioning at the FDA are many multiples beyond that by any drug company related to any other drug,” the FTC wrote in a press release. “ViroPharma knew that it was the FDA’s practice to refrain from approving any generic applications until it resolved any pending relevant citizen petition filings. ViroPharma intended for its serial filings to delay the approval of generics, and thus competition and lower prices,” FTC wrote in a press release.

The enforcement action taken by the FTC, according to Feldman, is the first action the agency has taken against a company for abuse of the citizen petition process. It’s also a major step in heading off pharmaceutical companies’ anti-competitive behavior, Feldman said.

“This is the problem. Shire ViroPharma may be a particularly egregious example, but it’s not the only one,” Feldman told IHP. “The behavior is widespread. Companies string these games out one after another to create competition-free zones for as long as possible.”

While both Carrier and Feldman say the majority of citizen petitions are denied by FDA, filing a petition to delay a generic can still have a major financial effect.

“The vast majority of (petitions) are rejected. However, a little delay can be worth a lot of money. For a blockbuster drug, a five-month delay — and that’s five months within (the time frame) of the citizen petition filing — can be worth half a billion dollars in sales,” Feldman told IHP.

#### 3. The CP remedies inefficiencies, solves generics

Kurt R. Karst 21. Director at Hyman, Phelps & McNamara, P.C., 4/30/21. “The Good, the Bad and the Ugly: New Legislation Would Reform the ANDA Suitability Petition Process and Require Timely Assignment of 505(b)(2) NDA Therapeutic Equivalence Evaluation Codes (“the Good”).” https://www.thefdalawblog.com/2021/04/the-good-the-bad-and-the-ugly-new-legislation-would-reform-the-anda-suitability-pettition-process-and-require-timely-assignment-of-505b2-nda-therapeutic-equivalence-evaluation-codes-th/

Modernizing Therapeutic Equivalence Rating Determination Act (S. 1463)

Beginning with the 36th (2016) edition of the Orange Book, the Orange Book Preface was updated to state that “[a] person seeking to have a therapeutic equivalence rating for a drug product approved in a 505(b)(2) application may petition the Agency through the citizen petition procedure (see 21 CFR 10.25(a) and 21 CFR 10.30).” Since then, FDA has received numerous citizen petitions requesting the assignment of a Therapeutic Equivalence Code (“TE Code”). In most cases, however, those petitions languish at FDA for an extended period of time (usually years). In the meantime, 505(b)(2) NDA holders must pay an annual PDUFA user fee for such products and request a refund contingent on FDA’s citizen petition determination. Prompt TE Code determinations (i.e., either “A” or “B” ratings) for drug products approved under a 505(b)(2) NDA would eliminate these inefficiencies, the costs to the Agency and the generic drug industry associated with those inefficiencies, and would clarify the substitutability of several drug products.

According to the press release on S. 1463:

The Modernizing Therapeutic Equivalence Rating Determination Act requires FDA to assign therapeutic equivalence ratings for 505(b)(2) applications at the applicant’s request, as it does for ANDAs. The 505(b)(2) approval pathway is used to approve new drugs while leveraging certain data from an already approved drug. To the extent that the drug candidate differs from the already approved drug, the sponsor has to generate sufficient data including clinical data to support the differences, but does not automatically receive a therapeutic equivalence rating. A therapeutic equivalence rating is necessary to trigger automatic substitution at the pharmacy level and thus critical to driving competition. Because 505(b)(2) is technically a new drug pathway, the statute does not require FDA to assign a therapeutic equivalence rating. Sponsors can request it via the citizen petition process, but this can take significant time. Requiring FDA to assign a therapeutic equivalence rating for 505(b)(2) applications will level the playing field for 505(b)(2) products to compete with name brand drugs.

Specifically, the bill would amend the statute’s Orange Book provisions FDC Act § 505(j)(7)(A) to require that FDA make a TE Code determination for a 505(b)(2) NDA “at the time of approval of such application or not later than 30 days after the date of such approval, provided that the sponsor requests such a determination in the original application, in a form prescribed by the Secretary.”

Like S. 1462, S. 1463 would make small, but very meaningful, changes to the statute to address and remedy current FDA inefficiencies. And if there’s one thing this German-blooded American likes, it is efficiency!

#### CP: The United States federal government should make patent examination an adversarial proves and eliminate skewed incentives. Everything listed is an alt cause to the affirmative! GK = BLUE

Ford 17 (Ford, Roger Allan. Associate Professor of Law, University of New Hampshire School of Law; Faculty Fellow, Franklin Pierce Center for Intellectual Property. "The Uneasy Case for Patent Federalism." Wis. L. Rev. (2017): 551.)

If state patent laws suffer from the flaws described in the last Part, then the burden is high to justify state attempts to meddle in patent policy. This Part provides a substantive case for a limited form of patent federalism: Vermont-style laws that seek to make it harder to bring patent-infringement claims. This is concededly an outcome-driven argument, not one rooted in any principles of federalism. It stems from the premise that the federal patent system has not settled at the best balance between innovation and competition, or the best means of achieving that balance. Instead, it assumes, federal patent law is distorted in favor of patent holders and has chosen means that are too costly for accused infringers. If those premises are correct, then state anti-patent laws could help provide helpful reforms.

There is a near-consensus that the federal patent system has problems. The Patent Office routinely grants invalid patents; patent trolls routinely bring nuisance cases asserting those invalid patents; and juries routinely hand out enormous damage awards to patent holders who never really invented anything, at the expense of companies developing successful products that really do benefit society. Or, at least, that is a common narrative; and while this narrative may be overstated, it contains some truth. States, in turn, can help restore the balance between innovation and competition by moving the broader system closer to the optimal point.

A. The Flawed Federal Patent System

Most patent scholars agree that the modern patent system does an imperfect job of encouraging innovation. This section highlights four common critiques: that the Patent Office grants low-quality patents; that patent holders bring nuisance lawsuits designed to extract settlements rather than enforce legitimate patent rights; that patent trolls and other nonpracticing entities bring cases against productive companies, extracting royalties for products that owe little or nothing to the patentees’ work; and that patent holders bring claims against end users and other defendants with low bargaining power.

The goal of this section is not to show that these critiques are correct; rather, I take it as an assumption that they apply to the patent system, or at least to significant parts of that system. Rather, my aim is to highlight critiques that are especially relevant for state anti-patent laws. These are, of course, not the only criticisms of the patent system,86 but they are the ones that state anti-patent laws are designed to target and on which such laws are likely to have the greatest effect.

1. THE PATENT-QUALITY CRITIQUE

The patent system’s biggest problem may be patent quality, with examiners granting many problematic patents. These problems fall into various categories. Some patents cover inventions that are not actually new, or are not meaningfully different from what came before.87 Others claim inventions broader than what an inventor actually invented, or fail to inform practitioners how to make and use the claimed invention.88 Still others are vague about what they claim, or have claims that seem deliberately obfuscated or designed to be difficult to compare to real-world products.89 These quality problems are surprising at first glance, since patent law is the only major form of intellectual property in which obtaining rights requires a detailed, substantive examination by an expert examiner.90 Yet there are several reasons quality problems persist.

One set of factors stems from the examination process itself. Patent examination is an ex parte process, so examiners do not have the benefit of adversarial presentation by parties on both sides of a dispute; instead, they see only information and arguments tending to show that an applicant is entitled to a patent. Though examiners are supposed to conduct independent prior-art searches to overcome this limitation, they have limited time to do so. Examiners also have skewed incentives: they are rewarded (in productivity measures and bonuses) for granting patents and penalized (in increased workload) for rejecting patent applications. This stems from one of the stranger quirks of the United States patent system, under which an application can never be conclusively rejected by an examiner; instead, an applicant can always revive an application after rejection. So for examiners, the only certain way to get a file off one’s desk is to grant the application.91

These examination limitations are compounded by applicants’ incentives to obtain vague patents claims. Applicants want to obtain patents as quickly and cheaply as possible while also ensuring that those patents will prove valuable; both goals can be furthered by writing vague claims. Vague claims can help an application move quickly through examination, since they can make it harder to find relevant prior art or to know if that prior art would invalidate the claims. And they help an applicant respond when an examiner issues a rejection, since vague claims can be twisted or interpreted flexibly to overcome whatever prior art an examiner does find. Vague claims are most valuable, though, after a patent is granted, since they can be asserted against a broader array of products and services, and since they can be interpreted after the fact to track industry developments. Patent law’s indefiniteness doctrine is designed to prevent applicants from obtaining overly vague claims, but in practice imposes minor obstacles.92

There are also innocuous sources of low patent quality. Because patents by their very nature deal with the cutting edge, it may inherently be harder to precisely describe a new invention than something conventional, since terminology may not yet exist to describe the invention. And even when a patent originates in a longstanding field, words can rarely be stripped of all ambiguity; patent law has long assumed that language has inherent ambiguities that make it impossible to craft perfect patent claims, or at least that patent drafters have incentives to use such ambiguous language.93

These patent-quality problems also feed into the nuisance-litigation and patent-troll critiques, discussed below, because they make it easier to obtain and enforce patent rights, even when those patent rights are undeserved or that enforcement is abusive.

2. THE PATENT-TROLL CRITIQUE

The most common, and most commonly debated, critique of the patent system in recent years is that it is overrun with patent trolls, or nonpracticing entities, or licensing firms—all names for firms that assert patent rights without making anything themselves. These firms are a problem, the critique goes, because they extract judgments or settlements from companies producing products without contributing any value to those products, or to society.

To a significant degree, patent trolls may be symptoms of other problems in the patent system rather than a problem in their own right.94 For instance, they sometimes extract settlements by bringing nuisance litigation; then there is essentially no difference between the patent-troll critique and the nuisance-litigation critique addressed in the next section.95 Other times, trolls bring reasonably strong patent claims, and the critique must be rooted elsewhere. One possibility is some sort of asymmetry between trolls and practicing entities, for instance because practicing entities face constraints that trolls do not.96 Another possibility is that trolls are more likely to engage in abusive tactics or behave in ways that reveal other flaws in the patent system.97 Yet the evidence is weak that trolls behave differently from other patent holders, at least in the aggregate; instead, they appear to get more attention for essentially the same behavior that other patent holders undertake.98

#### 2. CP: The United States federal government should not preempt state laws responding to nuisance litigation. GK = Blue

1AC Ford 17 (Ford, Roger Allan. Associate Professor of Law, University of New Hampshire School of Law; Faculty Fellow, Franklin Pierce Center for Intellectual Property. "The Uneasy Case for Patent Federalism." Wis. L. Rev. (2017): 551.)

State laws are not, however, a perfect response to the patent quality critique, since instead of focusing on invalid patents, they focus on a patent holder’s investigation into a target’s allegedly infringing conduct. This is a key disconnect in the state laws: no state has gone after low-quality patents directly, such as by forcing patent holders to undertake validity analyses or to justify their patents’ validity in demand letters. Such laws would almost certainly be preempted, since federal law is clear that patents are entitled to a presumption of validity.120 And although the overlap between low-quality patents and the pre-suit behavior targeted by the state laws is high, it is not perfect; in particular, state laws do more to affect patent holders with weak infringement cases than with weak invalidity cases, due to that presumption of validity.

Second, states can respond to nuisance litigation and end-user litigation by increasing the cost of these mass-litigation strategies enough to make them uneconomical. MPHJ, the scanner troll, sent more than 16,000 demand letters to small businesses,121 and just like senders of spam email, MPHJ’s entire business model depended on the low cost of sending letters. If even a small percentage of recipients agreed to license the asserted patents, then that small upfront cost would be more than covered by licensing revenue. But if state law increases the cost of sending demand letters, then a company cannot adopt the spammer strategy. And other provisions have similar effects; for instance, provisions that ban false threats to sue, or inflated royalty demands, reduce the effectiveness of the strategy because they limit the patent holder’s ability to extract settlements.

## 1NR

### Chilling DA---1NR

#### 2. Post-COVID landscape means our scenario is most probable.

Elise Labott 21, Adjunct Professor at American University’s School of International Service, Columnist at Foreign Policy, MA in Media Studies, New School for Social Research, BA in International Relations from the University of Wisconsin-Madison, “Get Ready for a Spike in Global Unrest”, Foreign Policy, 7/22/2021, https://foreignpolicy.com/2021/07/22/covid-global-unrest-political-upheaval/

To call 2021 the summer of discontent would be a severe understatement. From Cuba to South Africa to Colombia to Haiti, often violent protests are sweeping every corner of the globe as angry citizens are taking to the streets.

Each country has different histories and realities on the ground, particularly in Haiti, where years of violence and government corruption culminated two weeks ago in the assassination of President Jovenel Moïse. But they all faced a perfect storm of preexisting social, economic, and political hardships, which fallout from the COVID-19 pandemic only inflamed further. And they are merely a foreshadowing of the post-coronavirus global tinderbox that’s looming as existing tensions in countries across the world morph into broader civil unrest and uprisings against economic hardships and inequality deepened by the pandemic.

The coronavirus pandemic was a once-in-a-century crisis that not only shocked countries’ existing health systems but also demanded a response that impacted—and was itself shaped by—economic, political, and security considerations. The efforts to contain it may have curbed fatalities in the short term but have inadvertently deepened vulnerabilities that laid the groundwork for longer-term violence, conflict, and political upheaval and should serve as a danger sign to world leaders as countries reopen—including in the United States.

History is full of examples of pandemics being incubators of social unrest, from the Black Death to the Spanish flu to the great cholera outbreak in Paris, immortalized in Victor Hugo’s Les Miserables. Underlying it all this time around is a pervasive inequality. COVID-19 has ripped open economic divides and made life harder for already vulnerable groups, including women and girls and minority communities.

It has also exposed weaknesses in food security and dramatically increased the number of people affected by chronic hunger. The United Nations estimates around one-tenth of the global population—between 720 million people and 811 million—were undernourished last year. The impacts of climate change and environmental degradation have only compounded the despair.

Take the Sahel, where, due to a toxic cocktail of conflict, COVID-19 lockdowns, and climate change, the scale and severity of food insecurity continues to rise. Countries such as Ethiopia and Sudan are among the world’s worst humanitarian crises, with catastrophic levels of hunger. Droughts and locusts are coming at a critical time for farmers ready to plant crops and are stopping herders in their tracks from driving their livestock to greener pastures.

The global vaccine shortage is fueling the instability. A majority of Africa is lagging far behind the world in vaccinations, meaning COVID-19 will continue to constrain national economies and, in turn, become a source of potential political instability. The same is true for much of Latin America and Asia, where countries don’t have enough vaccines to protect their populations and simmering sources of protest—such as rising living costs and deepening inequalities—are more likely to boil over.

The global risk firm Verisk Maplecroft has warned that as many as 37 countries could face large protest movements for up to three years. A new study by Mercy Corps examining the intersection of COVID-19 and conflict found concerning trends that warn of potential for new conflict, deepening existing conflict, and worsening insecurity and instability shaped by the pandemic response.

The group found a collapse of public confidence in governments and institutions was a key driver of instability. People in fragile states, already suffering from diminished trust in their government, have felt further abandoned as they face disruptions in public services, rising food prices, and massive economic hardships, such as unemployment and reduced wages. Supply chains disrupted during the pandemic have seen food prices skyrocket, while in the global recession humanitarian aid budgets are being slashed, bringing many countries to the brink of famine. For the first time in 22 years, extreme poverty—people living on less than $1.90 a day—was on the rise last year. Oxfam International estimates that “it could take more than a decade for the world’s poorest to recover from the economic impacts of the pandemic.”

The shocks caused by the pandemic have also eroded social cohesion, further fraying relations between communities and deepening polarization. That is especially true in the United States, where social and political pressures both deepened the health crisis and were themselves worsened by it. All of this should serve as a clarion call to countries that they can’t prepare for, or respond to, future health crises in a vacuum—but must anticipate an economic, political, and social crisis. This is true for any severe shock, which brings the potential for a breakdown in public order.

#### 3. Turns food security.

Pam Fessler 12. NPR. "Recession Still Hurting U.S. Families Trying To Put Food On The Table". NPR.org. 9-5-2012. https://www.npr.org/sections/thesalt/2012/09/05/160623735/recession-still-hurting-u-s-families-trying-to-put-food-on-the-table

The number of U.S. families struggling to put enough food on the table remains at record-high levels, according to new figures out today from the government. Last year, 1 in almost 7 households were what the government calls "food insecure." That's about the same level as in 2010, but still far higher than before the recession. The problem finding enough food is especially severe among households headed by single mothers with children.

Before the recession, about 1 in 10 households had a problem getting enough to eat. But in 2008, things got a lot worse. And it's pretty much stayed that way ever since. The Agriculture Department today said that almost 18 million households had trouble putting food on the table last year, and that in about 7 million of those households, people didn't have enough to eat.

"There are many Americans who are still struggling with the lingering effects of the great recession," says James Ziliak, head of the Center for Poverty Research at the University of Kentucky.

#### 4. Turns disease and medical care.

Basu et al. ‘13 (Sepideh Modrek, PhD, David Stuckler, MPH, PhD, Martin McKee, MD, DSc, Mark R. Cullen, MD, Sanjay Basu, MD, PhD, “A Review of Health Consequences of Recessions Internationally and a Synthesis of the US Response during the Great Recession”, Public Health Reviews, Vol. 35, No 1)

There are at least two major pathways by which recessions might adversely affect health outcomes (see Figure 1 for conceptual model). One pathway by is through economic shocks. These include unemployment, loss of savings, foreclosure and eviction, and unpayable debt. In the US, each of these factors has been found to trigger health problems such as suicides, substance abuse, and deferment of medical care due to losses of income or increasing debt. There is a large literature debating variously why crude mortality rates often decline during recessionary periods, and recent advances in this area are presented below. However, from the perspective of public health agencies there appear to be vulnerable populations that are often “hidden” from public health surveillance.4 For example, while average drinking rates have typically declined during the recession (presumably as most people can afford less alcohol), a subpopulation has increased binging; this population appears to disproportionately include those at risk for unemployment.5 Hence, crude mortality rate declines may mask hidden public health problems. There is also some limited evidence that changes in housing tenure (e.g., foreclosures) and savings affect health during fiscal crisis. Knowing the effects of recessions on health, it should be possible to target interventions toward the most vulnerable, but discussion of what should be done in practice is nearly absent from the public health literature. A second pathway through which recessions may affect health outcomes is their effect, and that of fiscal austerity measures, on healthcare delivery systems and social safety nets. Many newly-unemployed people entered into public health insurance programs such as Medicaid (US government health insurance program for families and individuals with low income) at precisely the moment when government programs received less funding, due in large part to declines in income and associated tax-based revenues.6 Hence, healthcare programs had to decide what programs to continue funding as their revenue streams evaporated. Major insurance companies also made changes to their policies on deductibles, lowering the probability that even individuals with coverage would seek timely care.7,8 Depending on how healthcare delivery changes, amenable mortality—deaths that are avoidable with timely and effective healthcare—might be amplified or averted. Other types of safety net interventions also affected health by, for example, preventing or protecting the newly-impoverished from loss of nutritional support (“food stamp” Supplemental Nutrition Assistance Program) or becoming homeless (housing assistance programs), which itself modifies disease risk.

#### 3. Noerr is key to protect SEPs suing for injunctive relief---that incentives innovators and drives long-term economic growth.

Maureen K. Ohlhausen 15. Commissioner at the time of the U.S. Federal Trade Commission. “Antitrust Oversight of Standard-Essential Patents: The Role of Injunctions” Federal Trade Commission. 2015 IP and Antitrust Forum China Intellectual Property Law Association Beijing, China. 9-12-2015. https://www.ftc.gov/system/files/documents/public\_statements/800951/150912antitrustoversight-1.pdf

Finally, U.S. law requires more than a request for an injunction for liability to attach. Suing for injunctive relief is government petitioning that enjoys Noerr-Pennington immunity.34 For an antitrust claim to lie, there must be conduct beyond simply suing that is anticompetitive. For instance, deceptive conduct before a private standard-setting organization can suffice.35 But if there is no allegation that a SEP owner engaged in deception or other misconduct before the standard-setting body, Noerr presumably applies.36

3. Agencies can identify hold-up when it occurs

There are therefore many circumstances in which a SEP owner cannot harm competition, and hence cannot violate antitrust law, in seeking to enjoin a willing licensee. More importantly, there are cases in which denying a SEP holder injunctive relief will harm dynamic efficiency and dissuade participation in the standard-setting process. To date, agency action has not sufficiently addressed these complications.

Ultimately, the antitrust case against efforts to enjoin a willing licensee using a RANDencumbered SEP may be strong or weak, depending on the specific facts of the situation at hand. Why deny ourselves the flexibility to scrutinize each case on its own merits? That a standard implementer adopts the mantle of a “willing licensee” should not be a trump card that excludes the possibility of hold-out or other circumstances justifying injunctive relief.37

All told, even if a requested injunction violates a RAND-licensing guarantee, it is not always an antitrust problem. Rather, these issues sound in contract law, as litigants and courts have recognized.38 I submit that antitrust agencies should focus on conduct that actually harms the competitive process, as when a patentee’s deception before an SSO causes the adoption of proprietary technology over a substitute technology, followed by hold-up. Injunctions in violation of contractual promises, however, are generally matters to be resolved using conventional breach-of-contract principles.

IV. Conclusion

In conclusion, I hope you will agree that the issues surrounding injunctions in the standard-setting arena are more complex than is often supposed. Today’s common wisdom is that a SEP owner who has promised to license on RAND terms should never try to enjoin a potentially willing licensee. That position is understandable and intuitive. After all, a patentee can potentially use an injunction to extract royalties exceeding its technical contribution to a standard. Yet, despite good intentions, a strict no-injunction rule omits critical nuances. Above all, depriving SEP holders of injunctive relief against arguably willing licensees may undercompensate those who invent the most valuable technologies. That is a serious problem. The no-injunction rule would still be defensible if the administrative costs of distinguishing proand anti-competitive conduct were high, but competition agencies are eminently capable of investigating each case on its facts to weigh allegations of hold-up and the potential for hold-out. Overbroad rules inevitably result in false positives, which we should not countenance here.

This all leads me to my most important point: diluting property rights harms innovation. Technological progress is a critical driver of long-term economic growth. If domestic innovation is to flourish, then the law must instill appropriate incentives. Domestic firms will not invest large capital sums in R&D if they cannot protect their technological insights from appropriation. That principle is straightforward, but it is the foundation of patent systems around the world that have overseen unprecedented technological advance. As economies become increasingly knowledge-based, optimal innovation policy must evolve in turn. Speaking briefly about our host country, China enjoys near-limitless potential, in my estimation. The land that brought the four great inventions of paper, gunpowder, the compass, and printing can surely be a cradle of future innovation—not least given its vast economic power, rich history, and unyielding desire to improve. I submit that strong patent rights would play a key role in realizing that potential.

#### 4. That independently kills the economy and decks solvency.

Jonathan B. Baker 15. Professor of Law, American University Washington College of Law. “TAKING THE ERROR OUT OF “ERROR COST” ANALYSIS: WHAT’S WRONG WITH ANTITRUST’S RIGHT.” 80 Antitrust Law Journal No. 1 (2015). https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2333736

The error cost perspective evaluates antitrust rules—whether considered individually or as a whole—based on whether they minimize total social costs. The relevant costs include costs of “false positives” (**finding violations when the conduct did not harm competition**), costs of “false negatives” (not finding violations when the conduct harmed competition), and **transaction costs** associated with use of legal process.17 **False positives** and false negatives are harmful **to the economy as a whole** for reasons that go beyond the conduct in the case under review:18

**[FOOTNOTE 18 BEGINS]** From an economic perspective, antitrust rules benefit society primarily by deterring harmful conduct. See generally Jonathan B. Baker, The Case for Antitrust Enforcement, J. ECON. PERSP., Autumn 2003, at 27; cf. Louis Kaplow, Burden of Proof, 121 YALE L.J. 738 (2012) (highlighting a tradeoff between the benefits of deterrence and costs of chilling beneficial conduct that arises when the burden of proof in adjudication is set to maximize social welfare). Accordingly, the evaluation of **error costs** must look to the consequences of the decision or legal rule for conduct by other firms, not simply to the incidence of the decision on the parties to the case. For example, restricting analysis to the parties before the court would yield the misimpression that draconian punishments for parking in front of a fire hydrant will eliminate error costs. The prospect of such punishments would lead to 100% compliance with the no-parking rule, so there would be no court cases, no possibility for a court erroneously to convict or acquit a defendant, and no litigation expenditures. Yet such punishments would also chill parking in front of a hydrant when its social benefits (**e.g., allowing a doctor to arrive in time to save a life**) would outweigh its social costs. Such punishments would also discourage socially beneficial parking near hydrants (by drivers who fear that an aggressive parking enforcer would wrongly conclude that the hydrant is blocked and that a court would uphold the ticket). Restricting analysis to the parties before the court would yield the same misimpression with respect to an enforcement policy taken to the opposite extreme: A complete absence of enforcement of the rule prohibiting parking in front of hydrants would also lead to no court cases, and so would generate no judicial errors and no transaction costs of litigation. Yet such a rule would not deter parking in front of hydrants when the social cost (**the cost of impeding fire department access in the event of a fire discounted by the probability that a need for access would arise**) would exceed the social benefit. **[FOOTNOTE 19 ENDS]**

**False positives** and **false negatives** may **chill** beneficial conduct by other economic actors (potentially in other industries) that must comply with the rule; these errors may also fail to deter harmful conduct by other economic actors to which the same rule would apply. False positives and false negatives do not neatly map to overdeterrence and underdeterrence, respectively, however, because the deterrence consequences of **legal errors** depend in part on the way that those errors affect the marginal costs and benefits of conduct undertaken in the shadow of the law19.

**[FOOTNOTE 19 BEGINS]** See generally Warren F. Schwartz, Legal Error, in 1 ENCYCLOPEDIA OF LAW AND ECONOMICS 1029 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000). For example, a rule change that increases the frequency or cost (penalty) of **false positives** may increase deterrence, but it **could also do the reverse**. The latter may occur if more false positives mean that firms no longer obtain enough benefit from staying within the line separating legal and illegal behavior to justify being careful. For this reason, uncertainty about a rule or its application can **reduce compliance**. See generally Hendrik Lando, Does Wrongful Conviction Lower Deterrence?, 35 J. LEGAL STUD. 327, 329–30 (2006) (providing a simple technical example); Richard A. Posner, An Economic Approach to the Law of Evidence, 51 STAN. L. REV. 1477, 1483–84 (1999) (greater accuracy in judicial determinations increases the returns to compliance with legal rules); Steven C. Salop, Merger Settlements and Enforcement Policy for Optimal Deterrence and Maximum Welfare, 81 FORDHAM L. REV. 2647, 2668–69 & 2669 n.60 (2013) (a firm’s incentive to comply with a rule may fall **identically** when the probability of either type of error increases). **[FOOTNOTE 19 ENDS]**

#### Limiting the sham exception swallows Noerr---causes chilling and overdeterrence.

Daryl Joseffer et al. 21. Daryl Joseffer and Stephanie A. Maloney, U.S. Chamber Litigation Center. Ilana H. Eisenstein, Counsel of Record. Adam Pierson, Justin R. Sarno, Rachel A.H. Horton, Danielle T. Morrison, DLA Piper LLP (US). Counsel for Amicus Curiae. “Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioners”. https://www.supremecourt.gov/DocketPDF/20/20-1293/176027/20210419132645500\_Chamber%20of%20Commerce%20of%20the%20United%20States%20of%20America%20Amicus%20Curiae%20Brief.pdf

The Third Circuit’s incorrect analysis of the NoerrPennington doctrine will have a chilling effect far beyond the patent litigation context of this case. In addition to affecting other industry sectors, the Third Circuit’s decision risks curtailing businesses’ exercise of their First Amendment right to seek redress from all three branches of government, by chilling public statements aimed at inducing governmental action and changing prevailing legal standards. Moreover, the Third Circuit’s decision deepens the wide-spread confusion among courts and the public over the scope of the doctrine.

ARGUMENT

A. This Court’s Intervention Is Needed To Ensure That The “Sham” Exception Does Not Swallow Noerr-Pennington Immunity.

The Third Circuit’s opinion waters down important limits on the “sham” litigation exception to the NoerrPennington doctrine. Litigants, including members of the Chamber, will be deterred from filing suit to vindicate their rights, for fear that courts may declare their lawsuits a “sham”—even where, as here, a trial produced no evidence of subjective unlawful intent.

#### Their stricter test chills innovation.

J. Mark Gidley et al. 21. Eric Grannon, J. Frank Hogue, Alyson Cox Yates, White & Case LLP. “Brief of Amici Curiae Law Professors in Support of Petition for a Writ of Certiorari.” https://www.supremecourt.gov/DocketPDF/20/20-1293/176016/20210419113917235\_2021-04-19%20AbbVie%20v.%20FTC%20No.%2020-1293%20Law%20Professors%20Amicus%20Brief.pdf

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.

#### 2. Their standard has no brightline AND is determined post-fact---causes chilling. This comes from the same article as the 2AC card!

J. Mark Gidley et al. 21. Eric Grannon, J. Frank Hogue, Alyson Cox Yates, White & Case LLP. “Brief of Amici Curiae Law Professors in Support of Petition for a Writ of Certiorari.” https://www.supremecourt.gov/DocketPDF/20/20-1293/176016/20210419113917235\_2021-04-19%20AbbVie%20v.%20FTC%20No.%2020-1293%20Law%20Professors%20Amicus%20Brief.pdf

Beyond Hatch-Waxman litigation, the Third Circuit’s decision will negatively affect patent litigation and settlement agreements more generally. This Court’s requirement of subjective bad faith is a crucial safeguard in the context of ubiquitous patent validity issues raised in all patent lawsuits, as these legal standards are complex and constantly changing. See Asahi Glass, 289 F. Supp. 2d at 993 (“No one can be certain that he will prevail in a patent suit.”); Ted L. Field, “Judicial Hyperactivity” in the Federal Circuit: An Empirical Study, 46 U.S.F. L. Rev. 721, 722-23, 776 (2012) (concluding that “the overall reversal rate of the Federal Circuit—both unadjusted and adjusted for summary affirmances—was statistically significantly greater than the overall reversal rate of the representative regional circuits taken as an aggregate,” and “the Federal Circuit is more judicially hyperactive in patent cases than in non-patent cases”); Ted Sichelman, Myths of (Un)Certainty at the Federal Circuit, 43 Loy. L.A. L. Rev. 1161, 1164-71 (2010) (outlining categories of uncertainty in the patent system and the resulting high claim-construction reversal rates); David L. Schwartz, Pre-Markman Reversal Rates, 43 Loy. L.A. L. Rev. 1073, 1075 (2010) (providing that “[t]he Federal Circuit’s reversal rate . . . has hovered between 20 and 45 percent”). Indeed, the fact that the Third Circuit in this case reversed the district court in part, finding that AbbVie’s infringement suit against Teva was not objectively baseless, demonstrates that reasonable minds may differ on the merits of Hatch-Waxman cases. See AbbVie, 976 F.3d at 351. Because patent litigation is—to some extent— unpredictable, innovators must be able to bring a good-faith patent suit without the risk of treble damages if a court later, with the benefit of hindsight, finds their suit to be meritless.

Moreover, the particularly complex and fact-intensive nature of this case—in which the innovators claimed patent infringement based on the doctrine of equivalents, the generic company argued that prosecution-history estoppel applied, and the innovators contended that the “tangentiality” exception to prosecution-history estoppel applied—makes it even more difficult to determine whether a litigant would have reasonably expected to succeed on the merits. The Third Circuit’s inference of subjective bad faith is especially inappropriate under these circumstances, where the law is highly technical, case-specific, and constantly evolving.

In short, this Court should reverse the Third Circuit’s new and unfounded approach to the subjectivemotivation prong of the sham-litigation test, which will discourage patent owners from exercising their property rights in the face of potential treble damages and thus discourage innovation.

#### 3. They’re also wrong about squo petitioning---COVID means it’s happening now, and the alternative is mis-regulation.

William H. Rooney, Timothy G. Fleming and Michelle A. Polizzano 20. Willkie Farr & Gallagher LLP. “Antitrust Guidance for Collectively Seeking COVID Relief from Governmental Bodies.” May 6, 2020. https://www.willkie.com/-/media/files/publications/2020/05/antitrustguidanceforcollectivelyseekingcovidrelief.pdf

Conclusion

The economic hardship resulting from the COVID shutdown will overwhelm many industries, providing good reason for competitors collectively to seek urgent and creative forms of relief from governmental bodies and offices. In other cases, the government itself may propose economic relief that burdens some companies in favor of others and that would benefit from industry engagement with governmental bodies.

Although the Noerr-Pennington doctrine protects petitioning activity, it does not protect commercial activity. Careful planning can secure Noerr protection and reduce related antitrust risk.

#### 4. Companies must petition now---Noerr is key.

William H. Rooney, Timothy G. Fleming and Michelle A. Polizzano 20. Willkie Farr & Gallagher LLP. “Antitrust Guidance for Collectively Seeking COVID Relief from Governmental Bodies.” May 6, 2020. https://www.willkie.com/-/media/files/publications/2020/05/antitrustguidanceforcollectivelyseekingcovidrelief.pdf

The COVID-19 shutdown has caused widespread economic hardship from which business sectors are seeking governmental relief. That effort entails collective activity by competitors in formulating and advocating proposals to governmental bodies or governors’ offices (“petitioning activity”).

The requested relief may take many forms beyond governmental funding. For example, companies may petition for statutes or executive orders that mandate standard industry practices as businesses resume or require the formation of joint facilities that reduce the costs of addressing losses that the shutdown has caused.

In other cases, the federal or state government may propose economic relief that imposes obligations on some private companies, such as insurance companies, to reduce the losses of other companies. Affected businesses, often as a group, may respond by engaging with the governmental bodies to comment on the proposals or offer alternatives.

Once a dialogue among actual or potential competitors begins, obvious antitrust issues arise. This bulletin briefly addresses the scope of the Noerr-Pennington doctrine that protects petitioning activity and the risks that often accompany relying on the doctrine.

#### 2. The plan body blows innovation, sowing mass uncertainty in patents.

Seth Paul Waxman 20. American lawyer who served as the 41st Solicitor General of the United States from 1997 to 2001. Petition to the Supreme Court of the United States, “Abbvie Inc. v. F.T.C.,” https://www.docketalarm.com/cases/Supreme\_Court/20-1293/AbbVie\_Inc.\_et\_al.\_Petitioners\_v.\_Federal\_Trade\_Commission/03-18-2021-Petition\_for\_a\_writ\_of\_certiorari\_filed/0316180937477-Petition

A. This Court has “carved out only a narrow exception for ‘sham’ litigation” to “avoid chilling the exercise of the First Amendment right to petition.” Octane Fitness, 572 U.S. at 556; see BE&K, 536 U.S. at 528. A rigorous subjective element is critical to cabining that narrow exception and to protecting the First Amendment rights embodied in the Noerr-Pennington doctrine. Indeed, this Court has “never held that the entire class of objectively baseless litigation may be enjoined or declared unlawful even though such suits may advance no First Amendment interests of their own,” but instead has required an independent showing of bad faith to ensure the necessary “‘breathing space,’” consistent with broader First Amendment principles. BE&K, 536 U.S. at 531.

The decision below, however, deprives the subjective element of an independent role in the sham inquiry, allowing it to be satisfied by a commonplace intent to thwart competition inferred from a finding of objective baselessness. As a result, litigants exercising their First Amendment right to assert claims with uncertain prospects of success will do so at their peril.

That chilling effect will reach beyond litigation. As this Court has explained, the same sham exception “governs the approach of citizens or groups of them to administrative agencies” as to courts. California Motor Transp., 404 U.S. at 510. Thus, courts have applied PRE’s sham exception to citizen petitions submitted to the FDA to oppose entry of generic products, see Tyco, 762 F.3d at 1347 (citing cases), and to petitioning conduct before state or local agencies, see Kottle v. Northwest Kidney Centers, 146 F.3d 1056, 1059, 1062 (9th Cir. 1998); CSMN Investments, LLC v. Cordillera Metropolitan District, 956 F.3d 1276, 1282 n.8, 1286 n.13 (10th Cir. 2020); see also PRE, 508 U.S. at 59 (discussing sham exception “[w]hether applying Noerr as an antitrust doctrine or invoking it in other contexts”). The decision below thus jeopardizes a broad range of First Amendment petitioning activity.

B. The chilling effect will be especially pernicious in patent cases—and, in particular, in the important context of Hatch-Waxman litigation, thwarting Congress’s purposes in enacting that statute.

Congress designed the Hatch-Waxman Act to balance patent rights against the benefits of increased competition in the market for medicines. At the same time that it allowed generic manufacturers to take advantage of brand manufacturers’ research and development through streamlined approval pathways, Congress also incentivized “increased expenditures for research and development” by lengthening patent protection to compensate for time lost on patent life to the FDA approval process. H.R. Rep. No. 98-857, pt. 1, at 15 (1984). In addition, Congress sought to ensure that patent disputes could be resolved early—before the generic product goes to market—by providing for the statutory stay of FDA approval to reward patent owners that file infringement suits promptly. See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 407-408 (2012). Yet the court of appeals treated the fact that AbbVie followed and benefited from that congressional design as “[e]specially” supportive of an inference of bad faith. App. 70a. Indeed, the court went so far as to disparage the congressional design as giving rise to “a collateral injury” that a patent owner’s “mere use of legal process invariably inflicts” as “an anticompetitive weapon.” App. 50a; see App. 70a.

That is a perverse outcome—one that will affect nearly every litigant filing an infringement suit under the Hatch-Waxman Act. All litigants that promptly file infringement suits under the Hatch-Waxman Act benefit from the automatic stay, as Congress intended, and they invariably do so on the advice of experienced lawyers with the aim of securing a financial benefit by preventing or delaying competition from a potentially infringing product. Imputing bad faith to litigants’ mere participation in that statutory scheme is particularly unfair and destructive to incentives to innovate because a patentee is presumed to assert a “duly granted patent … in good faith.” C.R. Bard, 157 F.3d at 1369 (citing Virtue v. Creamery Package Mfg. Co., 227 U.S. 8, 37-38 (1913)). The court of appeals’ decision penalizes a patentee that enforces its patent against a potentially infringing competitor despite that presumption, even though such a suit may be entirely compatible with a “genuine[]” invocation of the Hatch-Waxman Act’s protections. Omni, 499 U.S. at 382.

That expansion of the sham exception would have significant practical impact. Ten percent of all patent-infringement suits filed in the United States are triggered by paragraph IV certifications under the HatchWaxman Act, and the number of such suits has been increasing. Brachmann, Hatch-Waxman Litigation: 60 Percent Increase in ANDA Lawsuits from 2016 to 2017, IPWatchdog (May 16, 2018). The court of appeals’ decision will deter patentees from availing themselves of their Hatch-Waxman remedy—and enforcing their patent rights more generally—for fear that they might be subject to antitrust liability and treble damages if the suit is subsequently adjudicated to be objectively baseless notwithstanding their subjective expectation of success. And, of course, where patent-holders face uncertainty about their ability to enforce their patent rights in court, their incentive to innovate in the first place is correspondingly diminished.

It is no answer to suggest that the requirement of objective baselessness adequately protects against an undue chilling effect. As explained above, objective baselessness is only one half of the sham-litigation test—and that is so for important reasons. Supra pp. 7- 9, 18-19. In addition, reasonable jurists can, and do, make errors in assessing objective baselessness or disagree about what constitutes such baselessness. That problem is highlighted by this very case: the district court ruled that AbbVie’s patent-infringement suit against Teva was objectively baseless, but the court of appeals reached the opposite conclusion (even while agreeing that the similar suit against Perrigo was objectively baseless).

That is not surprising, given that patent law is notoriously technical and subject to change. See Teva Pharm. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 327 (2015); see also, e.g., KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 419 (2007) (invalidating Federal Circuit’s test for obviousness); Festo, 535 U.S. at 737-738 (rejecting Federal Circuit’s “per se rule” for prosecution-history estoppel); cf. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1335-1373 (Fed. Cir. 2019) (per curiam) (eight opinions concurring in or dissenting from denial of rehearing, articulating different standards for subject-matter eligibility). Especially where, as here, the objective baselessness inquiry turns on issues of patent law, rather than disputed issues of underlying fact, it is dangerous to subject a patent litigant to antitrust liability based only on a decisionmaker’s later determination that the litigant got the law wrong—without any consideration of that litigant’s actual expectations in bringing suit.

#### 3. Anything less than absolute protection causes massive chilling.

Adam **Kreuzer 85**. Spring 1985. UIC Law Review. More Speech, Less Litigation: Extending the Noerr-Pennington Doctrine to the Law of Defamation, 18 J. Marshall L. Rev. 683. https://repository.law.uic.edu/cgi/viewcontent.cgi?article=2201&context=lawreview

In our increasingly litigious society, individuals and corporations frequently file defamation suits in response to statements concerning their persons.' The effect of this tendency to sue operates to **chill the first amendment right** of citizens to **petition the government** for a redress of grievances. 2 Because the cost and inconvenience of defending a defamation suit is overwhelming,3

**---FOOTNOTE 3 STARTS, MID-PARAGRAPH---**

3. Fees for defending a defamation suit were as high as $74,000 in 1980. Smith, The Rising Tide of Libel Litigation.: Implications of the Gertz Negligence Rule, 44 MoNT. L. REv. 71, 87 (1983) (fees required for defending libel litigation can be astronomical). Even the dissent in Webb recognized the **chilling effect** of defending a defamation lawsuit. Justice Neely stated that while the plaintiff could spend unlimited amounts on excellent legal advice, the defendants were hard pressed to hire counsel at all. "The potential for **chilling legitimate first amendment rights** where there is **anything less than absolute immunity** is awe inspiring." Webb v. Fury, 282 S.E.2d 28, 46 (W. Va. 1981) (Neely, J., dissenting).

**---FOOTNOTE 3 ENDS, PARAGRAPH CONTINUES---**

many citizens are **deterred** from lodging **good faith petitions** at the town meeting,4 to their congressional representatives, 5 and to the President of the United States.6 This conduct ultimately cripples the ability of a representative government to govern **democratically**.7

Due to the apparent inadequacies of the current laws of defamation, some courts have turned to the **Noerr**-Pennington doctrine to preserve the petitioning process.8 Although originally designed to safeguard a person's freedom to exercise his right to petition from the **fear of** an **antitrust** sanction,9 the doctrine now applies in **other areas of the law**. Courts have used the doctrine to protect the petitioning process from a wide range of civil sanctions10 which might otherwise **inhibit a person's freedom to petition** the government for a redress of grievances." The doctrine's application to the law of defamation, however, remains uncertain.

The purpose of this comment is to question the ability of the law of defamation to safeguard a person's access to the petitioning process. This comment advocates the **extension of** the **Noerr**-Pennington doctrine to the law of defamation. Like Noerr-Pennington in antitrust law, Noerr-Pennington in the law of defamation will act to **safeguard the constitutional right to petition**, and will consequently further protect our system of **representative government**.12

**---FOOTNOTE 12 STARTS, MID-PARAGRAPH---**

12. See generally Sherrard, 53 Md. App. at 553, 456 A.2d at 59 (the right to petition is a necessary element of our representative democracy). The first amendment right to petition is not a right which our forefathers always expected to be used in a wise or useful manner, but the forefathers knew of no other way by which free men could conduct a democracy. See Thomas v. Collins, 323 U.S. 516, 545 (1944) (Jackson, J., concurring).

The United States Supreme Court has stated that the right to petition would be but a hollow promise if allowed to be **eroded by indirect restraint**. United Mine Workers of Am. v. Illinois St. Bar Ass'n, 389 U.S. 217, 222 (1967). The right to petition is a right which **should not be lightly subjected to restraint**. Schneider v. imith, 390 U.S. 17, 25 (1968). Where exposed to the **air of autocracy**, the right to petition, despite its theoretical strength as a component of a democratic government, demonstrates **remarkable fragility**. Stern v. United States Gympsum, Inc., 547 F.2d 1329, 1346 (7th Cir. 1977), cert. denied, 434 U.S. 975 (1978).

**---FOOTNOTE 12 ENDS, PARAGRAPH CONTINUES---**

Whether the restriction takes the form of an **antitrust** suit or a defamation suit, the restraint on the right to petition remains the same. 13

**---FOOTNOTE 13 STARTS, END OF PARAGRAPH---**

13. Cf. Sherrard, 53 Md. App. at 569, 456 A.2d at 67 (economic harm caused by antitrust is as **devastating** as damage to one's reputation by defamation, thus, extension is a logical one).

**---FOOTNOTE 13 ENDS, NEXT PARAGRAPH---**

The first segment of this comment reviews the United States Supreme Court's development of the Noerr-Pennington doctrine and its association to the first amendment right to petition. 14 The second segment analyzes the current law of defamation. It concentrates on the New York Times standard of malice and explains why this standard is insufficient to adequately safeguard a person's freedom to exercise his right to petition.15 Third, this comment discusses the common law absolute privilege afforded legislative and judicial proceedings,' 6 and the problem of statements published outside the governmental arena. 17 This privilege parallels the evolution of the Noerr-Pennington doctrine; yet, each of the concepts have individual and distinct scopes which require discussion. The final segment sets forth a proposal designed to ensure that the right to petition remains uninhibited through the extension of the Noerr-Pennington doctrine to the law of defamation. 18 This extension will provide society with the benefits of a collective conscience by **guaranteeing the free exchange of ideas**,19 thus leading to a **healthy and knowledgeable democratic government**.

#### 4. Fear still chills petitioning---protection must be absolute.

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It can also be argued in favor of the fraud exception that the **truthful petitioner will not ultimately suffer liability** for his actions. Given the **track record** of verdicts in the Bendectin and breast implant litigation, one **cannot blame industry for not being sanguine** that truth will always be a successful defense. Moreover, unlike the current system where **immunity for** genuine **petitions is absolute** and comes at the pleading 281 stage, immunity that **depends on disproving the facts of fraud** could take years of costly litigation to even apply. A rational corporation or individual, particularly a moderate one without a financial stake in the politics at issue, could well decide that lobbying is simply **not worth the risk**. Alternatively, in situations where an entity's circumstances require petitions on an issue that is likely to be controversial, it might hedge the manner in which it communicates with the government, making its **speech less effective**. Either way, **political speech is chilled**. Still, some may argue that petitions by the defense are categorically less worthy than the arguments put forth by their plaintiff counterparts. 282 While this proposition may be emotionally appealing to many, its premise-that a constitutional right as fundamental as petitioning one's government may properly be made to depend on negative stereotypesharkens back to shameful times in American history and would hopefully be accepted by few. Some petitions are more fashionable than others, but history bears out that **popularity is not necessarily a proxy for justice**. 28 3 So while it is certainly the case that some petitions are both scientifically wrong and morally loathsome,284 the solution dictated by the First Amendment is **not to prohibit or deter such speech, but rather to counter it with truth**.285

#### 5. Exemptions chill petitioning.

James M. Sabovich 08. Senior associate in Gibson, Dunn & Crutcher, LLP's Environmental and Natural Resources Practice Group. J.D. from UCLA in 2001. "Petition without Prejudice: Against the Fraud Exception to Noerr-Pennington Immunity from the Toxic Tort Perspective." Penn State Environmental Law Review 17, no. 1 (Fall 2008): 1-54

By prohibiting laws "abridging the right of the people ... to petition the government for redress of grievances," the petition clause of the First Amendment of the United States Constitution gives safe harbor to all genuine efforts to influence government decisions.' Those words forbid the government from outlawing or punishing its citizens' petitions, so while the government may reject a petitioner's argument, it may never sanction him for making it. Under the Noerr-Pennington doctrine,2 the petition clause also forecloses private parties from invoking the government's coercive power to do the same through the tort system. The Noerr-Pennington doctrine accomplishes this by stating generally that one cannot be held civilly liable for genuine attempts to influence government action. Similar protections are also afforded in most states by statutory or case law privileges against liability for statements made in official proceedings.3

History teaches that protection of First Amendment freedoms requires considerable vigilance, especially against restrictions aimed at conforming speech to popular belief or prejudice. The petition clause, after all, only narrowly survived restrictions aimed at limiting politically unpopular abolitionist lobbying, which was argued to have been illegal.4 Today, a movement is afoot to create a sweeping "fraud exception" to petition immunity, thereby revoking it in the common circumstance where opposing viewpoints attribute deceit to each other.

The need for vigilance in the protection of the right to petition is demonstrated in the area of toxic torts.5 Born of Vietnam's Agent Orange 6 and the pharmaceutical cases of the 1960s and 1970s, the modem toxic tort is often typified by powerful political interests on both sides, billion-dollar stakes, entrepreneurial sophistication and broad social implications, all to a degree beyond that found in typical personal injury lawsuits.7 The toxic tort's core allegation is that some misconduct by a defendant caused a plaintiff to be exposed to a substance, which then brought on some ailment.8 In environmental toxic torts, this is often coupled with claims that the defendant knew it was contaminating the air or the groundwater, but misrepresented that information to regulators. 9 I refer to the subject of such allegations as "site-specific lobbying." In the case of more general lobbying, a plaintiff alleges that a defendant downplayed the danger of its substance to regulators. To separate this general lobbying from its more limited counterpart, I call the subject of such allegations "legislative lobbying."

Both types of allegations seek to impose tort liability for political speech, that is, behavior aimed at affecting government decisions; thus, they conflict with Noerr-Pennington. The name of the clash is the "fraud exception" to Noerr-Pennington, which states that in certain circumstances the petition alleged to be deceptive does not deserve protection. 0 If narrowly interpreted, most lobbying activity will remain protected against civil liability; if broadly interpreted, the exception threatens to swallow the bulk of petition immunity for environmental lobbying. After examining the cases that have fashioned the fraud exception, this article argues that there should be no such exception or that it should be narrowly drawn. This is because tying immunity to an opponent's view of the petitioner's veracity will only chill political speech. Instead, as is currently the prevailing view, communications genuinely meant to influence government action should be immune from tort liability without regard to allegations of fraud in the information communicated.

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