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**Innovation**

**Sham litigation is at a decade-long high – specifically, the tech industry is at risk**

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For nearly half a decade, patent troll suits have been on the decline. Indeed, as we reported last year, the Supreme Court has gone out of its way to curb the worst patent troll abuses in order to protect innovators and call the viability of many patent troll litigations into question. This started in 2014, with the seminal Alice v. CLS Bank (Alice) decision that questioned the patent eligibility of certain software and business methods. Then in 2018, the Supreme Court took aim at forum shopping by patent plaintiffs in TC Heartland v. Kraft Foods (TC Heartland). These two cases led to an overall decline in patent troll lawsuits over a period of years. However, **developments** from the Federal Circuit in 2019 **introduced** some **uncertainty into** the **patent landscape**, providing an opportunity for patent trolls to bring and maintain their litigations. For example, In Cellspin Soft v. Garmin USA (Cellspin), Garmin won its motion to dismiss the case on the ground that Cellspin Soft’s patent for uploading data from a device, such as a GPS tracker, was too abstract as a pure matter of law and, therefore, should be invalidated. However, the Federal Circuit court disagreed, holding that the patent eligibility analysis under Alice presented questions of fact. The case followed similar decisions from the court in Berkheimer v. HP and Aatrix Software v. Green Shades (Berkheimer), refusing to invalidate patents covering abstract ideas or intangible embodiments and showing a growing trend toward disallowing patent eligibility claims to be decided at the motion to dismiss or summary judgment stage. Despite hopes that the Supreme Court would provide additional guidance on Alice or TC Heartland, the Court has refused to take on cases addressing these issues. In January 2020, the Court denied the petitions for certiorari in Cellspin and Berkheimer, as well as several other patent eligibility cases, signaling that the Court is disinterested in providing additional clarity on these issues, or is hoping that Congress will address the issue through the legislative process. Draft bills introduced in Congress last year to codify and reform patent eligibility were also unsuccessful. In this environment of uncertainty, patent trolls have gained momentum in 2020, and the COVID-19 pandemic and resulting economic upheaval has done little to deter patent suits. In fact, **non-practicing entities have exploited the boom in Covid-related innovation**. In the first few months of the pandemic, **patent trolls targeted technology and healthcare companies** responding to the crisis, with the makers of tests and ventilators among those facing patent suits. Although public backlash led some patent plaintiffs to voluntarily drop their claims and offer royalty-free licenses for COVID-19-related uses, **the specter of patent litigation presents an ongoing concern** **for** companies involved in pandemic response efforts, and **innovators across all sectors**. Key Takeaways: The ability to quickly dismiss a patent troll lawsuit under Alice and TC Heartland has been curtailed, which may lead to increased costs in defending claims. COVID-19 has not slowed the tide of patent troll suits, which have continued to be filed at a steady pace. Companies should establish a comprehensive strategy to manage patent risk, including filing for and enforcing patents, identifying and clearing patent risks, instituting contractual strategies for risk-shifting, and defending allegations of patent infringement.

**But, Circuit Court splits render the success of retaliation under Noerr-Pennington uncertain, making Supreme court action necessary**

**Carson and Russell 21.** Dylan Carson and Scott Russell. February 2021. Dylan Carson is a Partner at Faegre Drinker Biddle & Reath LLP. From 2015–2020, Mr. Carson served as Trial Attorney in the Media, Entertainment, and Communications Section of the Antitrust Division of the U.S. Department of Justice. Scott Russell is an antitrust attorney who has practiced in Washington, DC and California over the past 20 years. “Circuits Reinforce Split over When Noerr-Pennington Shields Serial Litigants” <https://www.americanbar.org/content/dam/aba/publishing/antitrust_source/2021/feb-2021/atsource-feb2021-carson.pdf>

Although the Supreme Court expressly carved out a sham exception to Noerr-Pennington immunity, lower courts disagree over the applicable standard when multiple lawsuits are challenged as sham petitioning. In 2020, two cases solidified a 5-2 circuit split on this issue, but no cert petition was filed in either case. The majority of circuits—the Second, Third, Fourth, Ninth, and Tenth—have held that a different analysis applies when the legality of a pattern of lawsuits or petitions is challenged than when just a single petition is at issue. When multiple lawsuits are implicated, these courts have held antitrust immunity may be lost under the sham exception if the series of petitions demonstrates a pattern of filings made solely to inflict harm through burdensome process, without consideration of the merits or interest in the requested relief. As a result, the majority of circuits have held that the overall pattern of filings can qualify as a sham––therefore subject to antitrust scrutiny and damages––even if a small percentage of the petitions were objectively reasonable or ultimately proved successful. In contrast, two circuits—the First and Seventh––have held that a separate standard for immunity does not apply when scrutinizing a pattern of sham petitioning. In those circuits, every petition is subject to the same two-step test: (1) whether it was objectively baseless (i.e., had no reasonable chance of success) and if so, (2) whether the subjective intent of the petitioning was to harm a rival. Under this standard, only objectively baseless petitions can give rise to potential antitrust liability, and Noerr-Pennington shields a pattern of petitions which had merit, were successful, or at least were objectively reasonable. **As a result**, **an antitrust defendant** **who succeeds in barring entry** of a competitor or raising its rival’s costs **through** a long series of **unsuccessful lawsuits** or administrative petitions **may be immunized** from liability so long as each unsuccessful petition had a reasonable chance of success (even if achieving that success was not the purpose of the petitioning). With the split now covering more than half of the federal circuits, the issue of when the NoerrPennington doctrine shields litigants who file a series of lawsuits or regulatory petitions is ripe for Supreme Court resolution. In 2018, the Supreme Court declined to grant certiorari to review the First Circuit’s decision on the issue, and in 2020, the unsuccessful plaintiff declined to appeal the Seventh Circuit’s decision on the issue. **Until Supreme Court review occurs**, **antitrust practitioners** tussling with potential sham litigation claims—which frequently arise in pharmaceuticals, health care, telecommunications, and other patent-intensive sectors—**lack the certainty** **needed to advise historically litigious clients** **of the antitrust risk associated with filing additional lawsuits against rivals**. From the perspective of antitrust practitioners (and their clients) with a vested interest in the predictability of outcomes, this is unfortunate since “federal [antitrust] law, in its area of competence, is assumed to be nationally uniform, whether or not it is in fact.”7

**Baseless suits are set to increase without the plan**

Nicholas **Caspers 21**. 3-29-21. Associate Editor on the Michigan Technology Law Review . “Patent Trolls Show Immunity to Antitrust: Patent Trolls Unscathed by Antitrust Claims from Tech-Sector Companies” <https://mttlr.org/2021/03/patent-trolls-show-immunity-to-antitrust-patent-trolls-unscathed-by-antitrust-claims-from-tech-sector-companies/>

Patent trolls have become a prominent force to be reckoned with for tech-sector companies in the United States, and tech-sector companies’ recent failure in using antitrust law to combat patent trolls indicates a continuation of that prominence. **Patent trolls have been quite the thorn in the side of tech-sector companies**. The term “patent troll” is the pejorative pop culture title for the group of firms also known as non-practicing entities, patent assertion entities, and patent holding companies. These entities buy patents, not with the purpose of utilizing the patent’s technology, but with the purpose of suing companies for patent infringement. Patent trolls have made up around 85% of patent litigation against tech-sector companies in 2018. Moreover, in comparison to the first four months of 2018, **the first four months of 2020 saw a 30%** increase in patent litigation from patent trolls. At a high-level, antitrust law appears to be a proper tool for wrangling patent trolls. Antitrust law cracks down on anticompetitive agreements and monopolies for the sake of promoting consumer welfare. Patents are effectively legal monopolies over a claimed invention, and patent trolls use these legal monopolies to instigate frivolous patent infringement lawsuits on companies. Such lawsuits increase litigation and licensing costs for companies who can then push such costs, via increased product prices, onto the downstream consumer. In an attempt to go on the offensive, tech-sector companies have brought antitrust claims against patent trolls. The antitrust claims have operated on one of two theories. In Intellectual Ventures I LLC v. Capital One from 2017, Capital One counterclaimed antitrust remedies on the basis of a patent troll suing Capital One for patent infringement. More recently, Intel Corp. v. Fortress Investment Group LLC from 2021 entailed a motion to dismiss on Intel’s antitrust claims based on a patent troll’s accumulation of patents**. Both attempts have been thoroughly crushed in the district courts.** As indicated by Capital One, **the action by patent trolls of suing for patent infringement appears to be well-shielded by Noerr-Pennington immunity**. Noerr-Pennington immunity is immunity from antitrust claims for petitioning a government body. Suing a company for patent infringement is petitioning the judiciary and, therefore, falls under Noerr-Pennington immunity. However, lawsuits can be stripped of Noerr-Pennington immunity if the lawsuit constitutes sham litigation. Sham litigation entails litigation where no reasonable litigant could expect success on the merits and has the subjective intent to directly interfere with a competitor’s business relationships. **Capital One suggests that the most baseless lawsuits by patent trolls with the sole purpose of reaching a quick settlement are still unlikely to be sham litigation.** The opinion reiterated that the subjective prong requires the sued party to be a competitor, and patent trolls, who do not produce any products or services, are unlikely to be a competitor to sued companies who do produce products and services. As indicated by the dismissal of the antitrust claims at the pleading stage in Intel, an antitrust claim against the accumulation of patents by a patent troll has some inherent, potentially insurmountable, difficulties. Antitrust liability requires showing a relevant market followed by market power and a tendency towards anticompetitive effects or followed by direct evidence of anticompetitive effects. First, relevant markets for patents tend to be too broad, and broad relevant markets reduce the probability that a single entity wields enough market power to have an anticompetitive effect. With patent trolls, the relevant markets include the patent troll’s patents and any patents or technologies that are reasonably interchangeable with the patent troll’s patents. The set of reasonably interchangeable technologies is rather amorphous and large, given the multitude of ways in any area of technology to perform the same task and the total number of patents having surpassed ten million. Some of the relevant markets in Intel, such as “mobile device-to-device communication” and “device authorization,” were so broad as to make anticompetitive effects by the patent troll implausible. Second, even with a narrower market, a patent troll is unlikely to have market power. As suggested in Intel, the total set of patents and technology in the narrower market is likely far larger than the couple of patents being asserted by the patent troll. Third, evidence demonstrating that a patent troll creates anticompetitive effects is few and far between. Showing anticompetitive effects likely requires a combination of increased, supracompetitive prices and a drop in product output or quality. Showing that a patent troll creates a supracompetitive licensing price over a patent is difficult. As in Intel, the few licensing agreements for a patent troll’s patent are likely settlements from a patent troll’s previous assertions which are hidden by confidentiality. These recent decisions are only district court decisions. However, Capital One provides a strong, clear-cut view on Noerr-Pennington immunity for patent infringement suits by patent trolls, and Intel found that the antitrust claims against the accumulation of patents could not pass the low bar of plausibility in the pleading stage. With patent trolls’ exclusive existence in the instigation of patent infringement lawsuits and the accumulation of patents, **the recent decisions appear to significantly reduce the usefulness of antitrust law against the toll-taking patent trolls.**

**Innovation solves a litany of existential risks**

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Technological progress now offers us a vision of a remarkable future. The advances that have brought us onto an unsustainable pathway have also raised the quality of life dramatically for many, and have unlocked scientific directions that can lead us to a safer, cleaner, more sustainable world. With the right developments and applications of technology, in concert with advances in social, democratic, and distributional processes globally, progress can be made on all of the challenges discussed here. Advances in **renewable energy** and **related tech**nologies, and more **efficient energy use**—advances that are likely to be accelerated by progress in technologies such as **a**rtificial **i**ntelligence—can bring us to a point of **zero-carbon emissions**. New **manufacturing capabilities** provided by synthetic biology may provide cleaner ways of producing products and degrading waste. A greater scientific understanding of our natural world and the ecosystem services on which we rely will aid us in plotting a trajectory whereby **critical environmental systems are maintained** while allowing human flourishing. Even advances in education and women’s rights globally, which will play a role in achieving a stable global population, can be aided specifically by the information, coordination, and education tools that technology provides, and more generally by growing prosperity in the relevant parts of the world. There are **catastrophic** and **existential** risks that we will simply **not be able to overcome** **without advances in science and technology**. These include possible **pandemic outbreaks**, whether natural or engineered. The early **identification of incoming asteroids**, and approaches to shift their path, is a topic of active research at NASA and elsewhere. While currently there are no known techniques to prevent or mitigate a **supervolcanic** eruption, this may not be the case with the tools at our disposal a century from now. And in the longer run, a civilization that has **spread permanently beyond the earth**, enabled by advances in **spaceflight**, manufacturing, robotics, and terraforming, is one that is **much more likely to endure**. However, the breathtaking power of the tools we are developing is **not to be taken lightly**. We have been very lucky to muddle through the advent of nuclear weapons without a global catastrophe. And within this century, it is realistic to expect that we will be able to rewrite much of biology to our purposes, intervene deliberately and in a large-scale way in the workings of our global climate, and even develop agents with intelligence that is fundamentally alien to ours, and may vastly surpass our own in some or even most domains—a development that would have uniquely unpredictable consequences.

**Trolls devastate cloud computing and cause IT nightmare**

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Digital transformation is propelling business cloud-wards at prodigious rates: research company Gartner[1] forecasts (pre-COVID-19) that public cloud market will grow 17% in 2020, up from $228bn in 2019 to $266bn. At the same time scale economies are extending the cloud’s reach out from the data centre, connecting billions of intelligent IoT (Internet of Things) devices at the edge: by 2021, one million new IoT devices will be coming online every hour.[2] The concentration of computing resources into the expanding cloud is becoming increasingly attractive as a target for patent litigation to NPEs, non-practising entities that buy patents to sue others for infringement as their only revenue source. At a time when data security and privacy risks are front of mind for cloud service providers (‘CSPs’) and their customer, the **i**ntellectual **p**roperty risks to cloud service availability posed by NPE patent claims are attracting increasing attention. NPEs are well placed to monetise their patents at each stage of the litigation cycle. They have access to capital and all necessary forensic and legal resources; and an NPE doesn’t practise its patents so is immune to a defendant’s competitive counterclaim or cross-licence offer. Patent stats show consistently increasing NPE activity. Overall, NPE patent litigation increased 4% in 2019 over 2018, accounting for 58% of new cases in the US District Court.[3] **In the cloud sector, NPEs appear to have doubled down over the last five years**, acquiring more cloud patents for their armoury as well as filing more patent cases. As the cloud extends out to embrace IoT devices at the edge, early trends in the IoT patent space show a similar picture, with NPEs acquiring more patents and launching more claims year on year. NPE activities may attract opprobrium as arbitraging the patent system, but that is to miss the point: the defendant in a patent claim brought by a NPE generally has an unattractive real-world choice between the cost and distraction of litigation and the cost of settlement which, whilst low in relation to likely litigation costs, is high relative to the perceived merits of the claim. From the NPE’s standpoint this makes sense. Claiming that software in the CSP’s PaaS (Platform as a Service) or IaaS (Infrastructure as a Service) infringes the NPE’s patents can be an efficient way to threaten alternative objectives: the CSP risks an injunction stopping it from using the software that embodies the patented technology; and the CSP’s customers using that software also face disruption as they may be liable both for their own workloads and for their CSP’s infringing code that they use. From the standpoint of the CSP and its customers all this is bad enough, but **software patent risks are further exacerbated by ubiquitous use of OSS**, which now generally powers the cloud. OSS developments are created by communities of individual developers. With no single holder of software rights, patent infringement issues are unlikely to be top of mind; and if they are, developers will generally lack the resources to help them navigate the risks. Compare this with a corporate developer of proprietary software who holds all the rights to its technology and has both the incentive to address patent infringement risks and the legal and technical resources to do so. The rub is that, simply because they are open, OSS developments and communities are easier targets for NPEs than proprietary software as they don’t need to go to the same lengths to discover potential infringement. The softness of the target increases risk for CSPs using OSS and their users. **Cloud software patent risk is evident and growing**, so it is perhaps surprising that the regulatory response has been muted, especially when data protection, privacy and information security figure so large. Yet an unsettled cloud software patent claim runs risks to cloud service availability that are arguably of the same order as information security risks. In cloud guidance, regulators like the UK’s Financial Conduct Authority (‘FCA’) and the European Banking Authority (‘EBA’) do not expressly address IP risks but implicitly consider them in terms of business continuity, customer duties and reputational risk. So, the FCA says that firms should: “identify and manage any risks introduced by their [cloud] arrangements. Accordingly firms should carry out a risk assessment to identify relevant risks and identify steps to mitigate them, document this assessment, identify current industry good practice … assess the overall operational risks, monitor concentration risk and consider what action it would take if the provider failed ….”[4]

**New cloud tech is key to asteroid detection**

**Sichitiu et al 19** (Roxana E. Sichitiu (Avram), Marc E. Frincu Computer Science Department West University of Timisoara Ovidiu Vaduvescu Astronomy department Isaac Newton Group La Palma, Spain, School of Doctoral Sciences, “Digital Tracking Cloud Distributed Architecture for Detection of Faint NEAs”, http://www.euronear.org/publications/Sichitiu\_SYNASC\_2019.pdf)

[Abstract]

Abstract—There is an **exponential volume** of captured images, millions of captures taken every night being processed and scrutinized. Big Data analysis has become essential for the study of the solar system, discovery and orbital knowledge of the asteroids. This analysis often requires more advanced algorithms capable of processing the available data and solve the essential problems in almost real time. One such problem that needs very **rapid investigation** involves the detection of Near Earth Asteroids (NEAs) and their orbit refinement which should answer the question “will the Earth collide in the future with any hazardous asteroid?”. This paper proposes a cloud distributed architecture meant to render near real-time results, focusing on the image stacking techniques aimed to detect very faint moving objects, and pairing of unknown objects with known orbits for asteroid discovery and identification.

[Introduction]

Mankind has been attracted by the sky since its beginings, and astronomy has been studied since the earliest centuries. In the past couple of decades the information collected by ground, air and space instruments increased exponentially in comparison with the 20th century. The last five decades have witnessed a boom regarding the capacity to store the information, as well as the ease of accessing it in a distributed fashion. The information started by being kept on physical disks, but later it slowly migrated to a new concept of being processed and stored, namely cloud computing [1]. The offer of cloud solutions has an ascending trend due to the optimization of data losses, economic advantage, accessibility, and also processing power. [1].

Cloud computing is a very handy solution applicable in multiple domains and astronomy is one of them. Proved by some unfortunate asteroids collisions with the Earth (the most recent asteroid that impacted Earth in 2015 was 20m in size (!), leading to over 2,000 wounded victims in Chelyabinsk, Russia), the USA government mandated NASA to discover by 2030 all NEAs larger than 100m and to classify their path. Some of these bodies are defined as “virtual impactors” (VIs) (referring to a set of about 1000 known NEAs which have a slim but possible chance to impact the Earth in the future according to the current poor knowledge about their orbits). The classification of an orbit defining such VIs involves a varying observing coverage time, starting from a few days to a few weeks upon discovery of each object.

Storing and processing this data on clouds is a natural approach, however, most **existing tools were not designed with parallel and distributed capabilities** (cf. Section III. The collected information requires intelligent software pipelines to process very rapidly the big amount of images, and to scale large data volumes. There are more than one million tracks (unknown objects observed during only one night) in need of pairing with more than 800,000 known asteroids – **which requires a great calculation power and storage** as detailed below (see also Eq. (1)).

**Impact outweighs**

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Astronomers are fond of observing that the real question is not "whether" Earth will again be struck by a large asteroid, but "when." We can detect around the planet the remnants of scores of impact craters of diverse size and age left by previous NEOs, and the pockmarks are even more obvious on the Moon and other celestial bodies, where erosion has not degraded their silhouettes. As asteroids pinball around the Solar System, it is only a matter of time before the next jarring impact-time that might be measured in months or in millions of years. The potential consequences of such a collision beggar belief Prehistoric experience demonstrates that **all of human civilization**, as well as most or **all other forms of life on Earth, may hang in the balance**. Even a more moderately sized asteroid could devastate a community or a country in an instant. As Igor Ashurbeyli assesses the stakes, developing countermeasures to this apocalyptic threat "must become the **most important task** that humanity must solve **in the 21st century**. "211 But the **time frame matters**, too. If we knew, hypothetically, that an extinction-level event was not going to occur for thousands or millions of years, why would we devote time, attention, and money to it now? A known risk of extermination, eons into the future, would pose profound philosophical and psychological conundrums, but preemptively responding to it would not be on anyone's active "to-do list" for generations. Still, timing matters in another way, too. With our present state of astronomical intelligence, **we cannot be certain** about our planet's prolonged safety, and we must exhibit appropriate modesty about our confidence in the completeness of the inventory of known NEOs. Accordingly, the planet may **not have much advance notice** about the next Chicxulub, and we may be **no more able than the dinosaurs** to immediately invent our way out of an unanticipated fatal space specter. Frances Lyall and Paul B. Larsen summarize the issue this way: "Time might be too short adequately to deal with the crisis-missile or other **tech**nology **has to be prepared**." 2 12 It is **difficult for humans to think rationally about this** sort of problem-it is hard to get our collective minds around such enormous consequences and such tiny probabilities simultaneously-especially when people have so little first-hand experience with the causal phenomenon. A **2010 study** by the National Academy of Sciences referred to this as a **classic "zero times infinity" problem** that **thwarts human cognitive processing**.213 Cass Sunstein and Richard Zeckhauser label the resulting bias in decision-making as **"probability neglect"-**a propensity to **misunderstand the fearsome risks** that are so difficult to conceptualize.2 14 **Behavioral economics** literature abounds with examinations of the collective non-rationality in our species' approach to high-severity/low-probability events, leading to **extreme discounting of remote future catastrophes**, to the detriment of individuals and society.2 15 The underdeveloped state of international law on trans-border disasters reflects this cognitive deficit. Perhaps this should not be surprising-the tasks of preventing, responding to, and rebuilding after global catastrophes are daunting. These are topics that sovereign states, as well as individual human beings, **shy away from addressing-they are uncomfortable to think about**; they can involve sharing resources, as well as sympathy, with foreigners; and they seem to call for spending immense sums of money on vanishingly remote contingencies. It will never be easy to marshal political support for developing, improving, and sustaining planetary defense capabilities that in all likelihood will never be exercised during any government official's term in office or even lifetime.216 Nevertheless, planetary defense represents one of the occasions in which these **psychological barriers must be overcome**. The extended time frame in dealing with asteroids places special burdens on the effort to think rationally about very-low-probability dangers, because the people at risk are (likely) not ourselves but our far-distant progeny, generations so remote that the emotional connection to them is strained. We can appreciate that the good work of IAWN and SMPAG today may help increase the odds of our species' survival, but we must also be aware that the counter-asteroid technology available to earthlings a century or two from now will surely surpass today's puny capabilities in ways we cannot imagine.2 17 Collision with a body of 3-5 km diameter) could **kill**, say, **half the world's population** (soon to reach eight billion people) sometime in the next million years. On an actuarial basis, that works out to 4,000 statistical deaths annually. That is surely a significant fatality rate-enough to warrant substantial financial investment-even though the incidents would be extraordinarily "lumpy," in the sense that for almost all of those one million years, there would be no deaths at all due to asteroids, but in one year there would be an unprecedented catastrophe. At this rate, asteroids would rank above many other natural and bizarre phenomena that people fear (and that societies attempt to do something about), such as floods, tornados, airplane crashes, terrorism, or choking. Asteroids, however, would still fall far below other leading causes of death, such as automobile accidents, communicable diseases, and tobacco use. 2 18 This weird combination of probabilities and consequences promotes what many call **the "giggle factor"**: humans' seemingly **congenital reluctance to discuss planetary defense** seriously without retreating to the silliest tropes about alien attacks or sci-fi thrillers. The topic seems to be ripped from kitschy movie trailers, not news headlines. 2 19 An additional fear factor here is the **danger of surprise**. If a significant asteroid were to arrive without warning-as in the Chelyabinsk incident-the afflicted **country might perceive** that it had been **attacked by a hostile neighbor**, rather than by a fickle Mother Nature. If, by further malign luck, the event happened to occur during a period of **heightened international tensions**, the **propensity to misinterpret**, and to **respond precipitously**, would rise. The unforeseen space object could thus **catalyze a larger human-caused tragedy**.2 20 The easiest part of the policy prescription is to recommend that more should be done to gather and disseminate the relevant data about NEOs. NASA, IAWN, and other actors should press forward zealously to enhance the inventory of known asteroids and should expand their efforts to track and characterize those that might plausibly pose a threat. This survey may get expensive: space-based telescopes may be necessary in order to detect space objects that canbe obscured by the Sun, and long-distance space missions may be required in order to collect more information about the structure, composition, and flight characteristics of asteroids of interest.

**Lobbying**

**Noerr has been extended to give corporations a blank-check for lobbying**

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We live in a time when concerns about influence over the American political process by powerful private interests have reached an apogee, both on the left and on the right. Among the laws originally intended to fight excessive private influence over republican institutions were the antitrust laws of the 1890–1914 period, whose sponsors were concerned with monopoly, particularly its influence over legislatures and politicians. While no one would claim that the antitrust laws were meant to be comprehensive anticorruption laws, there can be little question that they were passed with concerns about the political influence of powerful firms and industry cartels. Since the 1960s, however, antitrust law’s **scrutiny** of corrupt and deceptive political practices has **been sharply limited by** the **Noerr**-Pennington doctrine,1 which provides immunity to antitrust liability for conduct that can be described as political or legal advocacy. The doctrine was created through apparent First Amendment avoidance, based on the premise that the Sherman Act could not have been intended to interfere with a right to petition government.2 The Noerr decision, dating from 1961, was strained when it was decided and has not aged well. As an interpretation of the antitrust laws, it ignored Congressional concern with political mischief undertaken by conspiracy or monopoly. Its legitimacy has always rested on avoidance of the First Amendment, and while Noerr itself may have legitimately reflected such avoidance, the subsequent growth of a Noerr immunity has blown past any First Amendment-driven defense of its existence. For that reason, others have suggested a reformulation of the doctrine.3 The better answer is that, lacking constitutional or statutory foundation, Noerr should be overruled. The First Amendment guarantees freedom of speech, assembly, and “to petition the government for a redress of grievances.” It therefore protects efforts to influence political debate as well as legitimate petitioning in the legislative, judicial or administrative processes.4 The First Amendment does not, however create a right to bribe government officials, deceive agencies, file false statements, or abuse government process through repeated filings designed only to injure a competitor. **Nonetheless, each of these activities has,** in some courts at least, **been granted immunity under** the overgrown **Noerr** immunity.5 It is an extraconstitutional outlier ripe for reexamination. The case for overruling Noerr is buttressed by the fact that, since its decision, Noerr’s theoretical foundations have weakened,6 and are “wobbly and moth-eaten.” 7 Written before the dawn of public choice theory or contemporary understanding of interest group influence, it relies on an exceptionally stylized model of politics that understates the potential for corruption and denial of majority will. Moreover, several decades of experience with a judge-made immunity have shown a pronounced tendency for doctrinal creep -- a well-known problem for doctrines anchored in avoidance (so-called “avoidance creep.”). 8 Constitutional avoidance, as Charlotte Garden argues, yields decisions that deliberately interpret the statute in a manner at odds with Congressional intent. Subsequent decisions building on that interpretation can easily leave behind both Congressional intent and the original justifications for the original reason for the avoidance.9 The result is a free-floating doctrine, as with Noerr, that becomes untethered to either statutory goals or Constitutional principle. Overruling Noerr would not make political petitioning illegal. It would, instead, require defendants to rely on the First Amendment when seeking to defend what would otherwise be conduct that is illegal under the antitrust laws. Doctrinally, this is to force courts to address whether conduct in question is actually an antitrust violation, and if, so whether it is protected by the First Amendment or not, drawing on an established jurisprudence for some of the problems presented in the Noerr context. For example, while the First Amendment protects false statements in some contexts,10 it has never protected perjury, or the making of false statements to government agencies.11 It should take no great leap of insight to conclude that the First Amendment might be the superior vehicle for adjudging a defendant’s First Amendment interests.12 Noerr could be overruled by the Supreme Court in an appropriate case. It could also be overruled by Congress. The legislature, of course, is not in a position to overrule the aspects of Noerr immunity that are anchored in the First Amendment.13 But Congress could do what this article calls for, namely, return the immunities granted political speech and petitioning to their Constitutional limits, while reaffirming the purposes of the antitrust laws. Part I outlines where Noerr itself went wrong; Part II, details the problem of doctrinal creep; Part III argues that Noerr should be overruled; and Part IV details what a First Amendment replacement would look like. **I. Where Noerr went wrong** The Noerr litigation arose out of a long-running battle over the 1930s through 1950s between two natural competitors: the railroad and the trucking industry, whose mutual animosity was the stuff of legend. The railroads were the older of the two industries, and had already had many run-ins with the antitrust laws.14 By the 1930s the railroads began to suffer from the competitive inroads being made by the newer trucking industry. In response, the railroads began a series of anti-truck campaigns to hold their market position by any means necessary. The railroads began using a technique then relatively new to the business world: a public relations campaign piloted through front groups and promulgated through the mass media. Among the front groups used were “the Empire State Transport League” the “Save Our Highways Clubs,” and the “New Jersey Tax Foundation.” 15 These groups portrayed truckers as villainous creatures whose driving of heavy vehicles destroyed bridges, fractured roads, and created other public dangers. As the trial court found, the campaign was “made to appear as spontaneously expressed views of independent persons and civic groups when, in fact, it was largely prepared and produced by [a PR firm] and paid for by the railroads.”16 The court summarized the approach as a "deception of the public, manufacture of bogus sources of reference, [and] distortion of public sources of information.”17 The trial judge wrote that “I prefer to treat the whole procedure in its true light, which is the technique of the ‘Big Lie.’”18 If unseemly, however, the campaigns were unquestionably legislative campaigns. The railroads had clear, if anticompetitive, political goals: to lower the statutory weight limits that kept truckers out of heavy transport and to increase the taxes they paid. To that end, the front groups presented data (allegedly false, though we don’t know for sure) that, they claimed, revealed the damage done by trucks to roads and bridges. The other main deception, at least as found by the district court, concerned the question of just whom was presenting the information.19 As suggested already, the complaints were made to seem as if they were from disinterested third parties, concerned citizens, when in fact, they were not. As a First Amendment case, Noerr is not an easy one. The railroads have in their favor that they were associating to engage in political speech, to present information relevant to government, and ask for changes in the law. As the Supreme Court put it “No one denies that the railroads were making a genuine effort to influence legislation and law enforcement practices.”20 The core speech at issue, moreover, if not impartial, was of value, expressing, as it did, the view that the truckers damaged public roads. More generally, as the Court held, a rule 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.”21 The trickier part comes from the deception: the use of the front groups to deceive government as to the source of the information presented, and the allegation that some of the information provided was false. No one has ever suggested that bans on impersonation in an official context violate the First Amendment, and the crime of making false statements to government is routinely prosecuted.22 The First Amendment defense is particularly challenging if it is true that plaintiffs intentionally and maliciously submitted false information to achieve an anticompetitive result — fraud on the legislature — and therefore were like the applicant who submits false information to obtain a patent.23 But if Noerr was just a case of creating a false impression of public support, something which is certainly unethical but happens with distressing regularity in public discourse, the question remains difficult. But leaving the First Amendment aside, what was the proper construction of the Sherman Act? Imagine the same case without government as the target of the campaign. It seems implausible that the Sherman Act would grant an automatic immunity in a case where an industry conspires **to exclude a competitor** by manipulating a body with the power to determine the conditions of competition. An effort to hamstring a rival by rigging a process to set exclusionary standards was the kind of thing condemned in cases like Allied Tube and Broadcom Corp. v. Qualcomm Inc.24 It is the kind of thing meant for a rule of reason analysis: as Justice Brandeis wrote in Chicago Board of Trade, the question would be whether the conduct is such that “promotes competition, or whether it is such as may suppress or even destroy competition….”25 Perhaps the railroads would have argued the weight-limits were competition enhancing in some way, yet it seems more likely that they were more of a bad-faith effort to exclude their competitors. But Noerr did involve bodies of government, and not a standard setting body. That could lead some to believe that the campaigns, even if deceptive, are still not the kind of thing that the Sherman Act or other antitrust laws were intended to have jurisdiction over. Yet even the quickest tour of the history of the passage of the Sherman, Clayton and FTC Acts reveals that this is a grossly mistaken view of what Congress was concerned with when it passed the antitrust laws. The famous editorial cartoons of the Standard Oil Octopus always have its tentacles encircling legislatures.26 More specifically, among the abuses of which companies like Standard Oil, and later, J.P. Morgan’s New Haven railroad were accused was the bribing of public officials to disadvantage smaller competitors, or to wrongly grant monopolies.27 The legislative history is replete with evidence of such concerns.28 As Robert Faulker writes, “there is nothing on the face of the [Sherman] Act to suggest that the Fifty-first Congress wanted to exempt concerted, unethical and anti-competitive activity.”29 He adds that it would be strange to do so “on the ironic premise that the Act permits a business combination to destroy or do grievous harm to a competitor by applying large sums of money to deceive elected officials.”30 The best reading of the Sherman and Clayton Act is that the framers had an overarching concern about monopoly influence over democratic institutions, but also a more specific concern with the obtaining or maintaining monopoly through corrupt means, and especially through bribery or fraud.31 For that reason, whether in pursuit of monopolization or the restraint of trade, corruption and fraud on the government ought to be understood as one form of prohibited conduct. If that’s so, it leads to the conclusion that Noerr must be understood as an exercise in constitutional avoidance, a conclusion many other scholars have also reached; or alternatively, that the deception wasn’t quite bad enough to amount to fraud on the legislature.32 That ambiguity is what makes the case frustrating, for despite Justice Black’s bold writing, **the Noerr opinion, by inventing an immunity instead of resolving the question, took the easy way out.** At this point we need briefly address an alternative view of Noerr that has nothing to do with the First Amendment but has shown up in Supreme Court opinions. That view holds Noerr to be a necessary implication of Parker immunity (and therefore, potentially, independent of the First Amendment). Parker stands for the proposition that state action is immune from antitrust scrutiny.33 Hence, if the federal government, or even the states, decide to establish a monopoly, that is nonetheless not a violation of the antitrust laws. That has led some — most notably Justice Scalia — to suggest that Noerr immunity is simply “a corollary to Parker” because as it is within the rights of government act anticompetitively, “the federal antitrust laws also do not regulate the conduct of private individuals in seeking anticompetitive action from the government.”34 If superficially appealing, this logic evaporates on further inspection. To pursue monopoly is not the same thing as to pursue it corruptly, but the view just described brushes over the difference. As already discussed the framers of the Sherman Act considered the activity of corruptly seeking of a state-granted monopolies to be within the concerns of the law, especially through bribery, threats or deception. Even if government can override the antitrust laws, it does not necessarily follow that the courts need immunize efforts to obtain state action, especially if they should go beyond the normal protections for advocacy provided by the First Amendment. This conclusion is reinforced by examining immunities outside of the antitrust context there is no such blanket “corollary” to be found. The government, unlike a private citizen, has special immunities when it puts people to death or seizes property. Yet those seeking to convince government to use those powers enjoy no special immunity to bribery laws, lobbying laws, or other criminal prohibitions. They have, instead, only the protections for political advocacy that come from the First Amendment. The existence of a government power has, outside of antitrust, never been read as a license to pursue it using independently illegal means. **It all returns to question of what the First Amendment protects**, which returns us to the case for overruling Noerr. These are conclusions that are further buttressed by the Court’s recognition of a sham exception in Noerr.35 Were Noerr meant to be the perfect mirror image of Parker, it might be thought that any purported effort to influence government, no matter how distasteful, might be thought to be immunized. But the sham exception better suggests First Amendment avoidance, because it tracks the well-known position that the First Amendment has limits, and does not protect everything that might plausibly be described as speech or petitioning. The sham exception looks very much like a placeholder for the limits of the First Amendment. Just like conduct falsely claiming to be speech is not protected by the First Amendment, **anti-competitive activity falsely claiming to be political petitioning is not afforded undue protection.** 36 Finally, the idea that Noerr was constitutional avoidance is buttressed by other cases finding fraud on the government to be actionable under the antitrust laws. In Walker Process, a party was alleged to have intentionally lied to the patent office about the state of the “prior art” so as to obtain a patent.37 The Court declined to create any special immunity for such conduct, instead stating that “the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present.”38 That result impeaches any idea that the Sherman Act was not meant to reach efforts to defraud government for anticompetitive purpose. All this suggests that while constitutional avoidance may be appropriate in some cases, it was mistaken in Noerr, because Noerr was hardly a one-off. It gave birth to a judge-made immunity, and in the process left a critical matter undetermined: **it would always be unclear whether a court**, **invoking Noerr, need rely on Constitutional avoidance** to do so, and thereby conduct a First Amendment analysis; **or whether it was free to just invoke Noerr as a free-floating immunity**. That would, in time, allow the immunity to expand far beyond any constitutional or statutory mandate. A different way of stating the critique is this: Noerr does not give the courts the tools or mandate to address the competing values of the First Amendment and the Antitrust laws in the cases it addresses. Unlike, say, the overlap between patent and antitrust, where the conflict is made explicit, it was instead buried by constitutional avoidance. **That burial would lead the courts to expand the immunity in directions entirely unrelated to First Amendment value**, a matter to which we now turn. The Relationship between the First Amendment and Antitrust Laws The antitrust laws and the First Amendment have shared goals. Both laws envision open societies and have their anchor in liberty. Both take as their device the promotion of competition in actual or metaphorical markets. And both have been justified as means for preventing abuses of power, whether by government or the monopolist. There is even some similarity in their methods: what is censorship if not the exclusion of a competitor from the marketplace of ideas?39 As laws serving roughly the same ends with similar philosophies, it might seem unlikely that the laws might come into conflict. But the tension we’ve seen arises from the fact that, as Noerr and similar cases show, the Firest Amendment blesses conduct -- petitioning -- that can be used to obtain anti-competitive ends. However, the First Amendment does not protect everything that might conceivably be called “speech,” suggesting it might be important to take a closer look at just what speech values are implicated in political influence campaigns. Imagine that the coal industry were concerned with the rise of wind power, an obvious competitor. It might react in more than one way. First, the coal industry or its owners might distribute information (here assumed to be factual) showing that wind power, in fact, creates its own waste problems or is more expensive than generally thought. It might distribute information suggesting that coal is not actually as “dirty” as widely believed (“clean coal”). And it might formally petition government with economic arguments for abandoning its subsidies of wind power. These activities are all within the core of First Amendment protection. The strongest argument for their protection is that, by providing information to government and the public relevant to an important debate, they serve the process of democratic selfgovernment, 40 both through the formation of public opinion and the provision of information necessary to making important public decisions. It is true that the volume of speech that the coal industry can afford might be said to give its speech an unfair advantage; yet as it stands, the First Amendment has stood for the premise that more is more in that context. 41 So much for a “clean” campaign of political influence that relies on the publication of factual information, correctly attributed. What about when the campaign becomes increasingly deceptive, corrupt, and abusive? The answer is that the First Amendment interests weaken until they, at some point, they disappear entirely. This point is key to understanding the First Amendment / antitrust analysis and a point largely neglected by Noerr and its Supreme Court progeny: **not all the techniques of political influence are “speech” or petitioning at all.** The coal industry might, as in Noerr, use front groups who lie about their funding to present its criticism of wind power, thereby deceiving the public and government as to the source of the critiques. It might, next, publish demonstrably false, or even defamatory information, such as the suggestion that wind turbines are highly harmful to human health (“wind power syndrome”).42 Finally, the coal industry might intentionally and maliciously present false information — say, false pricing information, or the defamation of individuals involved in wind — in its petitions to government. It might file endless procedural challenges to block the approval of wind farms by local authorities. Finally, it might give cash bribes to government officials in exchange for a local ban on wind power. Or it, at the extreme, hire thugs to sabotage wind turbines under the cover of darkness. As we run through these increasingly dirty advocacy campaigns, the First Amendment interests become progressively weaker to non-existent. Laws that ban bribery, defamation, deception of government and sabotage have all survived First Amendment challenges, either based on the strength of the government interest, or the idea that there really is no protected speech at issue, but merely conduct.43 On the antitrust side of the ledger, the strength of the government’s interests would similarly seem to depend on the spectrum of deception through outright corruption. Despite occasional academic suggestions that the antitrust laws should be indifferent to anticompetitive intent or malicious conduct, the nature of the conduct matters, as evidenced both by case law condemning intentional monopolization,44 deception, 45 and other tortious conduct, like fraud or sabotage. This short section cannot capture every conceivable type of advocacy campaign. But what is notably lacking in Noerr is any consideration of the relative strength of the First Amendment and antitrust interests. And as we shall see, **it has led the courts —** especially district courts — **to extend Noerr immunity beyond any justifiable boundary.** II. Leaving behind the Constitution If it might originally have been defended as an exercise in Constitutional avoidance, over the decades the Noerr doctrine has grown into its own creature, too unconnected and insensitive to the competing concerns of antitrust policy and the First Amendment. At its worst, **it has provided immunities to** classes of conduct, like **bribery**, **abuse of government process**, **and lying to government** which it seems clear that the antitrust laws were meant to punish and for which there are no constitutional protections. The 1991 decision City of Columbia v. Omni Outdoor Advertising, Inc did the most to make the doctrine insensitive to the competing concerns in this area.46 The jury, at trial, had found a corrupt conspiracy between the city of Columbia and a billboard company. Despite the fact that the First Amendment does not generally protect conspiracies, **Justice Scalia’s majority** nonetheless **held the conduct protected by Noerr.47** The key doctrinal move in Omni was to limit **Noerr’s sham exception** — **which**, as we’ve seen **can be understood as a proxy for the First Amendment’s limits**. The Court limited it to one category of sham, bad faith abuse of the political process, and declined to find any other possible exceptions, such as the “conspiracy” exception found by the court of appeals. Given that the sham exception can be understood as standing in for the limits of the First Amendment, **Omni gave courts an open door to use Noerr to protect conduct that would not be protected by the First Amendment.** Since that time, Noerr has, in lower courts, come to protect a range of conduct that would not be protected by the First Amendment, **including** not just **conspiracy**, but **bribery, false statements to government, deceit, and even abuse of process**—so long as some political objective can be claimed. Over-broad Noerr immunity and an underinclusive sham exception made courts reluctant to recognize areas of clearly anticompetitive action that should not enjoy any constitutional protection. Consider the following example of how Noerr is invoked to immunize bribery. In 2001, a district court in Louisiana heard allegations that a riverboat company was bribing government officials so as to prevent competitors from obtaining a license to operate.48 The court rejected the idea that “bribery, extortion and corruption” would “abrogate antitrust immunity.”49 It did so based on the premise that even corrupt and criminal activity is immune from antitrust scrutiny, under Omni, so long as the ultimate object is a favorable political outcome.50 In another departure from First Amendment principle, some courts have also interpreted Noerr to protect the making of false statements to government. For example, in a 2013 dispute between two asphalt firms, one alleged the other had lied to municipal governments about the relevant regulations so as to trick the governments into excluding rivals.48 When targeted in an antitrust suit the court upheld immunity,51 despite the analogy to obtaining a fraudulent patent condemned in Walker Process,52 evidence of effects on competition, and the fact the First Amendment, with rare exceptions, does not protect false statements made to government. Finally, there are **courts** that **have**, unaccountably, **immunized conduct that is nearly impossible to describe as political speech or petitioning**. Conduct that Noerr itself named as unprotected — the use of political process as an anticompetitive weapon (such as through repetitive, baseless filings). 53 Even when the goal of the filing is for “the principle purpose of harming [a] competitor,” courts have refused to consider the filing a sham.54 Courts have protected series of filings that petitioners never expected to win on.55 Similarly they have fully ignored distinction between standards for single and multiple filings and insisted on firm proof of “objective unreasonableness” for each action despite the obvious increased harm that comes from fielding many specious claims.56 Other examples of dubious extensions to Noerr include an immunity premised on the communication of a list of school accreditation to the state, 57 private and secret meetings at a governor’s mansion,58 and even boycotting competitors.59 At the risk of stating the obvious, the First Amendment goals served by immunizing these forms of conduct is unclear at best. It is worth pointing out that not every court has ignored the First Amendment foundations of the Noerr doctrine. 60 Courts have sometimes insisted on a First Amendment analysis prior to granting Noerr immunity. For example, consider litigation from the early 2000s, centered on allegations that a drug manufacturer sought to delay the entry of competitive generic drugs by wrongly listing its patent in the FDA’s orange book. In rejecting a Noerr defense, the district court agreed with the FTC that the listing was not a petition protected by the First Amendment, and therefore not entitled to Noerr immunity. It did so on the premise that, as the FTC argued, the FDA’s actions were ministerial, as opposed to discretionary: there is no Noerr immunity when the “government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations.” 61 Similarly, the FTC, at least, believes that misrepresentative communications to government are not protected by the First Amendment, and also not protected by Noerr.62

**The plan solves**

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” <https://heinonline.org/HOL/LandingPage?handle=hein.journals/thurlr40&div=9&id=&page=>

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. FS1153 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 ofpetition 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 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 FirstAmendment was in three cases which held that Noerr was inapplicable or distinguishable: NAACP. v. Claiborne HardwareCo.,'56 F.T.C. v. Superior Court TrialLawyers 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-Penningtondoctrine 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.' 59 Even in cases where the plaintiff would not have ultimately prevailed, simply having the case resolved before an impartial tribunal has its own 0 inherent benefits.16 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 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. 61 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. 62 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,a 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.

**Anticompetitive lobbying entrenches governmental distrust and enables anti-democratic tendencies**

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For years, the residents of Oxford, Massachusetts, seethed with anger at the company that controlled the local water supply. The company, locals complained, charged inflated prices and provided terrible service. But unless the town’s residents wanted to get by without running water, they had to pay up, again and again. The people of Oxford resolved to buy the company out. At a town meeting in the local high-school auditorium, an overwhelming majority of residents voted to raise the millions of dollars that would be required for the purchase. It took years, but in May 2014, the deal was nearly done: One last vote stood between the small town and its long-awaited goal. The company, however, was not going down without a fight. It mounted a campaign against the buyout. On the day of the crucial vote, the high-school auditorium swelled to capacity. Locals who had toiled on the issue for years noticed many newcomers—residents who hadn’t showed up to previous town meetings about the buyout. When the vote was called, the measure failed—the company, called Aquarion, would remain the town’s water supplier. Supporters of the buyout mounted a last-ditch effort to take a second vote, but before it could be organized, a lobbyist for Aquarion pulled a fire alarm. The building had to be evacuated, and the meeting adjourned. Aquarion retains control of Oxford’s water system to this day. The company denied that the lobbyist was acting on its behalf when he pulled the alarm; it also denies that its rates were abnormally high or that it provides poor service. Some Oxford residents supported Aquarion, and others opposed the buyout because they feared the cost and complication of the town running its own water company. But many residents, liberal and conservative, were frustrated by the process. The vote, they felt, hadn’t taken place on a level playing field. “It was a violation of the sanctity of our local government by big money,” Jen Caissie, a former chairman of the board of selectmen in Oxford, told me. “Their messiah is their bottom line, not the health of the local community. And I say that as a Republican, someone who is in favor of local business.” A New England town meeting would seem to be one of the oldest and purest expressions of the American style of government. Yet even in this bastion of deliberation and direct democracy, a nasty suspicion had taken hold: that the levers of power are not controlled by the people. It’s a suspicion stoked by the fact that, across a range of issues, public policy does not reflect the preferences of the majority of Americans. If it did, the country would look radically different: Marijuana would be legal and campaign contributions more tightly regulated; paid parental leave would be the law of the land and public colleges free; the minimum wage would be higher and gun control much stricter; abortions would be more accessible in the early stages of pregnancy and illegal in the third trimester. The subversion of the people’s preferences in our supposedly democratic system was explored in a 2014 study by the political scientists Martin Gilens of Princeton and Benjamin I. Page of Northwestern. Four broad theories have long sought to answer a fundamental question about our government: Who rules? One theory, the one we teach our children in civics classes, holds that the views of average people are decisive. Another theory suggests that mass-based interest groups such as the AARP have the power. A third theory predicts that business groups such as the Independent Insurance Agents and Brokers of America and the National Beer Wholesalers Association carry the day. A fourth theory holds that policy reflects the views of the economic elite. Gilens and Page tested those theories by tracking how well the preferences of various groups predicted the way that Congress and the executive branch would act on 1,779 policy issues over a span of two decades. The results were shocking. Economic elites and narrow interest groups were very influential: They succeeded in getting their favored policies adopted about half of the time, and in stopping legislation to which they were opposed nearly all of the time. Mass-based interest groups, meanwhile, had little effect on public policy. As for the views of ordinary citizens, they had virtually no independent effect at all. “When the preferences of economic elites and the stands of organized interest groups are controlled for, the preferences of the average American appear to have only a minuscule, near-zero, statistically non-significant impact upon public policy,” Gilens and Page wrote. Outlets from The Washington Post to Breitbart News cited this explosive finding as evidence of what overeager headline writers called American oligarchy. Subsequent studies critiqued some of the authors’ assumptions and questioned whether the political system is quite as insulated from the views of ordinary people as Gilens and Page found. The most breathless claims made on the basis of their study were clearly exaggerations. Yet their work is another serious indication of a creeping democratic deficit in the land of liberty. To some degree, of course, the unresponsiveness of America’s political system is by design. The United States was founded as a republic, not a democracy. As Alexander Hamilton and James Madison made clear in the Federalist Papers, the essence of this republic would consist—their emphasis—“IN THE TOTAL EXCLUSION OF THE PEOPLE, IN THEIR COLLECTIVE CAPACITY, from any share” in the government. Instead, popular views would be translated into public policy through the election of representatives “whose wisdom may,” in Madison’s words, “best discern the true interest of their country.” That this radically curtailed the degree to which the people could directly influence the government was no accident. Only over the course of the 19th century did a set of entrepreneurial thinkers begin to dress an ideologically self-conscious republic up in the unaccustomed robes of a democracy. Throughout America, the old social hierarchies were being upended by rapid industrialization, mass immigration, westward expansion, and civil war. Egalitarian sentiment was rising. The idea that the people should rule came to seem appealing and even natural. The same institutions that had once been designed to exclude the people from government were now commended for facilitating government “of the people, by the people, for the people.” The shifting justification for our political system inspired important reforms. In 1913, the Seventeenth Amendment stipulated that senators had to be elected directly by the people, not by state legislatures. In 1920, the Nineteenth Amendment gave women the vote. In 1965, the Voting Rights Act, drawing on the Fifteenth Amendment, set out to protect the vote of black Americans. The once-peculiar claim that the United States was a democracy slowly came to have some basis in reality. That basis is now crumbling, and the people have taken notice. In no small part that’s because the long era during which average Americans grew more wealthy has come to a sputtering stop. People who are asked how well they are doing economically frequently compare their own standard of living with that of their parents. Until recently, this comparison was heartening. At the age of 30, more than nine in 10 Americans born in 1940 were earning more than their parents had at the same stage of their lives. But according to eye-popping research led by the economist Raj Chetty and his co-authors, many Millennials do not share in this age-old American experience of improving fortunes. Among those Americans born in the early 1980s, only half earn more than their parents did at a similar age. Americans have never loved their politicians or thought of Washington as a repository of moral virtue. But so long as the system worked for them—so long as they were wealthier than their parents had been and could expect that their kids would be better off than them—people trusted that politicians were ultimately on their side. Not anymore. The rise of digital media, meanwhile, has given ordinary Americans, especially younger ones, an instinctive feel for direct democracy. Whether they’re stuffing the electronic ballot boxes of The Voice and Dancing With the Stars, liking a post on Facebook, or up-voting a comment on Reddit, they are seeing what it looks like when their vote makes an immediate difference. Compared with these digital plebiscites, the work of the United States government seems sluggish, outmoded, and shockingly unresponsive. As a result, average voters feel more alienated from traditional political institutions than perhaps ever before. When they look at decisions made by politicians, they don’t see their preferences reflected in them. For good reason, they are growing as disenchanted with democracy as the people of Oxford, Massachusetts, did. The politician who best intuited this discontent—and most loudly promised to remedy it—is Donald Trump. The claim that he would channel the voice of the people to combat a corrupt and unresponsive elite was at the very core of his candidacy. “I am your voice,” Trump promised as he accepted his party’s nomination at the Republican National Convention. “Today, we are not merely transferring power from one administration to another or from one party to another,” he proclaimed in his inaugural address, “but we are transferring power from Washington, D.C., and giving it back to you, the people.” Donald Trump won the presidency for many reasons, including racial animus, concerns over immigration, and a widening divide between urban and rural areas. But public-opinion data suggest that a deep feeling of powerlessness among voters was also important. I analyzed 2016 data from the American National Election Studies. Those who voted for Trump in the Republican primaries, more than those who supported his competition, said that they “don’t have any say about what the government does,” that “public officials don’t care much what people like me think,” and that “most politicians care only about the interests of the rich and powerful.” Trump has no real intention of devolving power back to the people. He’s filled his administration with members of the same elite he disparaged on the campaign trail. His biggest legislative success, the tax bill, has handed gifts to corporations and the donor class. A little more than a year after America rebelled against political elites by electing a self-proclaimed champion of the people, its government is more deeply in the pockets of lobbyists and billionaires than ever before. It would be easy to draw the wrong lesson from this: If the American electorate can be duped by a figure like Trump, it can’t be trusted with whatever power it does retain. To avoid further damage to the rule of law and the rights of the most-vulnerable Americans, traditional elites should appropriate even more power for themselves. But that response plays into the populist narrative: The political class dislikes Trump because he threatens to take its power away. It also refuses to recognize that the people have a point. **America does have a democracy problem**. If we want to address the root causes of populism, we need to start by taking an honest accounting of the ways in which power has slipped out of the people’s hands, and think more honestly about the ways in which we can—and cannot—put the people back in control. Matt Dorfman At the height of the Mexican–American War, Nicholas Trist traveled to Mexico and negotiated the Treaty of Guadalupe Hidalgo, which ended the hostilities between the two nations and helped delineate America’s southern border. Two decades later, the U.S. government still hadn’t paid him for his services. Too old and weak to travel to Washington to collect the money himself, Trist hired a prominent lawyer by the name of Linus Child to act on his behalf, promising him 25 percent of his recovered earnings. Congress finally appropriated the money to settle its debt. But now it was Trist who refused to pay up, even after his lawyer sued for his share. Though the contract between Trist and Child hardly seems untoward by today’s standards, the Supreme Court refused to uphold it out of fear that it might provide a legal basis for the activities of lobbyists: If any of the great corporations of the country were to hire adventurers who make market of themselves in this way, to procure the passage of a general law with a view to the promotion of their private interests, the moral sense of every right-minded man would instinctively denounce the employer and employed as steeped in corruption. Extreme as this case may appear, it was far from idiosyncratic. In her book Corruption in America, the legal scholar Zephyr Teachout notes that the institutions of the United States were explicitly designed to counter the myriad ways in which people might seek to sway political decisions for their own personal gain. Many forms of lobbying were banned throughout the 19th century. In Georgia, the state constitution at one time read that “lobbying is declared to be a crime.” In California, it was a felony. Over the course of the 20th century, lobbying gradually lost the stench of the illicit. But even once the activity became normalized, businesses remained reluctant to exert their influence. As late as the 1960s, major corporations did not lobby directly on their own behalf. Instead, they relied on collectives such as the U.S. Chamber of Commerce, which had a weaker voice in Washington than labor unions or public-interest groups. “As every business executive knows,” the future Supreme Court Justice Lewis F. Powell Jr. complained in 1971, “few elements of American society today have as little influence in government as the American businessman.” All of this began to change in the early 1970s. Determined to fight rising wages and stricter labor and environmental standards, which would bring higher costs, CEOs of companies like General Electric and General Motors banded together to expand their power on Capitol Hill. At first, their activities were mostly defensive: The goal was to stop legislation that might harm their interests. But as the political influence of big corporations grew, and their profits soared, a new class of professional lobbyists managed to convince the nation’s CEOs that, in the words of Lee Drutman, the author of the 2015 book The Business of America Is Lobbying, their activity “was not just about keeping the government far away—it could also be about drawing government close.” Today, corporations wield immense power in Washington: “For every dollar spent on lobbying by labor unions and public-interest groups,” Drutman shows, “large corporations and their associations now spend $34. Of the 100 organizations that spend the most on lobbying, 95 consistently represent business.” (Read about a principal architect of the lobbying industry—Paul Manafort—in our March 2018 cover story.) The work of K Street lobbyists, and the violation of our government by big money, has fundamentally transformed the work—and the lives—of the people’s supposed representatives. Steve Israel, a Democratic congressman from Long Island, was a consummate moneyman. Over the course of his 16 years on Capitol Hill, he arranged 1,600 fund-raisers for himself, averaging one every four days. Israel cited fund-raising as one of the main reasons he decided to retire from Congress, in 2016: “I don’t think I can spend another day in another call room making another call begging for money,” he told The New York Times. “I always knew the system was dysfunctional. Now it is beyond broken.” A model schedule for freshman members of Congress prepared a few years ago by the Democratic Congressional Campaign Committee instructs them to spend about four hours every day cold-calling donors for cash. The party encourages so many phone calls because the phone calls work. Total spending on American elections has grown to unprecedented levels. From 2000 to 2012, reported federal campaign spending doubled. It’s no surprise, then, that a majority of Americans now believe Congress to be corrupt, according to a 2015 Gallup poll. As Israel memorably put it to HBO’s John Oliver, the hours he had spent raising money had been “a form of torture—and the real victims of this torture have become the American people, because they believe that they don’t have a voice in this system.” Big donors and large corporations use their largesse to sway political decisions. But their influence goes far beyond those instances in which legislators knowingly sacrifice their constituents’ interests to stay on the right side of their financial backers. The people we spend time with day in and day out shape our tastes, our assumptions, and our values. The imperative to raise so much money means that members of Congress log more time with donors and lobbyists and less time with their constituents. Often, when faced with a vote on a bill of concern to their well-heeled backers, legislators don’t have to compromise their ideals—because they spend so much of their lives around donors and lobbyists, they have long ago come to share their views. The problem goes even deeper than that. In America’s imagined past, members of Congress had a strong sense of place. Democrats might have risen through the ranks of local trade unions or schoolhouses. Republicans might have been local business or community leaders. Members of both parties lived lives intertwined with those of their constituents. But spend some time reading the biographies of your representatives in Congress, and you’ll notice, as I did, that by the time they reach office, many politicians have already been socialized into a cultural, educational, and financial elite that sets them apart from average Americans. While some representatives do have strong roots in their district, for many others the connection is tenuous at best. Even for those members who were born and raised in the part of the country they represent, that place is for many of them not their true home. Educated at expensive colleges, likely on the coasts, they spend their 20s and 30s in the nation’s great metropolitan centers. After stints in law, business, or finance, or on Capitol Hill, they move to the hinterlands out of political ambition. Once they retire from Congress, even if they retain some kind of home in their district, few make it the center of their lives: They seem much more likely than their predecessors to pursue lucrative opportunities in cities such as New York, San Francisco, and, of course, Washington. By just about every metric—from life experience to education to net worth—these politicians are thoroughly disconnected from the rest of the population. The massive influence that money yields in Washington is hardly a secret. But another, equally important development has largely gone ignored: More and more issues have simply been taken out of democratic contestation. In many policy areas, the job of legislating has been supplanted by so-called independent agencies such as the Federal Communications Commission, the Securities and Exchange Commission, the Environmental Protection Agency, and the Consumer Financial Protection Bureau. Once they are founded by Congress, these organizations can formulate policy on their own. In fact, they are free from legislative oversight to a remarkable degree, even though they are often charged with settling issues that are not just technically complicated but politically controversial. In 2007, Congress enacted 138 public laws. In the same year, independent federal agencies finalized 2,926 rules. The range of crucial issues that these agencies have taken on testifies to their importance. From banning the use of the insecticide DDT to ensuring the quality of drinking water, for example, the EPA has been a key player in fights about environmental policy for almost 50 years; more recently, it has also made itself central to the American response to climate change, regulating pollutants and proposing limits on carbon-dioxide emissions from new power plants. While independent agencies occasionally generate big headlines, they often wield their real power in more obscure policy areas. They are now responsible for the vast majority of new federal regulations. A 2008 article in the California Law Review noted that, during the previous year, Congress had enacted 138 public laws. In the same year, federal agencies had finalized 2,926 rules. Such rules run the gamut from technical stipulations that affect only a few specialized businesses to substantial reforms that have a direct impact on the lives of millions. In October 2017, for example, the Consumer Financial Protection Bureau passed a rule that would require providers of payday loans to determine whether customers would actually be able to pay them back—potentially saving millions of people from exploitative fees, but also making it more difficult for them to access cash in an emergency. The rise of independent agencies such as the EPA is only a small piece of a larger trend in which government has grown less accountable to the people. In the latter half of the 20th century, the Federal Reserve won much greater independence from elected politicians and began to deploy far more powerful monetary tools. Trade treaties, from nafta to more-recent agreements with countries such as Australia, Morocco, and South Korea, have restricted Congress’s ability to set tariffs, subsidize domestic industries, and halt the inflow of certain categories of migrant workers. At one point I planned to count the number of treaties to which the United States is subject; I gave up when I realized that the State Department’s “List of Treaties and Other International Agreements of the United States” runs to 551 pages. Most of these treaties and agreements offer real benefits or help us confront urgent challenges. Whatever your view of their merit, however, there is no denying that they curtail the power of Congress in ways that also disempower American voters. Trade treaties, for example, can include obscure provisions about “investor–state dispute settlements,” which give international arbitration courts the right to award huge sums of money to corporations if they are harmed by labor or environmental standards—potentially making it riskier for Congress to pass such measures. This same tension between popular sovereignty and good governance is also evident in the debates over the power of the nine unelected justices of the Supreme Court. Since the early 1950s, the Supreme Court has ended legal segregation in schools and universities. It has ended and then reintroduced the death penalty. It has legalized abortion. It has limited censorship on television and the radio. It has decriminalized homosexuality and allowed same-sex marriage. It has struck down campaign-finance regulations and gun-control measures. It has determined whether millions of people get health insurance and whether millions of undocumented immigrants need to live in fear of being deported. Whether you see judicial review as interpreting the law or usurping the people’s power probably depends on your view of the outcome. The American right has long railed against “activist judges” while the American left, which enjoyed a majority on the Court for a long stretch during the postwar era, has claimed that justices were merely doing their job. Now that the Court has started to lean further right, these views are rapidly reversing. But regardless of your politics, there’s no question that the justices frequently play an outsize role in settling major political conflicts—and that many of their decisions serve to amplify undemocratic elements of the system. Take Citizens United. By overturning legislation that restricted campaign spending by corporations and other private groups, the Supreme Court issued a decision that was unpopular at the time and has remained unpopular since. (In a 2015 poll by Bloomberg, 78 percent of respondents disapproved of the ruling.) It also massively amplified the voice of moneyed interest groups, making it easier for the economic elite to override the preferences of the population for years to come. Donald Trump is the first president in the history of the United States to have served in no public capacity before entering to the White House. He belittles experts, seems to lack the most basic grasp of public policy, and loves to indulge the worst whims of his supporters. In all things, personal and political, Plato’s disdainful description of the “democratic man” fits the 45th president like a glove: Given to “false and braggart words and opinions,” he considers “insolence ‘good breeding,’ license ‘liberty,’ prodigality ‘magnificence,’ and shamelessness ‘manly spirit.’ ” It is little wonder, then, that Plato’s haughty complaint about democracy—its primary ill, he claimed, consists in “assigning a kind of equality indiscriminately to equals and unequals alike”—has made a remarkable comeback. As early as 2003, the journalist Fareed Zakaria argued, “There can be such a thing as too much democracy.” In the years since, many scholars have built this case: The political scientist Larry Bartels painstakingly demonstrated just how irrational ordinary voters are; the political philosopher Jason Brennan turned the premise that irrational or partisan voters are terrible decision makers into a book titled Against Democracy; and Parag Khanna, an inveterate defender of globalization, argued for a technocracy in which many decisions are made by “committees of accountable experts.” Writing near the end of the 2016 primary season, when Trump’s ascent to the Republican nomination already looked unstoppable, Andrew Sullivan offered the most forceful distillation of this line of antidemocratic laments: “Democracies end when they are too democratic,” the headline of his essay announced. “And right now, America is a breeding ground for tyranny.” The antidemocratic view gets at something real. What makes our political system uniquely legitimate, at least when it functions well, is that it manages to deliver on two key values at once: liberalism (the rule of law) and democracy (the rule of the people). With liberalism now under concerted attack from the Trump administration, which has declared war on independent institutions such as the FBI and has used the president’s pulpit to bully ethnic and religious minorities, it’s perhaps understandable that many thinkers are willing to give up a modicum of democracy to protect the rule of law and the country’s most vulnerable groups. If only it were that easy. As we saw in 2016, the feeling that power is slipping out of their hands makes citizens more, not less, likely to entrust their fate to a strongman leader who promises to smash the system. And as the examples of Egypt, Thailand, and other countries have demonstrated again and again, a political elite with less and less backing from the people ultimately has to resort to more and more repressive steps to hold on to its power; in the end, any serious attempt to sacrifice democracy in order to safeguard liberty is likely to culminate in an end to the rule of law as well as the rule of the people. The easy alternative is to lean in the other direction, to call for as much direct democracy as possible. The origins of the people’s displacement, the thinking goes, lie in a cynical power grab by financial and political elites. Large corporations and the superrich advocated independent central banks and business-friendly trade treaties to score big windfalls. Politicians, academics, and journalists favor a technocratic mode of governance because they think they know what’s best and don’t want the people to meddle. All of this selfishness is effectively cloaked in a pro-market ideology propagated by think tanks and research outfits that are funded by rich donors. Since the roots of the current situation are straightforwardly sinister, the solutions to it are equally simple: The people need to reclaim their power—and abolish technocratic institutions. This antitechnocratic view has currency on both ends of the political spectrum. On the far left, the late political scientist Peter Mair, writing about Europe, lamented the decline in “popular” democracy, which he contrasted with a more top-down “constitutional” democracy. The English sociologist Colin Crouch has argued that even anarchy and violence can serve a useful purpose if they seek to vanquish what he calls “post-democracy.” The far right puts more emphasis on nationalism, but otherwise agrees with this basic analysis. In the inaugural issue of the journal American Affairs, the self-styled intellectual home of the Trump movement, its founder Julius Krein decried “the existence of a transpartisan elite,” which sustains a pernicious “managerial consensus.” Steve Bannon, the former White House chief strategist, said his chief political objective was to return power to the people and advocated for the “deconstruction of the administrative state.” Mair and Crouch, Krein and Bannon are right to recognize that the people have less and less hold over the political system, an insight that can point the way to genuine reforms that would make our political system both more democratic and better functioning. One of the reasons well-intentioned politicians are so easily swayed by lobbyists, for example, is that their staffs lack the skills and experience to draft legislation or to understand highly complex policy issues. This could be addressed by boosting the woefully inadequate funding of Congress: If representatives and senators were able to attract—and retain—more knowledgeable and experienced staffers, they might be less tempted to let K Street lobbyists write their bills for them. Similarly, the rules that currently govern conflicts of interest are far too weak. There is no reason members of Congress should be allowed to lobby for the companies they were supposed to regulate so soon after they step down from office. It is time to jam the revolving door between politics and industry. Real change will also require an ambitious reform of campaign finance. Because of Citizens United, this is going to be extremely difficult. But the Supreme Court has had a change of heart in the past. As evidence that the current system threatens American democracy keeps piling up, the Court might finally recognize that stricter limits on campaign spending are desperately needed. For all that the enemies of technocracy get right, though, their view is ultimately as simplistic as the antidemocratic one. The world we now inhabit is extremely complex. We need to monitor hurricanes and inspect power plants, reduce global carbon emissions and contain the spread of nuclear weapons, regulate banks and enforce consumer-safety standards. All of these tasks require a tremendous amount of expertise and a great degree of coordination. It’s unrealistic to think that ordinary voters or even their representatives in Congress might become experts in what makes for a safe power plant, or that the world could find an effective response to climate change without entering cumbersome international agreements. If we simply abolish technocratic institutions, the future for most Americans will look more rather than less dangerous, and less rather than more affluent. It is true that to recover its citizens’ loyalty, our democracy needs to curb the power of unelected elites who seek only to pad their influence and line their pockets. But it is also true that to protect its citizens’ lives and promote their prosperity, our democracy needs institutions that are, by their nature, deeply elitist. This, to my mind, is the great dilemma that the United States—and other democracies around the world—will have to resolve if they wish to survive in the coming decades.

**Strength of US institutions solves conflict**

**Kasparov**, Chairman of the Human Rights Foundation, **2/16/2017**

Garry, “Democracy and Human Rights: The Case for U.S. Leadership” http://www.foreign.senate.gov/imo/media/doc/021617\_Kasparov\_%20Testimony.pdf

The Soviet Union was an existential threat, and this focused the attention of the world, and the American people. There existential threat today is not found on a map, but it is very real. The forces of the past are making steady progress **against the modern world order**. **Terrorist movements** in the Middle East, **extremist parties** across Europe, a paranoid tyrant in **North Korea** **threatening nuclear blackmail**, and, at the center of the web, an aggressive KGB dictator in **Russia**. They all want to **turn the world back to a dark past because their survival is threatened by the values of the free world,** epitomized by the United States. And they are thriving as the U.S. has retreated. The global freedom index has declined for ten consecutive years. No one like to talk about the United States as a global policeman, but this is what happens when there is no cop on the beat. American leadership **begins at home**, right here. America cannot lead the world on democracy and human rights **if there is no unity on the meaning and importance of these things**. Leadership is required to make that case clearly and powerfully. Right now, Americans are engaged in politics at a level not seen in decades. It is an opportunity for them to rediscover that making America great begins with believing America can be great. The Cold War was won on American values that were shared by both parties and nearly every American. Institutions that were created by a Democrat, Truman, were triumphant forty years later thanks to the courage of a Republican, Reagan. This bipartisan consistency created the decades of **strategic stability** **that is the great strength of democracies**. Strong institutions that outlast politicians **allow for long-range planning**. In contrast, dictators can operate only tactically, not strategically, because they are not constrained by the balance of powers**, but cannot afford to think beyond their own survival**. This is why a dictator like Putin has an advantage in chaos, the ability to move quickly. This can only be met by strategy, by long-term goals that are based on shared values, not on polls and cable news. The fear of making things worse has paralyzed the United States from trying to make things better. There will always be setbacks, but the United States cannot quit. The spread of democracy is the **only proven remedy for nearly every crisis that plagues the world today. War, famine, poverty, terrorism**–all are **generated and exacerbated by authoritarian regimes**. A policy of America First inevitably puts American security last. American leadership is required because there is no one else, and because it is good for America. There is no weapon or wall that is more powerful for security than America **being envied, imitated, and admired around the world**. Admired not for being perfect, but for having the exceptional courage to always try to be better. Thank you

**Citizen Petitioning**

**An expansive *Noerr-Pennington* doctrine immunizes anticompetitive citizen petitions aimed at delaying generic drugs approval**

**Kobayashi 20** (Bruce H. Kobayashi, Professor of Law, George Mason University, Antonin Scalia Law School, Antitrust Exemptions and Immunities in the Digital Economy, 10-4,

<https://gaidigitalreport.com/2020/10/04/exemptions-and-immunities/>, y2k)

The **H**atch-**W**axman **A**ct created a distinct regulatory scheme for securing **FDA approval** for pharmaceutical drugs—a scheme further complicated by patent and antitrust overlays.[175] The **citizen petition** process, which allows interested parties to **comment** on drug applications, may be used **anticompetitively**, much like **sham litigation**.

Pharmaceutical companies must obtain FDA approval before marketing new drugs. To market a new drug, a company must file a New Drug Application (NDA).[176] The NDA contains a list of patents associated with the new drug.[177] Subsequently, a generic manufacturer may file an **A**bbreviated **N**ew **D**rug **A**pplication (ANDA).[178] During the ANDA process, the generic manufacturer often selects what is called **Paragraph IV** certification—an attestation that the brand name drug’s patents are **invalid**, thus generic entry is **unhindered**.[179] Importantly, Paragraph IV certification is **incentivized** by a 180-day exclusivity window granted to the **first** ANDA applicant.[180]

Obviously, the patent holders (brand name drugs) accrue significant profits during the **life** of their patents. **An early challenge** to those patents **threatens** to **cut off** substantial amounts of **revenue**. Not surprisingly, then, brand name manufacturers employ various techniques to extend this period of exclusivity. One such technique is **the filing of citizen petitions to the FDA**, a process grounded in the **right to petition** and the **A**dministrative **P**rocedure **A**ct.[181] The FDA receives comments on ANDA applications and some brand name manufacturers have used this process to attempt to **delay** generic entry.[182] In addition to citizen petitions, a brand name manufacturer may file a patent infringement lawsuit against the party who filed the Paragraph IV certification. In fact, the decision to do so triggers a thirty-month stay, incentivizing brand name manufacturers to file lawsuits defending their patents.

When considering an ANDA, the FDA must assess whether the proposed generic drug is a bioequivalent to the brand name drug.[183] Thus, some brand name manufacturers use the citizen petition process to argue that the generic drug is not bioequivalent. In some cases, these petitions are **frivolous**.[184] Clearly, the brand name manufacturer’s aim is to **delay** the entry of generic competition;[185] **yet, this practice is presumptively immunized by Noerr-Pennington**. Importantly, the FDA must resolve citizen petitions within 180 days—a timeline intended to limit the dilatory effect of citizen petitions—though it does not always meet the deadline.[186] And although federal law allows the FDA to **disregard** blatantly dilatory petitions, in 2013, it had **yet** to do so.[187]

**Noerr-Pennington** broadly protects brand name manufacturers who attempt to **forestall** generic entry by filing citizen petitions. The **sham exception** only activates when the petition is **objectively baseless**. But this standard is **elusive**.

For example, in Louisiana Wholesale Drug Co. v. Sanofi-Aventis, the district judge instructed the jury that a citizen petition was not objectively baseless if “a reasonable pharmaceutical manufacturer could have realistically expected the FDA to grant [the] relief sought.”[188] Reviewing Sanofi-Aventis’ motion for judgment as a matter of law, the district court concluded that a reasonable jury could have found that the petition was not objectively baseless.[189] As this case illustrates, whether a petition is baseless will often be an inquiry purely decided by the factfinder.

Given the **fact-intensive** nature of citizen-petition **sham analysis**, a brand name manufacturer who files a citizen petition with a sound scientific basis is **less likely** to face antitrust liability.[190] On the flip side, if a citizen petition contains unsupported or faulty scientific evidence, the citizen petition is more likely to be found a sham.[191]

Another **pivotal aspect** of the sham analysis for citizen petitions centers on the **second prong of the PRE test**, which focuses on the defendant’s **intent**. Therefore, business documents discussing the citizen petition and the impetus for its submission will often be influential.[192]

Brand name manufacturers may also file patent infringement suits to challenge generic manufacturers that file Paragraph IV certifications. If the brand name manufacturer chooses to sue within 45 days, a 30-month stay halts the ANDA unless the patent expires or a court holds the patent invalid.[193] When faced with a patent infringement suit, some generic manufacturers respond with antitrust counterclaims. Presumably, the brand-name manufacturer’s lawsuit is **immunized** by Noerr-Pennington, but the PRE test still applies, determining whether the litigation falls within the **sham** exception.

Recently, **the Third Circuit** discussed the **sham exception** within the ANDA context, noting that, in some ways, it is more **difficult** to establish it in the **ANDA** context.[194] In FTC v. AbbVie, Inc., the court observed that Paragraph IV certifications are, by definition, infringing acts, thus a suit in response “could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification.”[195] Further, the court recognized that the **H**atch-**W**axman **A**ct deliberately incentivizes brand-name manufacturers to **sue**, thereby reducing the **likelihood** that serial lawsuits by brand-name manufacturers were brought with **anticompetitive** intent. In sum, the **H**atch-**W**axman **A**ct creates **a nuanced regulatory environment** where **Noerr-Pennington** still applies **but** presents additional hurdles for **antitrust plaintiffs** seeking to **overcome** immunity.

**Citizen petitions are a key avenue to delay drugs for years**

**Feldman et al**. **2018**. Robin Feldman - Harry & Lillian Hastings Professor of Law & Director of the Institute for Innovation Law, University of California Hastings College of the Law. John Gray - Program Associate, Institute for Innovation Law, University of California Hastings College of the Law. Giora Ashkenazi - Research Fellow, Institute for Innovation Law, University of California Hastings College of the Law. “Empirical Evidence of Drug Companies Using Citizen Petitions to Hold Off Competition” <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3116986>

IV.RESULTS The results of the study provide empirical evidence that the citizen petition process at the FDA has become a **key avenue** for strategic behavior by pharmaceutical companies to delay entry of generic competition. A. Rise in Citizen Petitions with the Potential to Delay As seen in Table I below, a notable percent of citizen petitions seems to have the potential to delay generic entry. Looking at the overall number of citizen petitions filed at the FDA on any topic, fourteen percent have the potential to delay a generic drug application, climbing to roughly twenty percent in some years. That means one in five of all citizen petitions to the FDA – not just those concerning pharmaceuticals – have the potential to delay generic competition in some years. This table also shows that starting around 2003 and 2004, petitions rose in popularity as a way to delay generics or raise issues about generics. Not only did the number of citizen petitions rise noticeably after 2002, but the number of delay-related petitions also sharply increased as a proportion of all petitions. [Table Omitted] B. When are Citizen Petitions Filed in Relation to Final Approval? The results also demonstrate that many drug companies are filing citizen petitions as a last-ditch effort in the period immediately before generic approval. Moreover, the timing suggests that **many of these citizen petitions appear to be the very last barriers standing in the way of final generic approval**. These implications emerged when we graphed the amount of time between when a citizen petition was filed and when the generic application was approved. In particular, our original hypothesis was that if citizen petitions are being used systematically to delay the approval of generics, petitions might be deployed most effectively for that purpose near the end of a generic approval cycle. If filed earlier, the petition could merely introduce a review process running parallel to the rest of the generic approval process. The data confirm this hypothesis. As seen in Figure I below, there is a clear trend in favor of citizen petitions filed shortly before the FDA approves a generic. In fact, the most common category was “0–6 months,” with 33 petitions, or 21 percent of the total,15 filed with up to six months or less remaining before the FDA approved the generic. Considering that **the average length of time from generic filing to approval is roughly four years**, this category occurs most often during the last leg of the approval process. In other words, the trend is toward an increasing number of petitions as one moves closer to the final approval date. Thus, this histogram suggests that delay-related citizen petitions are often filed in the final stages of generic approval to raise concerns at the last minute, rather than early or midway through the process. This pattern potentially extends the length of the generic application approval process, thus delaying the market entry of generic competition. [Table Omitted]

**And they’re a key driver of increased prices**

**Nadler 2020**. American lawyer and politician serving as the U.S. Representative for New York's 10th congressional district since 2013. A member of the Democratic Party, he is in his 15th term in Congress. “Stop Significant And Time-Wasting Abuse Limiting Legitimate Innovation Of New Generics Act” <https://www.govinfo.gov/content/pkg/CRPT-116hrpt694/html/CRPT-116hrpt694.htm>

\*footnotes omitted\*

Background and Need for the Legislation The FDA's citizen petition procedures were established to provide concerned citizens with an opportunity to solicit agency action regarding health and safety policy.\1\ The process, which is open to anyone, allows individuals to request that the FDA ``issue, amend, or revoke a regulation, or order or take or refrain from taking any other form of administrative action.''\2\ While various entities have used the citizen petition process to raise a variety of necessary health and safety issues, certain brand-name drug manufacturers have manipulated the process to stifle generic competition. For example, some branded manufacturers have responded to applications for drug approval by generic competitors by filing citizen petitions that question the safety, efficacy, and bioequivalence standards for approving generic drugs.\3\ Because the FDA must review and respond to every citizen petition it receives, including supplements or amendments to petitions,\4\ makers of generic drugs accordingly report that unwarranted petitions may cause manufacturing stoppages or significant delays in the FDA approval process.\5\ Studies have concluded that **while these petitions often lack merit, they can be very effective at delaying the entry of lower-cost generic competitors**.\6\ According to the FTC, abuse of this system allows some drug companies to unlawfully maintain a monopoly by delaying generic entry.\7\ For example, this abusive tactic has allegedly been used to delay life-saving treatments for opioid addiction and gastrointestinal infections.\8\ **Leading healthcare experts also agree that sham petitions are a significant driver of high prescription drug prices**. Dr. Aaron Kesselheim of Harvard Medical School testified last Congress that this abusive conduct can ``substantially delay[] entry of a more affordable generic product.''\9\ Professor Robin Feldman of the University of California at Hastings also found ``empirical evidence that the citizen petition process at the FDA has become a key avenue for strategic behavior by pharmaceutical companies to delay entry of generic competition.''\10\ Several witnesses discussed this problem at a Subcommittee on Antitrust, Commercial, and Administrative Law hearing this Congress.\11\ Congress previously attempted to stem the abuse of the FDA's citizen petition process. In 2007, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) to help prevent citizen petitions from being used to delay generic entry.\12\ The 2007 amendments authorized new regulations and required the FDA to respond to citizen petitions concerning generic applications within 180 days (shortened to 150 days in 2012);\13\ required that petition filers certify the petition's submission was not intentionally delayed; and authorized the FDA to summarily deny such petitions in certain circumstances.\14\ Although imposing a 150-day deadline for the FDA to respond may have reduced the length of delay, it--and other changes described above--have arguably failed with respect to deterring the behavior. The FDA recently reported to Congress that it ``continues to be concerned that section 505(q) does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues.''\15\ In support of this concern, based on data available in 2017, then-FDA Commissioner Scott Gottlieb suggested that the imposition of the 150-day deadline ``had limited impact in discouraging the submission of petitions intended primarily to block or delay generic competition.''\16\ The FTC has also tried to address the problem of sham citizen petitions. In 2017, the FTC filed a complaint alleging that Shire ViroPharma Inc. abused the citizen petition process to illegally maintain a monopoly on Vancocin Capsules, a drug used to treat a potentially life-threatening gastrointestinal infection.\17\ According to the FTC, ``[f]acing the threat of generic competition to its lucrative franchise, ViroPharma inundated the FDA with regulatory and court filings--forty-six in all--to delay the FDA's approval of generic Vancocin Capsules.''\18\ **The FTC complaint further states that** these ``**repetitive, serial, and meritless filings** lacked any supporting clinical data,'' but, nonetheless, ``**succeeded in delaying generic entry at a cost of hundreds of millions of dollars to patients and other purchasers**.''\19\ On March 20, 2018, the district court dismissed the complaint and, according to the FTC's appellate brief, ``held that no matter how egregious a defendant's past violation, the FTC cannot sue to enforce [section 13 of] the FTC Act unless it alleges facts showing that a further violation is not just reasonably likely but imminent.''\20\ On appeal, the Third Circuit Court of Appeals affirmed the district court's order of dismissal.\21\ The courts' narrow reading of section 13(b) could make it harder for the FTC to address wrongdoing by drug companies that have filed sham petitions. **Notably**, neither the district court nor the court of appeals reached the merits of whether ViroPharma's conduct violated antitrust law beyond the district court finding that the allegations, taken as true, **were sufficient to overcome the Noerr-Pennington presumption of antitrust immunity for government** petitions.\22\

**Delays in generic competition contributes to soaring drugs and health care costs and undermines access to medications**

**Rome 20** (Dr. Benjamin Rome is a primary care physician and health policy researcher. He is currently a postdoctoral fellow study prescription drug pricing and utilization with the Program On Regulation, Therapeutics, And Law (PORTAL) at Brigham and Women’s Hospital and Harvard Medical School, To Cut Prescription Drug Spending, Stop Delays for Generic Competition, 7-24, <https://blog.petrieflom.law.harvard.edu/2020/07/24/prescription-drug-costs-generic-competition/>, y2k)

**Prescription drug spending** in the U.S. remains **high** and **continues to rise**, accounting for about **20%** of national health expenditures. While generic competition is **crucial** for reducing **drug prices**, brand-name drug manufacturers can utilize several strategies to delay such competition by increasing the length of market exclusivity for their drugs.

Although **brand-name drugs** only account for 18% of all prescriptions filled, they comprise **78% of total drug spending**. By contrast, equally-effective, **interchangeable generic drugs** can offer discounts of up to **80% off** their brand-name drug counterparts.

Generic competitors can only be introduced after brand-name drugs have completed their period of market exclusivity, which typically lasts 12-16 years and is largely determined by the patents covering the drug. Brand-name pharmaceutical manufacturers have strong **financial incentives** to prolong this market exclusivity period and delay entry of generic products.

One commonly employed approach is for a brand-name manufacturer to obtain multiple patents—some issued after the original drug goes on the market—that protect different features of the same drug, such as how the drug is used, alternate chemical formulations, or delivery devices. This creates a **thicket of intellectual property protections** that generic manufacturers must challenge in court for their product to reach the market. These cases are often protracted and costly for generic manufacturers, but can also result in **settlements**, including some in which the brand-name manufacturer pays the generic manufacturer in cash or other deals to stave off generic entry (known commonly as “**pay-for-delay” settlements).**

In some cases, drug manufacturers introduce a slightly different version of their drug (like a long-acting formulation) with even more patent protections. Manufacturers then vigorously encourage physicians and patients to switch to the new version as time nears for generic entry of the original version, a strategy known as “product hopping.”

These strategies to **delay** generic competition have **substantial consequences** for patient out-of-pocket prescription drug costs and total prescription drug spending in the U.S. A recent study in Health Affairs found that Medicaid (which represents 10% of all US drug spending) spent an estimated $761 million over seven years on 31 drugs for which generic entry was delayed.

Perhaps more startling is how much the delay in generic competition for **a single drug** can cost the **entire health system**. In the case of glatiramer acetate, a commonly-used treatment for multiple sclerosis, the drug’s manufacturer effectively extended exclusivity of the brand-name drug by 2.5 years by introducing a new formulation with a different dosing regimen just before generic competition was supposed to begin. A new study in JAMA Internal Medicine found that this “product hop” resulted in $4.3 to $6.5 billion in excess U.S. health care spending since 2015.

As prescription drug spending continues to rise and concerns about patient affordability grow, ensuring that brand-name drugs face **timely generic competition** is essential to maintaining **fair access** to drugs at **reasonable** prices. Doing so will require policy changes that prevent manufacturers from unreasonably extending market exclusivity for their products while still encouraging incremental improvements to existing drugs that can improve patient care. So, what can be done?

The most obvious solutions involve re-examining the system that allows drug manufacturers to obtain numerous different patents on their drugs. This can be done a few different ways.

We know that many later-issued patents used to create thickets around prescription drugs end up being overturned in court (when there is no settlement). The U.S. Patent and Trademark Office, which reviews and approves patents, could reconsider its standards for issuing drug patents. An administrative procedure to review patents called inter partes review was created in 2011 to facilitate re-examination of patents after they have been issued. Firmer patent standards would make sure that new patents protect true innovations.

Another proposal would be to restrict drug manufacturers to only a single patent against generic entrants. This “one patent, one drug” option would still allow drug developers a monopoly period—during which they can recoup their research investments—but would prevent them from gaining additional patents to extend exclusivity once the drug is already on the market.

Delays in generic competition carry **a sizeable financial burden** for both patients and the health care system. This burden falls disproportionately upon certain patients who require high-cost, brand-name drugs. When generic competition is delayed, these drug prices remain high and access is restricted to only the patients who can afford them.

As a result, delayed generic competition can deepen already-existing health disparities. For example, mortality from opioid use disorder is associated with markers of lower socioeconomic status. Yet the manufacturer of Suboxone—a critical yet underused medication to treat opioid use disorder—delayed generic competition by heavily promoting a dissolvable film version over the original dissolvable tablet.

This move limited access to generic versions of the drug from 2013 until 2018, and Suboxone’s manufacturer recently agreed to a $1.4 billion settlement after the U.S. Justice Department filed charges that they had fraudulently promoted the film version as safer and less prone to abuse than the tablet version. This promotion led to continued use of the high-cost brand-name drug, and high costs may have contributed to underuse and non-adherence to this life-saving medication, particularly among socioeconomically-disadvantaged patients.

**Timely generic competition** will ensure **fairer** and more **equitable access** to prescription drugs at reasonable prices and that the benefits and **burdens of innovation** will be more **fairly distributed** without unduly harming certain patient populations.

**Generic drugs** have saved the U.S. health care system **$1.6 trillion dollars** over the last decade. However, to ensure these **savings continue**, generic drugs must be allowed to enter the market in a **timely fashion**, and current policies afford brand-name manufacturers a number of tools to undermine generic competition and sustain their monopoly periods.

Delays in generic competition are currently costing **billions** of dollars, harming patients, and increasing disparities and inequities in access to care. Changing patent policy to prevent manufacturers from using these strategies represents an important yet overlooked strategy to reverse rising drug prices and ameliorate the associated economic, clinical, and ethical ramifications.

**Key to widespread cell therapy during crisis**

**Shulka et al 19** (Vaishali Shukla Chapman University Enrique Seoane-Vazquez Chapman University, seoanevazquez@chapman.edu Souhiela Fawaz Chapman University, sfawaz@chapman.edu Lawrence M. Brown Chapman University, lbbrown@chapman.edu Rosa Rodriguez-Monguio University of California, San Francisco, “The Landscape of Cellular and Gene Therapy Products: Cost, Approvals, and Discontinuation”, https://digitalcommons.chapman.edu/cgi/viewcontent.cgi?article=1644&context=pharmacy\_articles)

Background Cell and gene therapy products belong to a diverse class of biopharmaceuticals known as advanced therapy medicinal products. Cell and gene therapy products are used for the treatment and prevention of diseases that until recently were only managed chronically. The objective of this study was to examine the characteristics of market authorizations, discontinuations and prices of cellular and gene therapy products worldwide. Data and Methods We conducted an electronic search of authorized cell, tissue engineered and gene therapy products from the databases of the main drug regulatory agencies. The analysis excluded hematopoietic progenitor cell cord blood products authorized by the US FDA. Price information was derived from the Red Book (Truven Health Analytics) for the US and from health technology assessment agencies, other public sector sources in Europe and company news. We also searched the scientific literature for authorizations, discontinuations and price information using MEDLINE/PubMed, Cochrane Library, Google Scholar, and EMBASE databases. All cost data were converted to US dollars. Descriptive analysis was conducted in this study. Results There were 52 different cell, tissue engineering and gene therapy products with 69 market authorizations in the world as of December 31, 2018. The products included 18 (34%) cell therapies, 23 (43.4%) tissue engineered products and 12 (22.6%) gene therapies. December 31, 2018. There were 21 (30.4% of all authorizations) cell therapy, 26 (37.7%) tissue engineered and 22 (31.9%) gene therapy market authorizations. The EMA withdrew the authorization for 2 tissue engineering products, 1 cell therapy and 1 gene therapy, and New Zealand lapsed approval of 1 cell therapy. Most products were first authorized after 2010, including 10 (83.3%) gene therapies, 13 (72.2%) cell therapies and 13 (56.5%) tissue engineered products. The treatment price for 4 allogenic cell therapies varied from $2,150 in India to $200,000 in Canada. The treatment price for 3 autologous cell therapies ranged from $61,500 in the UK to a listed price of $169,206 in the US. Tissue engineered treatment prices varied from $400 in South Korea to $123,154 in Japan. Gene therapy treatment prices ranged from $5,501 for tonogenchoncel‐L in South Korea to $1,398,321 for alipogene tiparvovec in Germany. Conclusions A significant number of new cell, tissue and gene therapies have been approved in the past decade. Most products were conditionally authorized and targeted rare cancers, genetic and other debilitating diseases. However, there are also products approved for cosmetic reasons. Cell, tissue and gene therapies are **among the most expensive therapies available**. Health care systems **are not prepared to assume the cost of future therapies** for a myriad of rare diseases and common diseases of **epidemic proportions**

**Cell therapy is key to make cancer, tuberculosis, and drug resistance.**

Off-target effects & dosage problems make small molecules inefficient for innovative R&D

**Fischbach et al 13** – Michael A., Associate Professor of Bioengineering at Stanford University and a member of the California Institute for Quantitative Biosciences, Ph.D. in Chemistry and Chemical Biology from Harvard University (2007), working in Christopher T. Walsh’s laboratory at Harvard Medical School on iron acquisition in bacterial pathogens and the biochemistry of natural product biosynthesis Jeffrey A. Bluestone is a Professor of Metabolism and Endocrinology and the Director of the Hormone Research Institute in the Diabetes Center at the University of California, San Francisco. He earned his B.S. in Biology and M.S. in Microbiology from Rutgers University in 1974 and 1977 respectively and his Ph.D. in Immunology from Weill Cornell Graduate School of Medical Sciences in 1980 with Carlos Lopez. Wendell Lim Ph.D. is a Professor of Cellular and Molecular Pharmacology at University of California, San Francisco. He is the Director of the UCSF/UCB NIH Nanomedicine development center and director of the SynBERC. He earned his A.B. in Chemistry from Harvard University and his Ph.D in biochemistry and biophysics from Massachusetts Institute of Technology under the guidance of Bob Sauer.[2] He then did his postdoctoral work with Frederic Richards at Yale University ("Cell-based therapeutics: the next pillar of medicine." *Science translational medicine* 5.179 (2013): 179ps7-179ps7)

The advent of **biologics**—recombinant hormones, soluble receptors, and antibody-based drugs—transformed the pharmaceutical industry. Once supported largely by a single pillar—**small-molecule drug discovery**—the industry now had a second foundational structure. Biologics paved the way to a broad range of new targets, functional capabilities, and disease applications and now represent a large fraction of new medicines brought to market. Today, biomedical science stands poised at the threshold of another pharmaceutical frontier: **cell-based therapies**. In this Perspective, we discuss the potential power of this new pillar of human therapeutics. BUILDING A THIRD PILLAR Historically, the establishment of a new pillar in the drug industry has been preceded by the emergence of a foundational engineering science. The shift from the use of natural products in drug screens to the small-molecule industry of today required the development of synthetic organic chemistry as a foundational science. In this realm, the singular innovation of Big Pharma was their definition and mastery of the science of turning small molecules into drugs: discovering or designing and synthesizing lead compounds that bind biological targets of interest; optimizing a drug’s target-binding properties, pharmacokinetics (PK), and pharmacodynamics (PD); and mitigating toxicity. The first biological therapeutics were natural proteins, such as purified porcine insulin and largely uncharacterized polyclonal antibodies. The modern biologics industry (which began in the early 1980s) was built on the molecular biology revolution, the creation of monoclonal antibody technology, and the foundational science of protein engineering. But the development of biologics exploded only after key start-up companies such as Genentech, Genzyme, and Amgen developed world-class expertise in an area that was entirely distinct from that of Big Pharma: designing and producing highly functionally optimized recombinant proteins. Today, biomedical science sits on the cusp of **another revolution**: the use of **human and microbial cells** as therapeutic entities (1). In principle, cells have therapeutic capabilities that are distinct from those of small molecules and biologics and that extend beyond the regenerative-medicine arena. **Part drug** and **part device**, cells can sense diverse signals, move to specific sites in the body, integrate inputs to make decisions, and execute complex response behaviors—**all in the context of a specific tissue environment**. These attributes could potentially be harnessed to treat **infections**, **autoimmunity**, **cancers**, **metabolic diseases**, and **tissue degeneration** as well as **realizing tissue repair and regeneration**. Indeed, pioneering clinical trials have highlighted the benefits of using cells as therapeutic agents (2–7). However, the complexity of cells and the challenge of controlling their actions in a therapeutic setting provide daunting scientific, regulatory, economic, and cultural obstacles to the establishment of cells as a widespread and viable pharmaceutical platform. With our deep mechanistic understanding of cellular systems biology, researchers are poised to harness these intricate behaviors in new ways to generate an array of precisely regulated weapons against a broad range of diseases. However, a critical step that will enable the emergence of cells as the next therapeutic pillar is the development of cellular engineering as a foundational science. This will include mechanisms for editing and recoding genomes, the assembly of a toolkit of molecular parts and regulatory modules that behave predictably, and a systems-based theoretical framework that can provide strategies for tuning and optimizing cellular behaviors. HOW WHOLE CELLS TRUMP THEIR PARTS If small molecules and biologics are tools, then cells are carpenters—and architects and engineers as well. Of the three pillars, only cells sense their surroundings, make decisions, and exhibit varied and regulable behaviors (Table 1). Devices share some of these advantages; indeed, some abiotic therapeutic nanodevices mimic cellular behaviors, although these equally fascinating new therapeutic candidates will not be discussed here. Cells naturally perform therapeutic tasks The human body has three kinds of natural agents that perform the tasks we demand of therapeutics. The first two are small molecules (for example, neurotransmitters) and biologics (such as antibodies, growth factors, cytokines, and peptide hormones). Cells are the third—and the only ones that can perform complex biological functions. For example, macrophages engulf pathogens and recruit adaptive immune cells; hematopoietic stem cells give rise to myeloid and lymphoid lineages; chondrocytes produce a cartilaginous extracellular matrix; pancreatic β cells sense glucose and respond by producing insulin; and gut bacteria convert indigestible fibers into short-chain fatty acids that fuel intestinal epithelial cells. Cell behavior is exquisitely selective Most small molecules and biologics are always active; they do not have ON or OFF switches, and if they reach their target, they will bind it and exert a biological effect. In contrast, cells sense their environment and respond with an action only when in the presence of a specific array of molecular inputs. Thus, cells can have exquisite sensitivity and specificity, which impart a greater ability to limit off-target action. Engineering and controlling key cellular receptors and how their signals are processed could, in principle, allow customization of responses such that only therapeutically relevant signals trigger activation of a selected cellular behavior (8). Cells are special delivery agents PK and PD properties and metabolism determine where in the body small molecules and biologics distribute. The inability to limit their distribution to a single tissue or cell type often results in off-target effects, which can be serious enough to **end a drug-development program**, **even at a costly late stage**. For example, the insulin sensitization activity of rosiglitazone, a peroxisome proliferator-activated receptor (PPAR)–γ ligand, results from its activity in adipocytes, but the increased risk of myocardial infarction observed in some patients arises from the drug’s action in cardiac cells. Although rare, **this outcome has had a chilling effect on drug sales and on the development of other PPAR-γ–targeted drugs**. Cells are **less likely to have off-target effects because they can selectively recognize and actively migrate** toward specific signals and exert their effects in a highly targeted manner. One can imagine an ideal cellular agent that is engineered to produce a PPAR-γ ligand, but only in the **local environment** of adipocytes. Cells can handle human genetic variability Determining the right dose of a drug for a diverse patient population can be challenging. Common polymorphisms in genes that encode drug transporters or drug-metabolizing cytochromes P450 can tweak the transport of a small molecule in and out of cells or alter drug metabolism, respectively; as a result, the same dose of a small molecule can, in different individuals, result in widely varying amounts of the active metabolite reaching its target. For example, common polymorphisms in the gene that encodes organic cation transporter 1 (OCT1) lead to reduced uptake of the type 2 diabetes drug metformin, resulting in differences in the efficacy of metformin among individuals (9). In contrast, **cells** could potentially be engineered to automatically adjust to differences in host metabolism and transport by harboring a rheostat-like circuit that produces more of a molecule when needed and degrades the excess when a threshold concentration is exceeded. Thus, in principle, cells could yield therapeutic responses that are **less variable** in different individuals. Cell behaviors can be engineered To manage their disease, patients with autoimmune (type 1) diabetes (T1D) have to monitor their blood sugar, inject insulin, and limit their diets. Failure to control T1D can have grave consequences, including blindness, limb amputation, and death. Because T1D results from the autoimmune destruction of insulin-synthesizing pancreatic β cells, simply replacing these cells is not a viable therapeutic strategy. Instead, introducing a cell that has been engineered to perform an unnatural yet important task—for example, a T lymphocyte that has been modified to sense glucose and produce insulin—is a provocative alternative. Such a cell is potentially within the reach of synthetic biology and, if it relieved the insulin dependency of T1D patients, would represent a major therapeutic breakthrough. For the subset of T1D cases characterized by the presence of autoantibodies that recognize and destroy insulin, this cell might be engineered to produce an insulin derivative that recognizes and modulates the activity of insulin receptors but evades binding by insulin autoantibodies. KILLER APPS FOR CELL THERAPY Although small molecules and biologics will always have important therapeutic niches, there are applications for which cells are better equipped. This section explores critical unmet needs in human disease that **cell-based therapeutics** are uniquely well suited to address (Fig. 1). We focus on three specific cases, although there are arrays of other promising applications that are not discussed here, including stem cell and dendritic-cell therapeutics, which have been the subjects of numerous reviews (10–13). Two of these cases are built on recent pioneering examples of cell-based therapies that have demonstrated clinical efficacy: chimeric antigen receptor (CAR)–modified T cells and fecal transplantations. Immune cells that seek and destroy cancer The **most effective new small-molecule** (kinase inhibitors) and biologic (antibody) cancer therapies offer as little as 6 to 36 months of disease-free survival before **cancer progression** (14, 15). Therefore, one of the major challenges for cancer therapy is to block the growth of drug-tolerant or resistant cancer cells that underlie progression and to kill metastatic cells that have broken free of the primary tumor mass and intravasated into a blood or lymphatic vessel. Combination therapies that prevent the outgrowth of resistant cells are one possible therapeutic avenue, but **small molecules and biologics have a difficult time being sentinels**. They cannot turn themselves on and off, and so they rely entirely on specific molecular recognition to determine whether or not they act. And because the target cell can evolve **resistance mechanisms** (14), the therapeutically useful lifetime of a small molecule or biologic is limited. The job of detecting and destroying a shape-shifting **cellular target may be better suited to a cell-based therapeutic**. Recent clinical studies have shown the efficacy of using engineered T lymphocytes in treating chronic lymphoid leukemia (3, 4). The ex vivo-transformed T cells were modified to express a CAR in which the receptor extra-cellular targeting domain has been replaced by an single-chain antibody that recognizes a tumor-specific molecule. These and related studies: (7) (i) prove that it is possible to retarget immune cells to detect and respond to new, non-natural signals and (ii) establish T cells as a favorable chassis for engineering. Future versions of CAR-modified T cells may encode control circuits that enable them to be activated or deactivated in a small-molecule–dependent fashion and to produce a biologic that counteracts adverse side effects, such as cytokine storm (for example, an anti–IL-6 antibody). Establishment of **drug resistance** is less likely to be a problem for a sentinel cell therapeutic than for small molecules and biologics. A therapeutic cell could be engineered to recognize multiple features of a target cell so that changing any one of them would not be enough to evade detection (in effect, a combination therapy). Given the ability of a cell-based therapeutic to adapt to an evolving pathogen, cells may be a natural choice for other surveillance jobs as well, including seeking and destroying activated cells from chronic infections, such as a latent **Mycobacterium tuberculosis** population.

**Contagious cancer is a serious possibility and threatens the existence of our species**

**Johnson 16** – George Johnson, columnist and science journalist for the New York Times, M.A. in Journalism and Public Affairs, American University (“Scientists Ponder the Prospect of Contagious Cancer,” *New York Times*, February 22nd, https://www.nytimes.com/2016/02/23/science/scientists-ponder-the-prospect-of-contagious-cancer.html?mcubz=0)

For all its peculiar horror, cancer comes with a saving grace. If nothing else can stop a tumor’s mad evolution, the cancer ultimately dies with its host. Everything the malignant cells have learned about outwitting the patient’s defenses — and those of the oncologists — is erased. The next case of cancer, in another victim, must start anew. Imagine if instead, cancer cells had the **ability to press on to another body**. A cancer like that would have the power to **metastasize** not just from organ to organ, but **from person to person**, evolving deadly new skills along the way. While there is no sign of an imminent threat, several recent papers suggest that the eventual emergence of a contagious human cancer is in the realm of medical possibility. This would not be a disease, like cervical cancer, that is set off by the spread of viruses, but rather one in which **cancer cells actually travel from one person to another** and thrive in their new location. So far this is known to have happened only under the most unusual circumstances. A 19-year-old laboratory worker who pricked herself with a syringe of colon cancer cells developed a tumor in her hand. A surgeon acquired a cancer from his patient after accidentally cutting himself during an operation. There are also cases of malignant cells being transferred from one person to another through an organ transplant or from a woman to her fetus. On each of these occasions, the malignancy went no further. The only known cancers that continue to move from body to body, evading the immune system, have been found in other animals. In laboratory experiments, for instance, cancer cells have been transferred by mosquitoes from one hamster to another. And so far, three kinds of contagious cancers have been discovered in the wild — in dogs, Tasmanian devils and, most recently, in soft shell clams. The oldest known example is a cancer that spreads between dogs during sexual intercourse — not as a side effect of a viral or bacterial infection, but rather through direct conveyance of cancer cells. The state of the research is described in a review, “The Cancer Which Survived,” published last year by Andrea Strakova and Elizabeth P. Murchison of the University of Cambridge. The condition, canine transmissible venereal tumor disease, is believed to have sprung into existence 11,000 years ago — as a single cell in a single dog — and has been circulating ever since. (Why did this happen in dogs and not, say, cats? Perhaps because of what the authors demurely call the dogs’ “long-lasting coital tie” — the half an hour or so that a male and female are locked in intercourse, tearing genital tissues and providing the cancer cells with a leisurely crossing.) Normally a cancer evolves in a single body over the course of years or decades, accumulating the mutations that drive it to power. But to have **survived for millenniums**, researchers have proposed, canine cancer cells may have developed mechanisms — like those in healthy cells — to repair and stabilize their own malignant genomes. Early on, cancer cells typically flourish by disabling DNA repair and ramping up the mutational frenzy. Somewhere along the way, the age-old canine cells may have reinvented the device to **extend their own longevity**. There is also speculation that this cancer may have learned to somehow modify canine sexual behavior in ways that promote the disease’s spread and survival. The second kind of contagious cancer was discovered in the mid-1990s in Tasmanian devils, which spread malignant cells as they try to tear off one another’s faces. Though it may be hard to sympathize, devil facial tumor disease threatens the creatures with **extinction**. With so few examples, transmissible cancer has been easy to dismiss as an aberration. But in December, scientists at the Universities of Tasmania and Cambridge reported in Proceedings of the National Academy of Sciences that Tasmanian devils are passing around another kind of cancer — genetically distinct from the first. It’s weird enough that one such cancer would arise in the species. What are the chances that there would be two? One theory is that the animals are unusually vulnerable. Driven so close to extinction — by climate change, perhaps, or human predators — the species is lacking in genetic diversity. The cells of another devil injected through a vicious wound may seem so familiar that they are ignored by the recipient’s immune system. If some of the cells carry the mutations for the facial cancer, they might be free to flourish and develop into a new tumor. But the scientists also proposed a more disturbing explanation: that the emergence of **contagious cancer** may not be so rare after all. “The possibility,” they wrote, “warrants further investigation of the risk that **such diseases could arise in humans**.” Cancer has probably existed ever since our first multicellular ancestors appeared on Earth hundreds of millions of years ago. The life spans of even the longest-lived animals may be just too brief for cancers to easily evolve the ability to leap to another body. Otherwise, contagious cancer would be everywhere.

**Drug resistant TB is an existential risk – new therepies key**

It’s good to securitize MDR-TB while giving universal access to health care!

**Enemark 13** – Christian Enemark, Professor of International Relations at the University of Southampton, PhD in International Relations (“Drug-Resistant Tuberculosis: Security, Ethics and Global Health,” *Global Society*, Vol. 27, No. 2, pages 159-177, Available through Taylor & Francis)

Introduction

The worldwide spread of **drug-resistant** strains of tuberculosis (**TB**) bacteria (Mycobacterium tuberculosis) is **out of control** and incidents of harder-to-cure TB illness are rising. This article explores the present and potential impact of extensively drug-resistant tuberculosis (**XDR-TB**)—a **deadly, contagious and virtually incurable disease**—on human health and state capacity. Detected cases of XDRTB can occasion the implementation of extraordinary control measures, because some governments are sufficiently fearful of the disease as to frame it as an issue of national security. Such framing has the potential to precipitate more financial resources and stronger legal powers to bolster public health, but it might also increase the risk that emergency response measures will be counterproductive and/or unjust. XDR-TB arguably poses an **existential threat** to local health systems (and the populations they serve) **around the world**, so difficult and costly is it to contain and cure this disease. It is the premise of this article that dealing with the problem is a security challenge as much as (or more than) a humanitarian one; controlling XDR-TB is not only about compassion, it is also about survival. Accordingly, this warrants the implementation of emergency measures that go beyond human rights rules and economic norms that would otherwise restrain government decision making. Framing XDR-TB as a security issue is empirically plausible, and doing so is a good thing provided that increased response efforts promote rather than hinder the **provision of universal access to adequate TB treatment** over the long term.

The article begins by outlining the ways in which policy makers and scholars have sought to draw a link between security and infectious diseases generally. In order to assess the plausibility of framing XDR-TB specifically in security terms, it is necessary first to understand the disease’s current and likely impact in public health terms. Beyond assessment of the morbidity, mortality and associated economic burden imposed by XDR-TB, the article then explores two disease control measures that are motivated particularly by security concerns (as distinct from mere health- and/or economy-oriented motivations). These measures are border control and patient isolation. Both involve curtailing individuals’ freedom of movement for the purpose of preventing or delaying contagion, so it is important to assess each measure by reference to public health ethics. Informing this ethical assessment is the notion that a person infected with a contagious disease like XDR-TB is both threatened and threatening. On the one hand, that person is a disease vector from whom the broader population should be protected (an immediate greater good). On the other hand, he or she is also a disease victim (and the bearer of human rights to life and liberty) whose health and wellbeing should be protected (an immediate individual good). A policy dilemma arises as regards the relative importance of achieving each immediate good. The diffi- culty is compounded by the notion that two long-term, greater goods are also at stake: public confidence in health systems and in the protection of individual rights.

Infectious Diseases, Security and Ethics

The idea of linking health and security concerns, as a matter of academic inquiry and public policy, has received support from two directions. For some members of the public health and human development sectors, the language of security is a means of rallying political support and financial resources to address neglected health issues. In the security sector, some analysts and practitioners argue that the impact of particular health challenges is sufficiently serious as to warrant prioritisation comparable to that traditionally accorded to the threat and use of armed force. Infectious disease (disease caused by bacteria, viruses and other microorganisms) is the health issue that has received the most attention in security-oriented policy documents and scholarly debates. AIDS (caused by the virus HIV) was arguably the first disease to receive the imprimatur of serious attention at the highest levels of security decision making. The passage in 2000 of UN Security Council Resolution 1308 was the first time a health issue was officially framed as a threat to international peace and security. The Resolution expressed concern about the potential adverse effects of HIV/AIDS on UN peacekeeping personnel, but it also stressed more generally that this pandemic, “if unchecked, may pose a risk to stability and security”.1 The belief that HIV/AIDS threatens security has led governments in rich and poor countries alike to take the disease more seriously, and to devote more resources towards controlling it through prevention campaigns and increased provision of life-prolonging medication. George W. Bush’s President’s Emergency Plan for AIDS Relief (PEPFAR), which in 2003 allocated $US15 billion over five years to international HIV/AIDS programmes—“the largest commitment ever by any nation for an international health initiative dedicated to a single disease”2 —is an example of this. The legislation that authorised this extraordinary allocation of resources included a security rationale, with HIV/ AIDS described as “destabilising communities” and being a disease that “weakens the defenses of countries severely affected”.3

Soon after PEPFAR was authorised, a highly pathogenic avian (and potentially pandemic) influenza virus (H5N1) emerged and began its rapid spread to dozens of countries worldwide. This prompted policy makers and scholars alike to begin contemplating the security implications of an influenza pandemic resembling the great “Spanish Flu” of 1918–1919 which killed an estimated 40 million people. Pandemic influenza is a prime candidate for securitisation because of its capacity to inspire dread on a large scale and in a short space of time. In 2007, for example, the World Health Organization (WHO) described this disease as “the most feared security threat”.4 Naturally occurring disease outbreaks have also come to be considered alongside the enduring problem of biological weapons. US President Barack Obama’s 2010 National Security Strategy emphasised the importance of continued efforts “to reduce the risk associated with unintentional or deliberate outbreaks of infectious disease”.5

The political process whereby non-military phenomena (such as naturally occurring disease outbreaks) come to be treated as security issues has been theorised by scholars of the Copenhagen School. The theory of ‘securitisation’ has attracted numerous attempts at contestation, development and refinement, but the theory’s straightforward central proposition continues to have great explanatory power: for threats to count as security issues, they must be distinguished from issues that are merely political. Specifically, they have to be “staged as existential threats to a referent object by a securitizing actor who thereby generates endorsement of emergency measures beyond rules that would otherwise bind”.6 Securitisation is not the same as mere prioritisation. Rather, securitisation theory emphasises and insists upon the emergency nature of threats and the extraordinary nature of responses. Both the threat of and the response to XDR-TB are assessed in later sections of this article. For present purposes, the central concern is societal functioning, with the referent object of security being the state’s ability to protect its population through public health and healthcare systems.

In assessing whether a particular infectious disease should be framed as a threat to security, the theoretical assumption is that a “security” element is what propels an issue to the top of a government’s political agenda. With this special status comes access to extraordinary legal, financial, military and/or other measures, the implementation of which may have adverse implications both for public health and for individual human rights. Although securitisation theory appears to be mainly descriptive of a political process of constructing “security”, it is important to note its built-in (albeit underdeveloped) normative dimension. In originally expounding their theory, Barry Buzan and his co-authors argued that “[a]voiding excessive and irrational securitization is ... a legitimate social, political and economic objective of considerable importance”.7 Moreover, they warned against idealising national security because “[i]t works to silence opposition and has given power holders many opportunities to exploit ‘threats’ for domestic purposes, to claim a right to handle something with less democratic control and constraint”.8 Regarding state responses to infectious diseases, Stefan Elbe points out that people living with HIV, for example, have been “ostracized and even persecuted by some states for their illness”.9 He argues that framing the disease as a national security threat “risks fuelling such exclusionary and dehumanizing responses and could serve as an implicit legitimisation of any harsh or unjust ‘emergency’ policies that states may adopt in relation to persons living with the virus”.10 These observations are a warning that emergency measures to address infectious disease threats must not in themselves curtail human rights to the point that securitisation becomes illegitimate and counterproductive. Although political claims about the security status of particular diseases often refer to the paramount importance of swift and aggressive responses, experience suggests that haste and zeal can sometimes undermine rather than assist disease-control efforts. There is thus a case for tempering security-oriented analysis with a concern for ethical principles.

Because disease control measures sometimes involve infringement of widely accepted individual rights and liberties, infectious diseases raise difficult ethical questions about how to strike a balance between the goal of protecting the greater good of public health and the goal of protecting individual human rights. Quarantine, isolation and travel restrictions, for example, violate the right to freedom of movement. Other public health measures—such as contact tracing and the reporting of the health status of individuals to authorities—can interfere with the right to privacy. Although measures such as these might sometimes be necessary to avert public health disasters, the question arises: how great must a public health threat be for such measures to be justified? Most scholars and policy makers would presumably accept that the goal of promoting the greater good of society through public health does not always take priority over the protection of individual rights and liberties, nor vice versa. The task of appropriately balancing and simultaneously pursuing these two sets of interests is then made more difficult—and more important—by the insertion of a security dimension. For example, the fear factor that is necessarily present in anything to do with “security” can have a distorting effect. It has been argued, for example, that infectious diseases’ powerful ability to engender fear often leads to “rapid, emotionally driven decision making about the care of individual patients and about public health policies”, even when these decisions “challenge generally accepted medical ethics principles such as patient autonomy, non-maleficence, beneficence and justice”.11 Securitisation of an infectious disease should thus be of such a form as can guard against these dangers.

Tuberculosis and Drug Resistance

The resurgence of TB in an **extremely drug-resistant form** since 2006, prompting extraordinary responses by some governments, presents an opportunity to consider anew the relationship between infectious diseases, security and ethics. Tuberculosis is an infectious bacterial disease transmitted via airborne droplets. Although **approximately one-third of the world’s population is infected with TB** bacteria, not all who are infected develop TB disease. Mycobacterium tuberculosis bacteria can lie dormant in the body for many years. If a person’s immune system is weakened (by HIV co-infection, some other medical condition or simply by old age), he or she can develop what is referred to as “active” TB. Only one in 10 infected individuals is likely to progress to an active TB episode during their lifetime in the absence of immune system suppression. The disease most often affects the lungs, but it can also affect the brain, kidneys or spine. Infectious bacteria can spread through the air when a person with active TB sneezes, coughs, spits or talks, and someone with untreated TB can potentially infect 10 to 15 others annually.12 The disease is today **a major cause of illness and premature mortality**, especially among people living with HIV, and the human toll it exacts is likely to increase as drug resistance makes TB treatment more difficult and expensive. According to the latest WHO report on global tuberculosis control, in 2011 there were an estimated 8.7 million new cases of TB globally, almost one million deaths among HIV-negative cases of TB, and an additional 430,000 deaths among people who were HIV-positive.13 People living with HIV who are also infected with TB are 21–34 times more likely to develop TB disease compared with those who are HIV-negative, and the highest rates of HIV–TB co-infection occur in Africa where 44% of TB patients with an HIV test result in 2010 were HIV-positive.14 Although the focus of this article is on the security significance of drug-resistant TB rather than the broader HIV–TB co-epidemic, suffice to say that any increase in HIV prevalence would exacerbate the spread of drug-resistant TB.

TB bacteria build up resistance to anti-TB drugs because of incomplete or inadequate treatment. In poorer countries especially, it can be difficult to ensure adherence to a course of antibiotics which, to be effective, needs to continue without interruption for six to eight weeks. Unsurprisingly, an individual who begins to feel better before such time has elapsed might decide to stop taking the drugs, especially if they are expensive. To reduce the likelihood of drug-resistant TB bacteria emerging, the longstanding approach to TB treatment is directly observed treatment—short course (DOTS), which focuses on supervised adherence to a fixed combination of drugs. Nevertheless, systemic incountry problems like inconsistent drug prescribing, erratic drug supply and unregulated over-the-counter drug sales increase the risk of inadequate TB treatment. Likewise, in many parts of the world, chronic shortages of trained medical staff and inadequate laboratory capacity make it difficult to track and properly treat incidents of TB illness. If drug treatment is stopped prematurely, the TB bacteria will not be completely eliminated from the body and those that remain may mutate into a form against which the drug is powerless; what did not kill the bacteria serves to makes them stronger. A person infected with TB bacteria that are resistant to first-line drugs—multidrug-resistant (MDR) TB—must then resort to stronger (and more toxic) second-line drugs administered over a longer period of time. Some anti-MDR-TB drugs are administered by injection, so individualised treatment requires a high level of medical expertise. If treatment with these second-line drugs is inadequate or incomplete, the targeted bacteria may mutate further into a form against which almost no drug is effective—extensively drug-resistant (XDR) TB.15

The WHO has reported that the total number of incident TB cases per year worldwide has been falling since 2006.16 However, the proportion of TB cases globally that are caused by **drug-resistant TB** bacteria is rising. In 2010, there were an estimated 650,000 cases of MDR-TB among the world’s 12 million prevalent cases of TB.17 Among the 27 countries that the WHO designates as high MDRTB burden countries, former Soviet Union countries are conspicuous in terms of the estimated percentages of new TB cases that are multidrug-resistant: Azerbaijan (22%), Belarus (26%), Estonia (18%), Moldova (19%) and Russia (18%).18 The four countries that had the largest number of estimated cases of MDR-TB in absolute terms in 2008 were China (100,000), India (99,000), Russia (38,000) and South Africa (13,000).19 The most worrying statistic is that “patients enrolled on treatment for MDR-TB in 2010 [104,000] only represented 16% of the MDR-TB cases estimated to exist among reported TB cases”.20 The remaining 84% are either not receiving treatment or are receiving inadequate treatment, and the latter poses an XDR-TB risk. As of the end of 2011, 77 countries had reported at least one case of XDR-TB.21 If the number of MDR-TB cases in the world is 650,000, the WHO estimate of global XDR-TB prevalence comes out at 58,500 cases worldwide. Given the low rate (16%) of MDR-TB treatment going to people who need it, it is reasonable to suppose that many if not most XDR-TB cases are also left untreated.

The disease called “extensively drug-resistant tuberculosis” was first described in 2006.22 Between January 2005 and March 2006, 221 cases of MDR-TB were identified at the Tugela Ferry district hospital in KwaZulu-Natal Province, South Africa. Of these, 53 patients were further diagnosed with XDR-TB. Half had never previously received TB treatment. The mortality rate was extremely high—52 of the patients (98%) died within a median of 16 days after initial sputum collection.23 Unsurprisingly, XDR-TB mortality rates resemble mortality rates from ordinary TB during the pre-antibiotic era. **Without drug treatment, TB victims are highly likely to die**. Studies of the natural history of the disease among sputum smear-positive and HIV-negative cases of pulmonary TB have shown that around 70% of victims died within 10 years. Treatment using combinations of anti-TB drugs developed in the 1940s and 1950s can dramatically reduce mortality rates, and in 2009 the treatment success rate globally among reported smear-positive cases of drug-susceptible, pulmonary TB reached 87%.24 But with increased and more widespread drug resistance has come **reduced rates of treatment success** for this strengthened form of TB illness. In low HIV-prevalence settings, patients with MDR-TB have been treated with a success rate of 60–80%, and the rate is 44–60% for XDR-TB patients.25 This means the mortality rate among treated MDR-TB and XDR-TB patients is as high as 40% and 56% respectively. Mortality rates are even higher in circumstances where a patient undergoing TB treatment is HIV-positive.26 Naturally, whether or not an MDR-TB or XDR-TB patient is HIV-positive, he or she is more likely still to die in circumstances of no treatment at all.

Beyond epidemiological data that evaluate the health burden of TB, it is worth considering also the disease’s economic burden—a burden that will surely increase as TB becomes harder to treat. In addition to the cost of lost productivity, the WHO estimates that TB treatment costs alone will reach US$16.2 billion by 2015.27 Although the six-month course of treatment for drug-susceptible TB is not prohibitively expensive, treating MDR-TB can cost US$144–265 per day, with the requisite two-year treatment costs totalling US$40,000 per patient.28 If every one of the 650,000 people estimated to have MDR-TB were to undergo adequate treatment, the cost would therefore be US$26 billion. According to the WHO, the cost of drugs alone for treating the average MDR-TB patient is 50 to 200 times higher than for treating a drug-susceptible TB patient, and the overall cost of care can be more than 10 times higher.29 In the case of XDR-TB, treatment could be of indefinite duration and indeterminate cost, possibly limited only by the patient’s life expectancy.

After establishing that drug-resistant TB is a serious and worsening problem from a health and economic perspective, the question remains: is the threat of XDR-TB severe enough to count as a security threat? For “security” to be invoked, it is not enough simply to point to a “threat”. Lots of things are threatening to a greater or lesser extent, so the Copenhagen School insists that **a threat must be an existential one**. To count as a security threat (as distinct from a mere economic and/or health threat), the very **survival** of something or someone **must be at stake**. The evidence presented so far suggests strongly that **this is the case**: **XDR-TB** arguably **endangers local and international health systems** because treating this disease is increasingly expensive and the burden of treating large numbers of patients could become **unbearable**. Securitisation as an intersubjective process is achieved, and emergency responses to the identified problem thus endorsed, once the notion of a threat is believed and accepted by others.30 In the case of XDR-TB, the available epidemiological data make a claim to security status plausible, as does a comparison to other infectious diseases that are already sometimes addressed in security terms. For example, compared to HIV which is not readily transmissible, it is much harder to protect oneself against infection by the airborne microorganisms that cause TB. And whereas pandemic influenza also spreads through the air, **TB bacteria can be far more deadly than influenza virus** if the former are drug resistant. Recent attempts at developing a broadly effective TB vaccine have met with little success,31 so antibiotics remain the primary pharmaceutical response to the disease. But as MDR-TB mutates into XDR-TB, and as drug resistance becomes more widespread, a pharmaceutical solution moves further out of reach. The relative importance of containing what is virtually incurable is increasing, and it is in this context that drastic disease control measures are being proposed and implemented. Adopting emergency measures to counter grave threats is the stuff of “security”, but the protection of public health must always be guided by ethical considerations. Accordingly, the remainder of this article addresses the question: how should XDR-TB be securitised?

**Anticompetitive petitions independently kill the cell-based meat market**

**Grafton 20** (Sean Grafton is a recently barred Washington, D.C. attorney with a background in genetic research. He currently works for the United States Court of Federal Claims as a law clerk, WELCOME TO THE WORLD OF TOMORROW: AN EXPLORATION OF CELL-BASED MEATS AND HOW THE FDA AND USDA MAY PROTECT INTELLECTUAL PROPERTY RIGHTS. Catholic University Journal of Law and Technology, 28, 175, y2k)

This tactic involves what is known as **an " 'eleventh hour' petition** because companies would file them 'on the **eve** of drug approval for the purpose of [\*208] delay.' " 351Citizen petitions are **long** and **complex**. 352Thus, the generic drug's approval is often delayed for the full one hundred and fifty days. 353 This tactic **effectively** delays the approval of generic drugs and **circumvents** the amended application process which Hatch-Waxman was designed to accelerate. 354 The concern for legislation protecting **cell-based meat** intellectual property and encouraging **competitors** to enter the market is that brand companies will use **citizen petitions** to **delay** the approval of any other "**generic**" version of **cell-based meat**. 355 Being delayed up to **half a year** has a **major effect on profits** that generic companies could **earn** and **profits** that brand companies could retain. 356 Any legislation would need to prevent or limit this stalling tactic in order to encourage fair market competition, to protect intellectual property rights, and to aid the consumer. 357

**Cultivated meat solves extinction**

**GFI 18** (Good Food Institute, “GROWING MEAT SUSTAINABLY: THE CULTIVATED MEAT REVOLUTION,” <https://www.gfi.org/files/sustainability_cultivated_meat.pdf>, y2k)

**Feeding the world’s growing population** with finite land and water resources will be one of the **greatest challenges** of the 21st century. United Nations scientists state that **animal agriculture** is one of the **major causes** of the world’s most **pressing** environmental problems, including **land degradation**, loss of **biod**iversity, **global warming**, and air and water **pollution** (FAO 2006). **Cultivated meat** could address these challenges by conserving **land** and **water**, preserving **habitat**, reducing greenhouse gas **emissions**, and preventing **manure pollution** and **antibiotic overuse**.

CULTIVATED MEAT IS MUCH BETTER FOR THE ENVIRONMENT

Like conventional meat, cultivated meat is made of animal cells. In a conventional system, meat comes from animals that must be fed, housed, and slaughtered. Cultivated meat comes from cells grown in cultivators to produce various cuts or varieties of meat. A cultivated meat supply chain will have some commonalities with conventional meat, like growing feed crops, operating farm equipment and buildings, and transporting products to supermarkets. But there are some crucial differences. Cultivated meat can be produced more quickly and efficiently, with little waste and no animals to slaughter. In the seven weeks it takes a farmer to raise a flock of 20,000 chickens, **a meat cultivation facility** could theoretically produce **a million times** as much meat from a starter culture the size of a **single** egg.1

Meat production is responsible for **most** of agriculture’s **environmental** impacts. More than three-quarters of agricultural land is used to support cows, pigs, and chickens, but animal products provide only 18% of global food calories and 25% of protein (Mottet et al. 2017). The impacts of conventional meat are difficult to reduce because they come from many different sources: fertilizer and feed crop production, transportation of grain and animals, manure, and the animals themselves. In its 2017 Sustainability Report, the U.S. Farmers & Ranchers Alliance reports a mere 2% improvement in energy use and greenhouse gas emissions across the beef supply chain between 2005 and 2011 (USFRA 2017). In contrast, simply running on **clean energy** would reduce the life cycle emissions of a meat cultivation facility by 40% to **80%**. So cultivated meat can provide a way to satisfy consumer demand for meat while easing **pressure** on the environment.

CULTIVATED MEAT CONSERVES LAND & WATER RESOURCES

Meat cultivation promises to be faster and less wasteful than raising animals. As a result, it will conserve **soil**, **water**, **habitat**, and other **critical resources**. Industrial animal agriculture requires massive quantities of **feed crops**. Most of those crops end up as **manure**, not meat. Studies show that cultivated meat would use land 60 to **300 percent more efficiently** than poultry and 2000 to 4000 percent more efficiently than beef (Hanna L. Tuomisto, Ellis, and Haastrup 2014; Mattick et al. 2015). For example, an acre of Iowa cropland can support the production of 1,000 pounds of chicken meat each year. That same acre would support 1,700 to 3,500 pounds of cultivated meat, freeing up cropland to produce grains, vegetables, or fruits for people.

Due to its efficiency, cultivated meat would also prevent and counteract one of humanity’s most **destructive** actions: clearing **forests** and **grasslands** for animal feed. Cultivated meat would allow producers to meet the growing demand for animal protein while eliminating the pressure to clear wild land for feed crops worldwide. This more **innovative approach** will also reduce the **unsustainable use** of synthetic fertilizers and help to prevent the “**biological annihilation**” of habitat for feed and pasture (Ceballos, Ehrlich, and Dirzo 2017). Losing **critical habitat** would not only cause a mass **extinction**, but also destabilize the **water cycle**, **climate**, and other global systems on which **humanity depends** (Steffen et al. 2015).

**Citizen petition costs billions even if they are ultimately denied---prefer data**

**Robin 20** (Feldman Robin, Arthur J. Goldberg Distinguished Professor of Law, Director of the Center for Innovation (C4i), University of California Hastings Law, Robin Feldman, The Burden on Society from Eleventh-Hour “Citizen Petitions” Filed to Slow Generic Drugs, 79 Md. L. Rev. Online 1, y2k)

Often companies file their **citizen petition** in the **months right before** their generic competitors’ approval is **anticipated**. In the **vast majority** of cases, the FDA **denies** these petitions.6 **Yet**, the drug companies’ motives are **easy** to identify: delaying a **lower-priced generic** from entering the market for **even ninety days** can earn the companies **hundreds of millions of** dollars of revenue, making their **bogus** citizen **petitions** worth their while.

Protecting the availability of low-cost generic drugs **matters** to the American public. **Affordable** generic drugs, in addition to being **critical** to **public health**, translate into **huge savings** for the American public and government-funded **insurance programs**.8 The availability of a **generic equivalent** can **reduce** the price of a prescription drug **significantly9** ; more than three-quarters of prescriptions are now filled with their generic equivalents.10 Thus, bringing generics to market is **an essential part** of **controlling drug costs**.

Despite the **documented** abuse of the citizen petition system,11 the **cost to society** of these delays has not been calculated, which may hinder the push for policy solutions. Following the analytic techniques that Congress uses for estimating the likely impact of reform, this Article will identify a set of citizen petitions that could be described as the **sole**, “but for” **cause** of keeping a particular generic **out of the market**.12 It will use the criteria that the petition was denied; the FDA approved the generic within one business day of denying the petition; and the generic came to market within one week of the FDA’s approval, signaling that the petition was the final obstacle standing in the way of the generic’s entry to market.

Drawing from a **previously published data** set of 249 citizen petitions,13 this Article will analyze **four** petitions from a two-year period that are highly likely to have been the **final obstacle to a generic drug entering the market**, and for which **sufficient volume** and **usage data exist**. Using these four dubious citizen petitions, this Article will show that the total financial cost to society of citizen petition delays was $1.9 billion— which equals roughly **$3.6 million *per day***.14 Additionally, this Article will find that the total financial cost to government-provided insurance programs in the same period was roughly $782 million.15 Due to the **conservative methodology** employed16 (choosing only petitions that met the criteria of “but for” this citizen petition the generic would have gone to market), the estimates are likely **low**. Citizen petitions that contributed to a generic’s delay to market as one of multiple tactics or for which there was not sufficient volume and usage information were eliminated from consideration in this estimate.

This is an **extraordinarily narrow method** of identifying citizen petitions that contribute to generic drug delays. This approach **significantly underestimates** the financial impact when pharmaceutical companies misuse the regulatory system by filing baseless citizen petitions. By counting financial costs only associated with citizen petitions that stand alone during the twelve-year period rather than when they may be contributing to the delay as part of an arsenal of tactics, the total cost is undoubtedly underestimated. Moreover, this Article does not include in the calculation any costs to public health that may come from patients **foregoing medication** due to the lack of a lower cost generic alternative. Nonetheless, these delays bring **substantial** and **sobering costs**.

**Solvency**

**The United States federal government should substantially increase its prohibitions on anticompetitive petitioning by the private sector.**

**The “objectively baseless” standard is unwinnable – the aff brings the two Supreme Court standards in line by lowering the first prong of the PRE standard**

**Fulbright 2019.** Paul W. Fulbright. Assistant Professor of Business Law, University of Houston. “Antitrust Law, Entrepreneurship, And The “Patent Bully”: The “Sham” Exception To Noerrpennington Petitioning Immunity In Patent Infringement Litigation After The Professional Real Estate Decision” proquest.com/scholarly-journals/antitrust-law-entrepreneurship-patent-bully-sham/docview/2298280771/se-2

IV. THE WAY FORWARD: MOVING TOWARDS A CLARIFICATION OF PRE In the hypothetical problem presented at the opening of this paper, John Smith, the CEO of BigCorp, has proposed filing a lawsuit against a startup competitor even though its objective prospects for success are extremely poor. “I don’t care about the merits of the case,” said John. “I just want to pick the best patents we can and file suit, even if we have a 95% chance of losing the lawsuit. Winning or losing the lawsuit doesn’t matter. By filing suit now, we’ll do two things. First, it’s entirely possible that we’ll scare off WhiteKnight. I mean, after all, who wants to invest in a lawsuit? Second, without WhiteKnight’s funding, we’ll be able to bury SmallCorp in legal bills. The cost of the lawsuit alone, to say nothing of the effect it will have on SmallCorp’s customers, will likely drive it into the grave.” Unfortunately, when his general counsel performs her due diligence and consults with experienced antitrust and patent counsel, she is likely to be advised that, under the current state of the law, the strategy may very well succeed. **This is contrary to the substantive goal of antitrust**: to encourage competitors to compete on the basis of the quality and pricing of the goods and services that they offer, and, in the case of a monopolist, to ensure that it doesn’t engage in unreasonable anticompetitive exclusionary conduct. Here, CEO Smith is trying to arrange for his monopolist corporation to compete not on the basis of its superior products and services, but, rather, on the basis of filing a meritless lawsuit against a less-well-funded startup in the hope that the litigation costs and uncertainty can exclude / destroy this competitor. The question is: what can be done to discourage this kind of game-playing in the future?

A. The Door to Improvement of the PRE Test – A Finding of Ambiguity As stated hereinabove, the PRE “objectively baseless” objective test suffers from two maladies: (a) it is ambiguously framed; and (b) to the extent that a single test is discernible from the express text of the decision, it is likely a sub-optimal test, a variant of the “objectively baseless” archetype. Although this undoubtedly causes great heartache to the clients and attorneys dealing with the Noerr-Pennington “sham” exception in the field (the courtroom), there is a silver lining. Court decisions create ambiguous tests, and court decisions can eliminate them.116 So **the** practical **path** **forward** for curing the infirmities of PRE **is a future U.S.** **Supreme Court decision** **that** clarifies or **corrects117 PRE.** What is the preferred clarifying formulation? An objective test that constitutes a variant of the “objectively unreasonable” archetype seems best.

B. The Holding and the Dicta in PRE Clarification of PRE would be simplest if there was a cogent argument that the “**true” objective test** of PRE is, in fact, one of the variants articulated in PRE that most closely resembles the “objectively unreasonable” archetype. Fortunately, **there is just such an argument**. The argument is this: the precise holding in PRE is narrow, and the other formulations and guidelines appearing in the decision are dicta. Consider the time-honored approach to identifying the single holding in a decision when confronted with several alternatives. Which formulation is the holding? The formulation essential to the decision is the holding, and its siblings are the dicta.118 In the instant case, the core holding in PRE is simple: an objectively reasonable effort to litigate cannot be a sham regardless of subjective intent. 119 That simple (but profound) statement is all that was needed to actually dispose of the case. All of the other formulations regarding the PRE objective test are interesting, and informative, but, **under the Court’s own tests** **for distinguishing holdings** from dicta, **they would not be viewed as the** definitive, **binding legal test**. It should be noted that Justice Stevens’ concurring opinion in PRE supports this view: While I agree with the Court’s disposition of this case and with its holding that “an objectively reasonable effort to litigate cannot be sham regardless of subjective intent,” I write separately to disassociate myself from some of the unnecessarily broad dicta in the Court’s opinion. Specifically, I disagree with the Court’s equation of “objectively baseless” with the answer to the question whether any “reasonable litigant could realistically expect success on the merits.” There might well be lawsuits that fit the latter definition but can be shown to be objectively unreasonable, and thus shams. It might not be objectively reasonable to bring a lawsuit just because some form of success on the merits – no matter how insignificant – could be expected.120

C. **A Proposed Clarification** to the PRE Objective Test Several guidelines can now be enumerated regarding the contours of a clarification to the PRE objective test. The overall two-part structure for identifying “sham” claims, utilizing both subjective and objective tests, and how those tests interrelate (as shown in the matrix in Exhibit 1), remains unchanged. First, and foremost, the clarifying **court should** **clarify** that the **PRE objective test is in fact a variant of the “objectively unreasonable**” **archetype**. Language of the following sort could be profitably employed: A “sham” claim is an objectively unreasonable claim; **it lacks any reasonable chance of success in producing a reasonably favorable outcome**, based on the nature of the claim, from the vantage point of the reasonable prudent claimant. A “genuine” claim has a reasonable chance of succeeding in producing a reasonably favorable outcome, based on the nature of the claim, from the vantage point of the reasonable prudent claimant. Second, after clarifying the general nature of the PRE objective test, **the court could** **seize the opportunity to re-affirm various subsidiary matters relating to that test** (as described in relation to the court decisions referenced herein).121

\*\*\*\*\*\* FOOTNOTE 121\*\*\*\*

121 For example, the court could re-affirm that: (1) the objective reasonableness of asserting a claim is evaluated based upon the totality of the circumstances known to the claimant at the time of filing; (2) the duty to only pursue objectively reasonable claims is a continuing one (so that, if a litigant becomes aware of facts or law that converts what was once a genuine petition for redress into a sham, the citizen has an affirmative duty to timely correct the matter (including, potentially, discontinuing the proceeding)); and (3) the considerations bearing on objective reasonableness would include, but not be limited to, the following: (a) the evidentiary basis for any factual contentions upon which the suit is based; (b) the legal basis upon which the claim and prayer for relief are based; (c) the diligence of the claimant in ascertaining, prior to filing and throughout the prosecution of the matter, whether it has reasonable grounds to sue; (d) the presence or absence of effective legal advice from competent counsel; and (e) the likelihood, nature, and expected magnitude of success (considering both financial and non-financial measures of success), and the risk-adjusted cost, that a reasonable prudent person would perceive in relation to the litigation.

\*\*\*\*\*\*\*FOOTNOTE ENDS

Third, **the clarifying court could re-affirm that**, **only if challenged litigation is objectively unreasonable** **may a court examine the litigant’s subjective motivation.** Sham litigation is litigation motivated by something other than a genuine prayer for relief, and the litigant’s subjective motivation may be proven by direct or circumstantial evidence. The court should focus on whether the unreasonable lawsuit conceals an attempt to violate the Sherman Act through the use of the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon. **Fourth, the clarifying court could harmonize and unify the PRE and Walker Process lines of authority** through the use of language along the following lines: “Fraudulent and objectively baseless claims are claims presented in bad faith and are objectively unreasonable. Claims depending upon close questions of law, or claims warranted by a reasonable argument for the extension, modification, or reversal of existing law, are not.” It is respectfully suggested that **formulations along the lines described above**, consistently applied in litigation everywhere and, in particular, in the patent field, **would dramatically increase the utility and predictability of the Noerr-Pennington** standard by capitalizing on all that has been learned since PRE was originally decided.

## 2AC

**T – Expand the Scope**

**Counter-interp-- Expand the scope means new activities are covered that were not before**

**Breyer 7 –** Stephen Gerald Breyer is an American lawyer and jurist who has served as an associate justice of the Supreme Court of the United States since 1994, ‘7 127 S.Ct. 2301 (2007) 551 U.S. 142, Lisa WATSON, et al., Petitioners, v. PHILIP MORRIS COMPANIES, INC., et al.

The upshot is that a highly regulated firm cannot find a statutory basis for removal in the fact of federal regulation alone. A private firm's compliance (or noncompliance) with federal laws, rules, and regulations does not by itself fall within the scope of the statutory phrase "acting under" a federal "official." And that is so even if the regulation is highly detailed and even if the private firm's activities are highly supervised and monitored. A contrary determination would expand the scope of the statute considerably, potentially bringing within its scope state-court actions filed against private firms in many highly regulated industries. See, e.g., Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a (2000 ed. and Supp. IV) (mandating disclosure of testing results in the context of pesticide registration). Neither language, nor history, nor purpose lead us to believe that Congress intended any such expansion.

**That means Courts or Congress can enlarge the scope of antitrust prohibitions.**

Donald F. **Turner 90**. Professor of Law, Georgetown University Law Center. "The Virtues and Problems of Antitrust Law," Antitrust Bulletin 35, no. 2 (Summer 1990): 297-310.

However, unsound interpretations of antitrust laws have adverse economic effects. Court-formulated rules have **varied** from time to time over the years since antitrust statutes were passed, and the **scope of antitrust prohibitions** were either **enlarged or reduced**. While there are extensive disputes as to what the precedents' defects have been and are, it is generally recognized that antitrust law has had and still has some undesirable features that the **courts or Congress should correct**.

**T – Per Se**

**Rule of reason is a prohibition – the distinction is arbitrary**

Sarah E. **Light 19**, Assistant Professor of Legal Studies and Business Ethics, The Wharton School, University of Pennsylvania, “The Law of the Corporation as Environmental Law,” 71 Stan. L. Rev. 137, Lexis

While antitrust law can serve as an environmental mandate by prohibiting collusive behavior that keeps environmentally preferable goods from the market, there is also conflict between antitrust law's goals of promoting competition and environmental law's goals of promoting [\*177] conservation. 192 Because **antitrust** law**'s** **per se** rule and **rule of reason** operate on a somewhat **fluid continuum**, 193 this Subpart discusses the two doctrines together. The **per se** rule operates as a **prohibition**, whereas the **rule of reason** operates as **both a prohibition and a disincentive**.

As noted above, antitrust law generally **prohibits certain types of market activity** - price fixing, horizontal boycotts, and output limitations - as illegal **per se**, and harm to competition is **presumed**. 194 For example, if an industry association declines to award a seal of approval necessary for a product's sale without any good faith attempt to test the product's performance, but rather simply because that product is manufactured by a competitor, such an action would be illegal per se. 195 Under this Article's framework, a **per se** violation is **thus a prohibition**.

The more fact-intensive inquiry under the **rule of reason** tests "whether the restraint imposed is such as merely **regulates** and perhaps thereby **promote**s competition or whether it is such as may **suppress** or even **destroy** competition." 196 While this extremely broad statement might suggest that **any fact** is relevant to the inquiry, the salient facts under the rule of reason are "those that tend to establish whether a restraint increases or decreases output, or decreases or increases prices." 197 **If** an **anticompetitive effect is found**, **then the action is illegal** and the rule of reason **operates, like the per se rule, as a prohibition**. 198 The rule of reason can also operate as a disincentive, even if no [\*178] court finds an anticompetitive effect, as uncertainty and litigation risk may discourage firms from undertaking legally permissible, environmentally positive industry collaborations. 199

**The court stopped using per se prohibitions as absolute**

**Abramson 8** (Brian Dean Abramson, Private intellectual property attorney. J.D., Florida International University College of Law, 2005, LET THEM EAT SMOKE: THE CASE FOR EXEMPTING THE TOBACCO INDUSTRY FROM ANTITRUST, 6 Cardozo Pub. L. Pol'y & Ethics J. 345, y2k)

Initially, the Supreme Court ruled that the Sherman Act constituted **an absolute prohibition** against **contracts restraining trade**, no matter what the intent of these contracts was. 29 The Court soon realized that such a standard would be **unworkable**, 30 because **every** contract **necessarily** involves **some** restraint of commerce. For example, if party A agrees to work full-time for party B for a year, then party A may be restrained from working even part-time for any other company. Because of this, the Court sought to establish **some standard** by which it could determine which contracts were **intended to fall** under the Sherman Act.

**C/I Prohibit can mean ‘severely hinder’---doesn’t necessitate a ban.**

**Washington Court of Appeals 19** (KORSMO-judge. Opinion in State v. Kimball, No. 35441-5-III (Wash. Ct. App. Apr. 2, 2019). Google scholar caselaw. Date accessed 7/13/21).

His argument runs counter to the meaning of the word "prohibit." It means "1. To forbid by law. 2. To prevent, preclude, or severely hinder." BLACK'S LAW DICTIONARY 1405 (10th ed. 2014). As **"severely hinder"** suggests, a "prohibition" **need not be** an all or nothing proposition.

**Buddhism K**

**Sham litigation—Alt ensures cooption by digital capitalists and worker exploitation. Aff and perm are necessary non-reformist reforms**

**Frase 13** (Peter, editorial board of Jacobin and the author of Four Futures: Life After Capitalism. “Property and Theft”, https://jacobinmag.com/2013/09/property-and-theft)

Both of these essays demonstrate the absurdities and injustices of a strengthening IP regime. Yet each, in a different way, shows that simply denouncing all **i**ntellectual **p**roperty is inadequate, as are the political battle lines that are often drawn today. On one side, we find pirates and free-culture advocates, insisting that “information wants to be free” and that any attempt to enclose the copying of patterns within legal restrictions is an affront and an inanity. This view unites a sort of Left-Right coalition that can encompass the libertarian economist David K. Levine and the amorphous rebellion of Europe’s Pirate parties. Arrayed against them are those who may acknowledge the corporate corruption of the patent and copyright systems, but who nevertheless hold up a reformed IP system as a bulwark against the depredations of a “sharing economy” that all too often amounts to a handful of Internet monopolists profiting from the uncompensated labor of creative workers. Jaron Lanier, author of the recent Who Owns the Future?, is one of the more strident proponents of this view.

We have here something a bit like the old “reform or revolution” dichotomy, which arrays the advocates of smashing the existing system against the timid meliorism of those who only want to make it more humane. But **the contrast fails here** just as it did in the larger drama of twentieth-century socialism, where revolution and reform both ultimately led back to capitalist restoration and neoliberal retrenchment. We need another path — one that **recognizes the necessity of reformist struggles within capitalist institutions**, while still attempting to move toward a break with the system and the creation of a fundamentally new kind of economy and society. André Gorz called this the “non-reformist reform”: a project of “reforms which advance toward a radical transformation of society” by making a “modification of the relations of power” which could “serve to **weaken capitalism and to shake its joints**.”

What would constitute a non-reformist reform of intellectual property? The revolutionary overthrow of all **i**ntellectual **p**roperty, even if it were possible, leaves unanswered the question of how to ensure that **those who create knowledge and culture are provided for**, and how to control the exploitation of the cultural commons by digital capitalists. The anarchist championing of online piracy **only allows for some resistance around the edges**, without posing a fundamental challenge to the system. And yet the idea of reforming IP into something better and more egalitarian, something that truly rewards all who participate in the work of creation, seems like another iteration of the naïve dream of a just and democratic capitalism.

**Taxation CP**

**Options are restricted**

Paul R. **Gugliuzza 2015**. Professor of Law at Temple University. Professor Gugliuzza has testified before both the U.S. Senate and the U.S. House of Representatives on the topic of patent law, and his scholarship has been cited in over a dozen judicial opinions across all levels of the state and federal courts "Patent Trolls and Preemption" <https://www.virginialawreview.org/articles/patent-trolls-and-preemption/>

The Federal Circuit’s erroneous expansion of Noerr immunity is not only wrong as a matter of doctrine, it also has several destructive policy implications. For instance, it grants patent holders a license to lie in their demand letters, so long as those letters also contain objectively plausible allegations of infringement. Thus, patent holders can lawfully send letters stating that many recipients have already purchased licenses to the asserted patents even if, in fact, few if any recipients have done so.44 And patent holders can lawfully claim that the validity of the asserted patents have been upheld in court or in reexamination at the Patent and Trademark Office, even if that is not true.45 In addition, **because the Federal Circuit purports to derive its Noerr-based immunity standard from the First Amendment,**46 **that standard makes it unconstitutional for not just states but also the federal government to condemn any but the most fantastical allegations of patent infringement**. Thus, although the President, members of Congress, and the Federal Trade Commission have all recently voiced concerns about “patent trolls,”47 **Federal Circuit law significantly limits the regulatory** **options**.

**Can’t do anything**

Paul R. **Gugliuzza 2015**. Professor of Law at Temple University. Professor Gugliuzza has testified before both the U.S. Senate and the U.S. House of Representatives on the topic of patent law, and his scholarship has been cited in over a dozen judicial opinions across all levels of the state and federal courts "Patent Trolls and Preemption" <https://www.virginialawreview.org/articles/patent-trolls-and-preemption/>

IV. IMPLICATIONS OF CURRENT DOCTRINE Questions about the appropriate doctrinal basis for limiting government power to regulate patent enforcement—the Supremacy Clause, the Noerr doctrine, or the long-standing good faith rule—are not merely academic. As discussed above, the Supremacy Clause arguably gives the states authority to condemn deceptive schemes of patent enforcement.303 The rule of good faith immunity, as understood prior to the Federal Circuit’s creation, would limit that authority somewhat, but **the Federal Circuit’s expansive application of Noerr immunity renders the states—and the federal government—almost powerless.** To properly frame a normative analysis of current Federal Circuit doctrine, it is worth highlighting several practical implications of the status quo for government efforts to address questionable tactics of patent enforcement.

**Uncertainty kills access and innovation**

**Paradise 18** (Jordan Paradise, Professor of Law, Loyola University Chicago School of Law, Regulatory Silence at the FDA, 102 Minn. L. Rev. 2383)

The **widespread uncertainty** resulting from the two case studies generates **several implications** that may prove **damaging** for **access** and **innovation**, as well as **patient safety**. These include **hefty litigation costs** as courts continue to wrestle with the **case law** and statute. Despite the Supreme Court decision in Sandoz, Inc. v. Amgen, Inc. and the Federal Circuit's decision regarding federal preemption in the context of the BPCIA, for example, **procedural questions** resulting from the legislation promise future **litigation**. Likewise, litigation is pending on varying aspects of the REMS statutory provisions. Given industry **uncertainty about the law**, generic and biosimilar sponsors may decide to **delay development** until there is more resolution, or **abandon development efforts entirely**. There may be **a direct impact** on **drug costs**, as the longer an innovator product enjoys the totality of the market, **the higher the overall costs** for that drug or biologic will be for **consumers**. In fact, one study published in July 2014 estimated that approximately $ 5.4 billion per year has been lost in prescription-drug savings due to distribution restrictions imposed by brand manufacturers under the auspices of REMS. Last, and perhaps most troubling, is that industry behavior using REMS to **block competitor** uses may also be **detrimental** to the long-term safety of users. Physicians have already identified refusing access to products for bioequivalence studies and the blocking of REMS through patents as a direct threat to patient safety.

**Patent trolls capitalize on uncertainty---undermines innovation**

**Heinecke 15** (Grace Heinecke, J.D. Candidate, 2016, Fordham University School of Law; B.A., 2009, University of Pennsylvania. PAY THE TROLL TOLL: THE PATENT TROLL MODEL IS FUNDAMENTALLY AT ODDS WITH THE PATENT SYSTEM'S GOALS OF INNOVATION AND COMPETITION, 84 Fordham L. Rev. 1153)

Many note that a majority of software patents are vague or overly broad, making it difficult for others to discern what they cover. 229 **Patent trolls** make a **business out of capitalizing on** this **uncertainty**. According to one study, 82 percent of defendants sued by patent trolls were sued on the basis [\*1177] of a software patent, compared to 30 percent of defendants sued by non-trolls. 230 Software-patent litigation is also problematic because it can deter innovation and present economic issues. 231 Julie Brill, a commissioner of the FTC, reported that the FTC "found that trivial and overbroad patents - including software and business method patents - can undermine competition, with no offsetting benefits to consumers, by leading a competitor to forgo research and development in an area the patent supposedly covers, deterring follow-on innovation and new market entry." 232

Because of rapid technological growth, a single product today can incorporate the use of **thousands** of patents. 233 Therefore, in ensuring efficient licensing, the scope of these patents must be clearly defined. According to the FTC, an overly broad or unclear patent harms competition because "it is much more difficult to license and cross-license patents in a manner that promotes innovation and competition." 234 Patent trolls have exploited this growth in technology and the unclear boundaries of software patents. 235

Patent **trolls** also have exploited other areas of **legal uncertainty** surrounding software patents. First, because of the **vague boundaries** of these patents, it becomes **difficult** for defendants to **predict** whether the patent will be **invalidated** in court. 236 Additionally, because **litigation** is **expensive**, defendants usually find it more **economical** to pay **the licensing fees** for these weak patents than to **challenge them** in court. 237 According to the Department of Commerce, "Litigation and … **licensing costs** represent a **significant tax on innovation**." 238

**Business Confidence DA**

**Current FTC action thumps overstretch and biz con and is popular**

**Scwartz and Vose 10/28** ““DON’T KNOW WHERE WE’RE GOING, BUT WE’RE ON OUR WAY”: FTC’S ANTITRUST REMODELING CREATES CHILLING UNCERTAINTY FOR DEAL MAKING” Edward B. Schwartz, a partner in the Washington DC office of Reed Smith LLP, and Gregory Vose, an associate in the firm’s Pittsburgh, PA office. October 28, 2021, https://www.wlf.org/2021/10/28/publishing/dont-know-where-were-going-but-were-on-our-way-ftcs-antitrust-remodeling-creates-chilling-uncertainty-for-deal-making/

Riding a wave of populist support for tougher enforcement of the antitrust laws, the Federal Trade Commission (FTC) has announced a number of changes over the last several months making clear that it intends to **significantly expand** its antitrust enforcement role, particularly with respect to mergers and acquisitions. But in its zeal to usher in a new era of more robust enforcement and to reframe antitrust doctrine, these changes leave businesses with fewer enforcement signposts to guide them in strategic planning, and are likely to deter procompetitive transactions that would be good for competition and consumers alike.

Recently installed FTC Chair Lina Khan is a progressive reformer who, before being tapped by President Biden, was an academic fellow at Columbia Law School and had never worked in the private sector. Her brief and remarkable career trajectory was launched by an article she wrote in 2017 while in law school at Yale—Amazon’s Antitrust Paradox. The article forcefully challenged the consumer welfare test orthodoxy, arguing that platform-based business models such as Amazon’s can harm competition even while they offer increased output and lower prices.1 The Senate confirmed Khan as a Commissioner on June 15, 2021 with bipartisan support. To the chagrin of some Senators who voted for her confirmation as a Commissioner, President Biden appointed her to be FTC Chair later that same day.

The changes have been **swift** and **dramatic**. At Khan’s first FTC meeting on July 1, 2021, the FTC voted along party lines to rescind an Obama-era Bureau of Competition policy statement setting out the Commission’s analytical framework for enforcing the FTC Act’s Section 5 proscription against “unfair methods of competition.”2 While that 2015 policy statement broke from the policies of the prior administration by stating the scope of Section 5 was broader than the Sherman and Clayton Acts, the Commission also committed to be “guided by” the consumer welfare standard, and to exercising restraint in bringing enforcement actions targeting conduct that, standing alone, would not violate the Sherman or the Clayton Act.

By scuttling the 2015 policy statement, the Commission under Chair Khan has signaled its intent to recast enforcement policy and to expand the scope of the conduct and transactions it will investigate and challenge. As Khan observed in her statement at the time “the time is right for the Commission to rethink its approach and to recommit to its mandate to police unfair methods of competition even if they are outside the ambit of the Sherman or Clayton Acts.”3

Left unaddressed by the Commission in withdrawing the 2015 policy is the question posed by Commissioners Wilson and Phillips in their dissenting statements:4 if the consumer welfare standard and over 100 years of Sherman and Clayton Act jurisprudence will not supply the analytical framework for the Commission’s analysis under Section 5, what will? Until now, antitrust counsel could turn to a wealth of authorities grounded in the consumer welfare standard and Sherman and Clayton Act enforcement, including case law, joint DOJ-FTC guidelines (including the horizontal merger guidelines), and agency precedent to help advise clients as to what conduct and transactions are likely to raise significant concerns by the FTC. Even with that wealth of guidance, assessing merger-clearance risk can be challenging. What do companies and their counsel look to today? How do companies know what conduct and transactions will be condemned?

“We know it when we see it” may be a suitable standard for obscenity, but not for anticompetitive conduct

and competition-reducing mergers. It is difficult for businesses to make informed decisions regarding their critical growth strategies when it is virtually impossible to gauge what level of cost and delay an unfocused and wide-ranging antitrust investigation can take. To those businesses brave enough to be willing to weather the storm, negotiating such contingencies in the transactional documents has also become increasingly difficult. This guilty-until-proven-innocent approach to antitrust enforcement amounts to an added “deal tax” by significantly increasing legal costs and uncertainty.

At the same July 1 meeting, the FTC also approved rulemaking changes that make it much easier for Staff to launch merger investigations and force merging parties to respond to compulsory process (subpoenas or civil investigative demands), prioritizing mergers involving technology companies and healthcare businesses.5 In addition, to combat the increase in merger filings, the FTC announced on August 3, 2021 that some companies awaiting merger approval may face further investigation and that some deals may be challenged even after an initial review period expires.6

And the beat goes on. On August 26, 2021, the FTC reversed prior FTC guidance by announcing that debt must now be included when calculating the size of a transaction for purposes of the HSR filing threshold,7 making more transactions reportable. Two months later, the FTC announced that second requests—already overbroad and unduly burdensome—are going to become even more so as the FTC will now seek “additional facets of market competition that may be impacted,” including “how a proposed merger will affect labor markets, the cross-market effects of a transaction, and how the involvement of investment firms may affect market incentives to compete.” The scope of these investigations appears now to be **virtually unbounded**; and worse, there is little to nothing the parties can practically do to reign them in. And most recently, the Commission reinstated a “prior-approval” policy not in force since the mid-1990s, that requires companies operating under a merger consent decree to notify the Commission of all proposed transactions in “each relevant market for which a violation was alleged,” whether the transaction is reportable or not.

Not every proposed transaction benefits competition and consumers. But the vast majority of mergers and acquisitions spur innovation and efficiency by providing smaller companies with the capital they need to grow. Mergers of more established companies often result in synergies that promote innovation and manufacturing efficiencies, and allow the merged company to get its products and services into the hands of more consumers.

Vague enforcement standards, ever-expanding investigations, and the consideration of factors like the impact of proposed transactions on labor and the environment will all undoubtedly have a **chilling effect** on deal making. Even the threat of an investigation lasting one to two years can be enough to kill a deal that would have been a win for competition and consumers, or if the parties endure, impose enormous uncertainty and costs, and erode the value of the target company as it twists in the enforcement winds.

Much of the impetus for more muscular and malleable antitrust enforcement comes from concerns on both **sides of the aisle** about the perceived market power and conduct of the large digital platforms. The competitive dynamics of the markets in which those companies operate, and some of the business strategies they have adopted, raise difficult and novel issues for antitrust enforcement that may warrant new approaches to thinking about competition and consumer harm in those markets. And, reasonable antitrust minds can and do differ over how to approach merger enforcement: we see that dynamic with every change in Administration, sometimes even if the same party remains in power. But the FTC’s recent policy and process changes leave businesses handicapped in their strategic planning and their attempts to assess the antitrust risk arising from those strategies and contemplated transactions. Hopefully, the Commission will move expeditiously to take steps to fill the current policy void, and to establish policies and procedures to reduce the (perhaps) unintended consequences of the recent changes to merger policy and process. But for now, and as a young philosopher once quipped as he careened, uncontrolled, down a steep hill to an uncertain end, we “don’t know where we’re going, but we’re on our way!”8

**Turn – sham litigation harms legitimate suits**

**Klein 07.** Christopher C. Klein. Associate Professor, Economics and Finance Department, Middle Tennessee State University. “"Anticompetitive Litigation and Antitrust Liability"” <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.568.758&rep=rep1&type=pdf>

IV. Conclusion When suits may be legitimate or sham and defendants can countersue for damages from sham suits, the resulting equilibria are of three basic types. If countersuits have no deterrent value, defendants either always or never countersue. If suits can be deterred, defendants countersue at least part of the time and either some or all sham suits are deterred, or all sham suits and at least some legitimate suits are deterred. Pre-trial settlements do not occur. Furthermore, broader definitions of illegal litigation tend to reduce the total frequency of litigation by increasing the deterrent effects of countersuits. **These broader definitions may also produce a chilling effect on legitimate litigation.** The English rule for the allocation of court costs, however, neutralizes this effect on legitimate litigation. Thus, **broader standards for defining illegal suits in conjunction with the English rule** **for allocating court costs** **may minimize** both **the frequency of illegal suits** **and the probability of countersuit, without affecting the frequency of legitimate suits**. Unfortunately, the Supreme Court has chosen to avoid a chilling effect on legitimate suits by enforcing “baselessness” as a requirement for suits to face countersuit liability. **This also minimizes the desirable chilling effect on suits motivated by collateral anticompetitive,** abusive, or malicious **gains**. **The likely result is an unnecessary maximization of litigation of these types**. The analysis conducted here and the frequency of citations to sham litigation decisions are both consistent with this outcome. Nevertheless, the “baselessness” requirement only applies to cases involving a single allegedly sham proceeding, due to the limited circumstances of the case before the Court. The subsequent attention to multiple suits or “pattern litigation” in the legal literature stems from the limited scope of the Court’s decision. Moreover, the shift in the legal literature toward the effect of fraud and misrepresentation on sham litigation is illuminated. If one seeks to successfully achieve an anticompetitive goal by bringing a suit that has no chance of winning on its true merits, then fraudulent or misrepresented evidence may be the only means to sustain such a suit. On the other hand, defendants seeking to countersue may raise the fraud issue to justify the necessary claim that the plaintiff’s suit is baseless. If countersuits focused on the economics of the initial suit, such claims would be less likely.

**Objectively basis bad- has a 1% conviction rate of cases**

**Fulbright 2019.** Paul W. Fulbright. Assistant Professor of Business Law, University of Houston. “Antitrust Law, Entrepreneurship, And The “Patent Bully”: The “Sham” Exception To Noerrpennington Petitioning Immunity In Patent Infringement Litigation After The Professional Real Estate Decision” proquest.com/scholarly-journals/antitrust-law-entrepreneurship-patent-bully-sham/docview/2298280771/se-2

C. The PRE “Objectively Baseless” Objective Test – An Overly Narrow Test As stated,107 the second problem with the objective test established by the Court in PRE is that, despite any ambiguity that may exist in the PRE decision, if the Court did indeed intend for the objective test to be a variant of the “objectively baseless” archetype, then a powerful argument can be made that it has chosen unwisely. The fact is that, in litigation generally, and in patent infringement lawsuits particularly, the PRE objective test, so construed, is too narrow. 1. PRE and Anticompetitive “Possible Technical Wins” Recall that the scope of the “objectively unreasonable” archetype for “sham” claims is broader than the “objectively baseless” archetype and that that is by design. The principal evil of the “objectively baseless” archetype is that it allows the claimant to pursue claims that have some non-zero chance of securing victory on the technical subject of liability (a “possible technical win”), even though no reasonable prudent claimant would file such a claim if he / she were genuinely seeking redress and evaluating the decision to sue on an objective cost-benefit basis. 2. Anticompetitive “Possible Technical Wins” in Patent Infringement Under the “objectively baseless” formulation, even if the claimant is a patent holder, bearing monopoly power, who has been advised by counsel that his patent is ninety percent (90%) likely to be found invalid, and also ninety percent (90%) likely to be found not infringed by the Defendant’s product, so that **the likelihood of success** on the subject of liability **is a mere one percent (1%),**108 **the claimant may** file suit, fully **expect**ing **to lose,** **knowing** that the **costs of the litigation will serve as a significant “street tax**

**---**

” on the profits of its less-financially-capable startup competitor. **Scenarios of this sort aren’t mere fantasy**. One of the consistent policy questions that has confronted the public and the patent bar, almost since the latter’s inception but certainly as well since the veritable explosion in patent litigation that has occurred since the mid-1980’s after the U.S. Court of Appeals for the Federal Circuit was created, is the striking rise in the size of patent damages awards, the similarly striking rise in the costs of said litigation,109 and, finally and equally importantly, the increasing use of patent litigation proceedings as a tactical mechanism for imposing a patent “street tax” on competitors and derailing mergers, acquisitions, and other competitor business plans.110 **Would the employment of an “objectively unreasonable”** archetype – type test **ameliorate these problems?** There is reason to believe that **it would, at least in part**. Note that the test requires that the claimant believe that it has a reasonable chance at securing a favorable outcome “based on the nature of the claim.” That is, the expectation against which the claimant will be judged must be the legal relief sought and expected, and not (for example) any “street tax” or other collateral burdens the litigation might impose upon the defendant. **Does empirical evidence support the suggestion that the current PRE test is insufficiently deterring “sham” litigations?** Empirical estimation of the effects of legal tests is extremely difficult and complex, but at least one probative observation can be made. **Rule 11** of the Federal Rules of Civil Procedure **is a** “some chance” / “**objectively baseless” – type standard**. What percentage of complaints, across all kinds of litigations, typically trigger Rule 11 proceedings? According to at least one study, **the answer** (albeit based on an estimate) **is approximately one percent (1%).**111 This invites the question as to whether one believes that, of all of the patent infringement complaints that are filed, a similarly small percentage of them are “objectively baseless” despite the articles in the business and legal press about gamesmanship in patent infringement litigation. **If one doubts that gamesmanship exists, remember: (a) eliminating competitors can be very profitable;112 and (b) under the PRE “objectively baseless**” **test, it is highly unlikely that one’s patent infringement claim will ever be found to constitute a “sham**.” Remember also that, although the burden of proving infringement rests with the patent holder,113 a patent is presumed to be valid,114 and the burden of proving invalidity rests on the party asserting invalidity.115

**Advantage CP**

**The courts are only comfortable with antitrust in patents**

**Kroll 16** (Kyle R. Kroll, J.D. Candidate 2016, University of Minnesota Law School, Anticompetitive Until Proven Innocent: An Antitrust Proposal To Embargo Covert Patent Privateering Against Small Businesses, 100 Minn. L. Rev. 2167, y2k)

**A rebuttable presumption** is not an **uncommon mechanism** in **antitrust** law. 294 Therefore, it is **more likely** that **courts** or legislative bodies would be **comfortable** in employing such a tool. Federal courts have **adopted a rebuttable presumption** in at least one instance involving **patent litigation already**. 295 Given the **precedents** already set by the federal courts and the fact that this solution would likely **be most effective at deterring patent privateering**, it should be adopted.

**Antitrust liability is key---it’s the only remedy that sufficiently deters**

**Zain 14** (Saami Zain, J.D., LLM (Antitrust); Assistant Attorney General, New York State Attorney General's Office, Antitrust Bureau. The views expressed here are those of the author and do not reflect those of the New York State Department of Law or the Antitrust Bureau, ANTITRUST LIABILITY FOR MAINTAINING BASELESS LITIGATION, 54 Santa Clara L. Rev. 729, y2k)

IV. Analysis

As evidenced by the cases discussed, **filing** and **maintaining baseless lawsuits** may have **anticompetitive** [\*756] effects. And while the cases focused primarily on initiation of litigation, it was recognized that maintaining the actions was also improper. Indeed, where maintaining baseless litigation has anticompetitive effects, there is no compelling rationale for creating a legal distinction between the filing and maintaining of a baseless action. 145 And in situations where a litigant is able to offer a questionable but potentially legitimate basis for filing an action (thereby making the suit unlikely to qualify as a sham), the greater need for imposing liability for continuing to litigate after it becomes clear that the action is meritless. Consequently, this section provides the argument for **antitrust liability** for maintaining baseless litigation.

A. Antitrust Sham Litigation for Maintaining Baseless Litigation is Good Policy

There are several justifications for imposing **antitrust** liability for continuing to litigate a baseless action for anticompetitive purposes. And where such litigation may cause anticompetitive effects - such as in Hatch-Waxman litigation - the potential for incurring antitrust liability may be an important deterrent.

First, **antitrust liability** is needed because laws **prohibiting** frivolous and bad faith litigation (such as Section 285 or Rule 11), are **inadequate deterrents** in many situations. Granting fees under Section 285 is largely within [\*757] a court's discretion, and thus a court may decline to impose fees in even egregious circumstances. 146 Similarly, Rule 11 is not only discretional, but several courts have interpreted it as only governing the filing of litigation and thereby rejected its application to conduct done in the course of litigation (including continuing to maintain a baseless action). 147 Moreover, **the remedies available** under these provisions - mostly **payment** of defendant's **fees** and **costs** - are **not** particularly **onerous** and thus not likely to **discourage frivolous litigation**. As **monopoly profits** may be quite **large**, a firm may well be quite **content** risking having to **pay fees** and **even sanctions** (in contrast to the risk of **treble damages for antitrust violations**).

Second, to the **extent** that **continuing** to litigate a **baseless** action is **anticompetitive**, there is no rational basis for **only** imposing liability on the **filing** of the action but not on **maintaining** it. And where the litigation circumvents legislative policies, such as those created by the Hatch-Waxman Act, it should be prevented to the fullest extent possible. Thus, imposing liability on **both** filing and maintaining baseless, anticompetitive litigation would likely have the **favorable** effect of further **deterring** such deleterious conduct.

**Courts will narrow the counterplan**

**Ostas 07.** Daniel T. Ostas. Assistant Professor at the College of Business and Management, University of Maryland. He holds both aJ.D. and a Ph.D. A member of the Indiana Bar since 1980. “The Law and Ethics of K Street: Lobbying, the First Amendment, and the Duty to Create Just Laws” <https://www.jstor.org/stable/pdf/27673157.pdf?refreqid=excelsior%3A51dcc3d5e0be8682cb67189baea962d3>

E. Summary The above **survey of the law demonstrates that lobbyists have been entrusted with wide latitude** in determining who, what, when, where, and how to lobby. This is largely true because of the societal respect afforded to First Amendment liber ties. Whether one characterizes the right to lobby as a free speech right, a right to petition the government, or as an amalgam of the two, **it is clear that lobbying and lobbyists enjoy First Amendment protections**. Hence, **the government is constitutionally constrained in regulating lobbying**. The legal analysis also demonstrates that the various substantive areas of the law that address lobbying are more often than not conflicted, gap riddled, and/or poorly enforced

. For example, revolving-door legislation provides for cooling-off periods, but currently applies only to direct lobbying contacts and not to other public-relations activities. Hence, the revolving door remains ajar, leaving both an incentive for and the appearance of inside dealing. Similarly, bribery law makes it illegal to give, offer, or promise anything of value in exchange for a public favor; yet, regulators routinely leave government to work for companies that they previously regulated. Although not technically a bribe, the economic incentives to act with favor for one's future employer would seem hard to resist. In addition, there appears to be no federal law that directly prohibits a lobbyist from lying to a legislator. For better or worse, **the primary means of regulating lobbying activities currently resides in public registration** **and disclosure** statutes. Perhaps sunlight is indeed the best way to assure public confidence in the lobbying process. Although disclosure regulations do not directly address the issues of who, what, when, where, or how, the public information that reporting provides could have much the same effect. In the end, **whether a lobbyist cooperates with the policies that underlie lobbying regulations** **or feels free to exploit regulatory loopholes and constitutional freedoms will largely depend on his or her personal values and ethics.** It is to these questions of ethics that the discussion now turns.

**The court will explicitly ignore FDA guidance and regulations on citizen petition by super-imposing the Noerr-Pennington immunity---that creates a perverse incentive for firms to submit petitions**

**Liu 17** (Franklin Liu, Associate at Kirkland & Ellis LLP, JD, Boston College of Law, ARTICLE: WEAPONIZING CITIZEN SUITS: SECOND CIRCUIT REVISES THE BURDEN OF PROOF FOR PROVING SHAM CITIZEN SUITS IN APOTEX v. ACORDA THERAPEUTICS, 58 B.C. L. Rev. E. Supp. 147, y2k)

II. PHARMACEUTICAL DRUG ANTITRUST LITIGATION IN THE SECOND CIRCUIT

The **pharma**ceutical industry is particularly **ripe** for **antitrust** claims and counterclaims given the **statutorily created monopolies** that brand-name drug companies enjoy by **virtue of** their **exclusivity periods**. 55 In May 2016, in *Apotex* Inc. v. Acorda Therapeutics, Inc., the United States Court of Appeals for the **S**econd **C**ircuit **refused** to extend antitrust liability to Acorda, a brand-name drug manufacturer that had allegedly filed **a citizen petition** to delay approval of Apotex's competing generic. 56 Section A of this Part discusses [\*157] prior Second Circuit precedent applying antitrust principles to citizen petitions, and the FDA's recent interpretative guidance ("Guidance for Industry"). 57 Section B discusses the Second Circuit's evaluation of the FDA Guidance for Industry and the reasoning in Apotex behind its holding that the evidence at bar was insufficient to state a claim for an antitrust violation under Section Two of the Sherman Act. 58

A. In re DDAVP and the FDA Guidance for Industry on Citizen Petitions

The *Noerr-Pennington* antitrust immunity doctrine **does not** protect sham litigation and indeed, the Second Circuit has specifically held that sham citizen suits can be analogized to **sham litigation** and form the **basis** of a claim for a violation of Section Two of the Sherman Act. 59 In 2009, in In re DDAVP Direct Purchaser Antitrust Litigation, the U.S. Court of Appeals for the Second Circuit heard a case with very similar facts to Apotex that involved a generic drug application that the FDA approved on the same day that the FDA denied the citizen petition, leading to the inference that the petition had played a role in delaying approval of the generic. 60

In re DDAVP involved a suit by a class of direct purchasers who alleged that the defendant manufacturer, a licensee of antidiuretic DDAVP tablets, suppressed generic competition by filing a sham citizen petition to delay a generic competitor's ANDA, all for the purpose of inflating the price the defendant could charge for DDAVP. 61 The Second Circuit held that the plaintiffs presented sufficient evidence to state a claim for antitrust liability based on a theory that the defendant's citizen petition was a sham. 62

In November 2014, after In re DDAVP, the FDA released Guidance for Industry, a document that the Second Circuit deemed persuasive in reaching its decisions in Apotex. 63 The **FDA Guidance** for Industry outlines the **FDA's interpretation** of Section 355(q) of the FDCA with respect to **citizen** [\*158] **petitions** and, in particular, how citizen petitions related to a pending ANDA are to be evaluated. 64 Guidance for Industry states that, with respect to the **timing** of an ANDA review and a citizen petition, the FDA's priority is to protect the **procedural rights** of ANDA applicants to challenge adverse agency decisions with respect to their application, including notice of an opportunity for a hearing. 65 Because a ruling on a citizen petition is considered final agency action **reviewable only by the courts**, a FDA ruling on a citizen petition before a FDA decision on whether to grant an ANDA would leave the ANDA applicant unable to challenge the FDA's finding at the agency level. 66 Thus, according to Guidance for Industry, the FDA prefers to wait to decide on a citizen petition until after it renders a decision on the ANDA application at issue. 67

B. The Second Circuit's Reasoning in Apotex

In Apotex, the **S**econd **C**ircuit **unanimously** affirmed the district court's decision after a de novo review, denying **generic** drug **manufacturer** Apotex's claim that brand-name drug manufacturer Acorda had filed a **sham citizen petition** in violation of U.S. antitrust law. 68 The **key issue** in Apotex was whether the **brand**-name **manufacturer's** citizen petition was **objectively and subjectively baseless** and therefore **a sham litigation** that could serve as the **sole basis of an antitrust claim. 69**

The Second Circuit held that Apotex had failed to meet the first prong of the test because it had not shown that Acorda's citizen petition was objectively baseless. 70 Because both prongs of the test need to be satisfied in order to show litigation is a sham, it was therefore unnecessary for the Second Circuit to go on to consider whether the citizen suit also constituted a subjective sham. 71

In light of the Guidance, the Second Circuit held that the FDA's actions with respect to approving the ANDA application and ruling on the [\*159] brand-name manufacturer's citizen suit reflected a concerted effort by the FDA to protect the generic manufacturer's procedural rights with respect to its ANDA application. 72 Because the FDA Guidance suggests that the FDA prefers to rule on citizen suits and the implicated ANDA application contemporaneously in order to protect ANDA applicants' review rights, the Second Circuit held that it was significantly less likely for Acorda's citizen petition to have been a sham and used in an anticompetitive fashion. 73 Thus, the Second Circuit ultimately ruled that the generic manufacturer had not stated a claim under Section Two of the Sherman Act and that the district court did not abuse its discretion in its disposition of the case. 74

III. THE SECOND CIRCUIT'S ANALYSIS OF FDA GUIDANCE MISAPPLIES U.S. ANTITRUST LAW AND INCENTIVIZES DILATORY SHAM LITIGATION

Despite the factual similarity to its own precedent, the U.S. Court of Appeals for the Second Circuit in 2016, in Apotex Inc. v. Acorda Therapeutics, Inc., dismissed a generic drug manufacturer's claim that a brand-name drug manufacturer violated U.S. antitrust law by filing a sham citizen suit to delay the FDA's approval of the generic. 75 In so deciding, the Second Circuit effectively raised the **burden of proof** for showing a **particular** citizen suit is a sham by reducing the **presumptive weight** it had previously afforded to the **timing of the FDA's decisions**. 76 After Apotex, the significance of the timing of the FDA's review of an ANDA and its disposition of a related citizen suit has been **downgraded** from sufficient to state a claim of sham litigation to **merely relevant** in that assessment. 77 Despite the fact that the Second Circuit had held that the petitioners in 2009 in In re DDAVP Direct [\*160] Purchaser Antitrust Litigation had stated a claim for sham litigation based purely on the timing of the FDA's actions, the Second Circuit in Apotex suggested that such evidence is not enough and that plaintiffs must plead additional facts that the petition is **baseless** in order to **survive a motion to dismiss**. 78

Although the FDA Guidance that the Second Circuit relied on is certainly **persuasive** authority, it is, by its own terms, **nonbinding**. 79 Even assuming, arguendo, that the Second Circuit's interpretation of the FDA Guidance was **correct**, its decision in Apotex risks **undermining the very goals that the Sherman Act** and the Hatch-Waxman Act were designed to achieve. 80 The Sherman Act, like the other U.S. antitrust laws, was enacted to protect competition and consumer welfare and ensure that businesses have sufficient incentives to compete on both price and quality. 81 The Hatch-Waxman Act was designed in part to provide the public with access to lower cost drugs upon the expiration of a brand-name drug's exclusivity period. 82 Both statutes were therefore designed specifically to help promote free competition in furtherance of the public welfare. 83

Generics are not only much cheaper than brand-name drugs, but each generic that enters the market puts additional downward pressure on the price of the incumbent brand-name drug. 84 The Second Circuit's ruling that [\*161] there was insufficient evidence to infer that Acorda's citizen petition was being deployed as **an anticompetitive weapon** against Apotex risks harming not only the health and viability of generic drug manufacturers like Apotex going forward, but the American public as well. 85 The Second Circuit's ruling in Apotex will hurt generic manufacturers in the **short** and **long-run**, because brand-name manufacturers, **seeing the increased degree of difficulty** facing generic manufacturers to prove **sham suits**, may choose to **follow Acorda's** lead and **file** their own **citizen suit**

**s** whenever generic manufacturers attempt to enter the market. 86 The purpose of the brand-name manufacturer's citizen suit would be to extend its exclusivity period, which would undermine generic competition in contravention of the goals of the Hatch-Waxman Act. 87 Should that reality come to pass, the public will be harmed, as they will be forced to pay for high-priced brand-name drugs longer than the law intends. 88

CONCLUSION

The U.S. Court of Appeals for the Second Circuit's 2016 decision in Apotex Inc. v. Acorda Therapeutics, Inc.--that the FDA's simultaneous granting of a generic ANDA and denial of a brand-name's citizen petition is insufficient evidence to infer that the citizen petition was deployed as an anticompetitive weapon--risks harming not only the health and viability of generic drug manufacturers, but the American public as well. By devaluing **the presumptive weight** previously afforded to the precise timing of the FDA's disposition of citizen suits and ANDA approvals, the Second Circuit has made it considerably more **difficult** for parties to prove that a particular citizen suit is a sham and thus **an anticompetitive weapon of the type prohibited by the Sherman Act.**

The Second Circuit's ruling creates a **perverse incentive** that may **induce** other brand-name drug companies seeking to **extend the life of** their **monopolies** to file their own **citizen suits** with the sole purpose of undermining their generic competitors. In such circumstances, the public will be [\*162] forced to continue to pay for higher-priced brand-name drugs, as there will be no other choices in the absence of generic competitors.

Apotex not only represents a stark departure from recent case precedent, but the Second Circuit's holding is also contrary to the intent of Congress in enacting the Hatch-Waxman Act and the Sherman Act, both of which were intended to protect the public by ensuring unfettered operation of the free market system and preservation of consumer choice. In the context of the prescription **drug market** and given the public health ramifications, it is especially **vital** that U.S. courts consider the underlying policies of the statutes they are interpreting or else **risk greater harm to the public** by their oversight.

**FTC DA**

**FTC overload now.**

**Burke ’21** [Henry and Andrea; May 28; B.A. in Political Science and Labor Studies from the University of California at Los Angeles; Research Assistant, B.A. in Economics from the University of Maryland; Revolving Door Project, “Hobbled FTC Lacks Budget to Combat Corporate Buying Spree,” <https://therevolvingdoorproject.org/hobbled-ftc-lacks-budget-to-combat-corporate-buying-spree/>]

Even if the **will** to stop it exists, the FTC doesn’t have the **funding** to stop this boom. In fact, it hasn’t had the funding to **keep up** with a **steady uptick** in mergers in **years**. Aside from the recent spike, the **total** number of premerger filings [**increased**](https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-bureau-competition-department-justice-antitrust-division-hart-scott-rodino/p110014hsrannualreportfy2019_0.pdf) by **80 percent** over the last 10 years. In 2010, corporations filed 1166 premerger notifications. By 2019, yearly filings almost **doubled** to 2089.

While the **number** of transactions the FTC is charged with regulating has **increased** steadily, the **number** of enforcement actions — challenges to anticompetitive mergers or conduct — has **stagnated**.  A 2020 paper from Equitable Growth showed that while the number of [enforcement actions](https://equitablegrowth.org/wp-content/uploads/2020/11/111920-antitrust-report.pdf) from both the FTC and DOJ hovered at about 40 challenges per year from 2010 to 2019, even as the number of corporations seeking merger approval grew. The FTC’s enforcement actions over the past ten years show the agency hasn’t kept up with increased HSR filings: while FY 2010 saw **22** enforcement actions for **1166** reported mergers, a ratio of approximately one enforcement action for every 53 mergers, FY 2019 saw a mere 21 enforcement actions for **2089 mergers**, meaning there was **only one** FTC enforcement action for **every 99** mergers.

Overall **funding** and **staffing levels** at the FTC have similarly **stagnated**. Then-FTC commissioner Rebecca Slaughter said in 2020 that it is an “[**indisputable**](https://www.ftc.gov/system/files/documents/public_statements/1583714/slaughter_remarks_at_gcr_interactive_women_in_antitrust.pdf)” fact that FTC funding has **not kept up** with market demands; according to Slaughter, the FTC budget has only increased by **13%** since 2010 and the employee headcount **decreased**. This budget increase has not come from increased discretionary appropriations from Congress however, but from a massive increase in merger filings and their accompanying fees. Startlingly, Slaughter notes that “the FTC had roughly **50% more** full-time employees at the beginning of the **Reagan** Administration than it does today.” The situation has become so dire that increased budgets for the enforcement agencies has become a rare [bipartisan](https://www.law360.com/articles/1368496/klobuchar-says-congress-has-rare-shot-at-antitrust-overhaul) issue in the Senate.

**We solve**

1. **Litigation - the FTC has been locked since 2011 over Abbvie and will keep going after patent trolls**

**Brachmann 5-25**. Steve Brachmann. Freelance journalist located in Buffalo, New York. He has worked professionally as a freelancer for more than a decade. He writes about technology and innovation. His work has been published by The Buffalo News, The Hamburg Sun, USAToday.com, Chron.com, Motley Fool and OpenLettersMonthly.com. “Federal Trade Commission Urges SCOTUS to Deny AbbVie Petition” <https://www.ipwatchdog.com/2021/05/25/federal-trade-commission-urges-scotus-deny-abbvie-petition/id=133880/>

On Wednesday, May 19, the response brief of the Federal Trade Commission (FTC) was filed with the U.S. Supreme Court in AbbVie v. FTC. The petition for writ of certiorari filed by AbbVie asks the nation’s highest court to decide whether lower courts erred in finding that AbbVie’s Hatch-Waxman district court litigation involving patents covering its AndroGel testosterone treatment met the sham litigation exception to Noerr-Pennington doctrine. The FTC’s brief urged the Supreme Court to deny AbbVie’s petition for writ, a decision that arguably could cast into doubt pharmaceutical firms’ ability to enforce their patent rights under decades-old legislation meant to balance the economic interests of innovative drug developers with the public interests served by generic drug makers.

AbbVie Faces FTC Antitrust Action After Settling Hatch-Waxman Suits Against Teva and Perrigo

**The present appeal stems back to patent infringement litigation** **filed** by AbbVie **in 2011** against generic drug makers Teva Pharmaceuticals and Perrigo Company over Paragraph IV certifications those companies made in their abbreviated new drug applications (ANDAs) for generic versions of AbbVie’s AndroGel that Teva and Perrigo filed with the U.S. Food and Drug Administration (FDA). By certifying to the FDA that their generic testosterone treatments would not infringe AbbVie’s AndroGel patents, or in the alternative that those patents were invalid, Teva and Perrigo provoked district court litigation under the Hatch-Waxman Act, legislation implemented by Congress in 1984 to incentivize branded drugmakers to quickly bring suits to adjudicate infringement claims after a Paragraph IV certification. The Paragraph IV certifications filed by Teva and Perrigo noted that their generic testosterone treatment didn’t literally infringe AbbVie’s Androgel patent claims, which covered the use of isopropyl myristate, and that any doctrine of equivalents argument advanced by AbbVie would be overcome by prosecution history estoppel as AbbVie had amended its patent from claiming the use of any penetration enhancer to claim only isopropyl myristate.

Although both the Teva and Perrigo suits were ultimately settled by AbbVie, the FTC filed a September 2014 lawsuit in the Eastern District of Pennsylvania alleging that AbbVie’s lawsuits were sham lawsuits **meant purely to delay** the market entry of generic versions of AndroGel. The district court ordered AbbVie to pay $448 million in disgorgement, finding that the lawsuits met the sham exception to Noerr-Pennington doctrine, which immunizes private companies from federal antitrust suits under an interpretation of the First Amendment when those companies are litigating valid rights that create anticompetitive effects. The sham litigation exception to Noerr-Pennington required the FTC to prove (1) that AbbVie’s lawsuits were objectively meritless; and (2) that AbbVie’s subjective intent in filing the suits was only to interfere with the business interests of its competitors.

The district court found objective baselessness in AbbVie’s suits as AbbVie had “no plausible argument to overcome… the application of prosecution history estoppel” as argued by Teva and Perrigo in their FDA filings. Although there was no direct evidence of AbbVie’s subjective intent, the district court inferred subjective intent from the fact that AbbVie’s lawyers were very experienced with patent matters and would know that litigation would delay generic competition. On appeal to the U.S. Court of Appeals for the Third Circuit, the district court’s ruling was upheld in part on the reasoning that the objective and subjective elements of the sham litigation exception are interrelated and the objective baselessness of the suit, coupled with the experience of AbbVie’s attorneys, satisfied the subjective element.

FTC Argues Proper Application of Noerr-Pennington Sham Litigation Exception **Should Prevent Appeal**

In the agency’s brief in opposition, counsel for the FTC argued that the Supreme **Court could simply deny AbbVie’s petition** based on the Court’s regular practice of denying interlocutory review in cases where further lower court proceedings could affect the issues in AbbVie’s petition. Although the Third Circuit affirmed the district court’s sham litigation finding, it reversed the finding that AbbVie’s settlement with Teva constituted an illegal reverse-payment agreement and remanded for further proceedings on that claim. “The current interlocutory posture of the case is a sufficient reason to deny the petition for a writ of certiorari,” the FTC argued.

Should the Supreme Court disagree on that point, the FTC argues that both the district and circuit courts properly found subjective intent in the circumstantial evidence of the case, including AbbVie’s lawyers’ knowledge of prosecution history estoppel, their knowledge of AndroGel’s commercial success, and the regulatory context in which AbbVie’s Hatch-Waxman suit triggered an automatic 30-month stay of FDA approval for generic competitors. The FTC also addressed AbbVie’s arguments on petition that the lower courts’ application of the Noerr-Pennington sham litigation exception conflicted with Supreme Court precedent. Lower courts were free to credit objective baselessness as having evidentiary weight for the subjective prong of the test, the FTC argued, and that the collateral injury inflicted by the 30-month stay under the Hatch-Waxman framework was evidence that AbbVie was abusing a governmental process to directly interfere with competitors’ business relationships. Even if AbbVie is correct that the subject prong of the sham litigation exception required evidence of actual knowledge or belief of the meritless nature of the Teva and Perrigo suits, the FTC noted that the district court ruled that AbbVie acted with “actual knowledge that the suits lacked merit” and “with no expectation of prevailing.” Further, there was no conflict with circuit court precedent because the Federal Circuit’s presumption that patent suits are brought in good faith can be overcome by circumstantial evidence of acting in bad faith.

The FTC’s response brief also mitigated concerns raised by AbbVie’s petitions that the lower courts’ decisions would harm innovation by impacting patent rights negatively and undermine attorney-client privilege. AbbVie’s petition noted that 10% of all patent litigation filed in U.S. district courts is filed under the Hatch-Waxman regulatory process and by relying on objective evidence upon which reasonable decisionmakers could disagree, pharmaceutical firms now face heightened antitrust scrutiny diminishing their incentive to innovate even if they subjectively believe that their patent suit has merit. As well, the court of appeals shifted the burden onto AbbVie to prove subjective intent by presenting evidence of the opinions and mental impressions of AbbVie’s patent lawyers, which would have required the waiving of privilege. In response, the FTC contended that AbbVie raised no argument that the vast majority of Hatch-Waxman litigation would be objectively baseless. Further, AbbVie’s privilege argument relies on the unusually facts of the underlying case, in which no business executives signed off on the Teva and Perrigo lawsuits. While attorney-client privilege is an important concern to balance, the FTC argued that barring courts from inferring subjective intent could lead pharmaceutical firms to simply delegate all legal decisions to in-house attorneys in order to invoke privilege.

FTC Enforcement Actions Against AbbVie Are Far from Over

AbbVie’s patent portfolio has taken a great deal of flak in Washington in recent weeks, especially regarding the company’s blockbuster anti-inflammatory drug Humira. On May 18, a group of House Democrats called for an FTC inquiry into AbbVie’s patent practices which have delayed market entry for a generic version of Humira, and the House Oversight Committee grilled AbbVie CEO Richard Gonzalez on those same practices. “We want drug companies to be successful, but abusive, unfair pricing and anticompetitive practices mean these medicines **are out of reach** for too many Americans,” said Representative Carolyn Maloney (D-NY), one of the House Democrats calling for an FTC investigation into AbbVie’s Humira, at the House Oversight Committee hearing. Although President Biden has yet to nominate someone for FTC Chair, Acting Chair Rebecca Kelly Slaughter’s comments surrounding Qualcomm’s successful appeal of antitrust enforcement against that company’s patent licensing practices indicates that the FTC under President Biden may become very active in raising antitrust charges against patent owners.

**b) Private and state enforcement - Plan is net-better for enforcement---eases the barriers for proving a claim AND allows private and state AGs to prosecute trolls**

**Gugliuzza 15** (Paul R. Gugliuzza, PATENT TROLLS AND PREEMPTION, Virginia Law Review , October 2015, Vol. 101, No. 6 (October 2015), pp. 1579-1647, y2k)

Furthermore, a return to the **traditional** standard would **free courts** from the **Noerr**-based principle, embraced in Innovatio and Activision, that any false statement must relate to the issues of validity or infringement to strip a patent holder of immunity. Pre-Federal Circuit decisions, for example, condemned patent holders who circulated notices that "falsely stated and pretended that certain patents owned by the [patent holder] ha[d] been adjudicated and sustained in contested cases."374 This change in the law would enable **private plaintiffs** and government law enforcers, such as the FTC and **state attorneys general**, to **impose** civil liability on **unscrupulous patent holders** without **difficult additional step** of **disproving** the merits of the **underlying infringement claim**

## 1AR

**Case**

**Trolling increases uncertainty in the ~cloud~**

**Aymeric 17** (Sébastien Aymeric is an associate in the Auckland office of James & Wells, a national intellectual property firm. If you are interested in finding out more about protecting your intellectual property, contact Sébastien. “Fighting back against the patent trolls”, https://idealog.co.nz/venture/2017/06/fighting-back-against-patent-trolls)

**Patent trolls on the prowl**

Patent trolls, however, do not let themselves get bogged down with such minor details. Whether their case for patent infringement is strong or not is irrelevant. “Patent troll” is a pejorative term given to individuals or companies whose primary activity is to assert or threaten to assert patent rights in court against other companies. This is often through hardball tactics. These companies rarely exploit the patent themselves, and are also often called **N**on-**P**ractising **E**ntities. The sole reason for the operation of these companies is to make a living by negotiating financial settlements and licensing deals.

Cloud computing

Over the past few years, cloud computing has become a fertile hunting ground for patent trolls. They are going after both service providers and users. Cloud computing is currently a booming industry, and this why patent trolls are becoming rampant. Cloud computing also relies a lot on open source software, as is illustrated by the case against Netflix. The patents for business methods or software can be very wide in scope; the **inconsistency** in the United States Patents Office’s approach to patent eligibility for business methods and software – and that of the US courts – has also **created uncertainty and caused questionable patents to be granted over the years.**

### Taxation CP

**1st Amendment Pic**

**Greene 15** (Hillary Greene, Professor of Law, University of Connecticut School of Law, MUZZLING ANTITRUST: INFORMATION PRODUCTS, INNOVATION AND FREE SPEECH, 95 B.U.L. Rev. 35, y2k)

2. **First Amendment Interfaces** in **Non-Antitrust** Contexts

The foregoing discussion identified non-immunized speech such as price fixing (no First Amendment solicitude) and **immunized speech** such as **government petitioning** (**absolute** First Amendment protection) as two extreme points on the First Amendment and antitrust spectrum. This Section examines two non-antitrust contexts in which the Supreme Court created more nuanced legal standards to better protect the First Amendment as well as other, potentially conflicting, values. The first example concerns commercial speech, i.e., advertising, for which the Court explicitly adopts an "intermediate" [\*59] approach. More specifically, government restrictions on **commercial speech** are subject to a **unique** level of **constitutional review**, intermediate scrutiny, in contrast to either strict or rational basis scrutiny. The second example concerns defamatory speech and the adoption of a "conditional privilege" if a certain condition is met, i.e., no actual malice by the speaker. This approach to defamation contrasts with recognizing an absolute privilege or no privilege at all. While these two examples differ from the antitrust circumstances at issue herein, they represent important examples wherein the Court transcended unduly simplistic approaches to protecting speech

a. Commercial Speech

Throughout much of the twentieth century, "commercial speech" received little or no direct First Amendment solicitude in the context of government restrictions. In particular, earlier in the century, several Supreme Court cases expressly rejected any such constitutional protection. 116 Over time, even though the Court did not champion First Amendment protection for commercial speech, it avoided reaffirming the exclusion of commercial speech from protection. In 1976, the Court explicitly held in Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc. 117 that commercial speech, in the form of unadorned advertising, deserved some measure of First Amendment protection. The case invalidated a state law prohibiting certain advertising by pharmacies. 118

Virginia State Board of Pharmacy introduced several key themes that would receive further amplification in later years. The Court recognized that the economy's operation is clearly a matter of vital importance and political significance to society, and that the exchange of commercial information is critical to the functioning of economic actors. 119 It observed, moreover, that individuals may at times find information regarding commercial goods to be as important as, or more important than, political discourse. 120 The importance of commercial speech is a function of multiple interests: the speakers (sellers), the [\*60] potential audience (buyers), and society as a whole. 121 While acknowledging the immense importance of commercial speech, the Court also established its subordinate position in the First Amendment hierarchy. The First Amendment provided a basis for "insuring that the stream of commercial information flows cleanly as well as freely," but such speech receives a different, lesser, standard of protection. 122

The commercial speech standard received its seminal articulation in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York. 123 The majority further emphasized many of the general themes characterizing Virginia State Board of Pharmacy. 124 Central Hudson's most important contribution, however, lay in its delineation of an intermediate scrutiny framework.

At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest. 125

**Intermediate scrutiny** is an additional treatment category applicable to the constitutional analysis of government **restrictions** on speech. Through development of this category, the Court recognized that commercial speech can be **vital** to **society**, and at the same time imposed some limits on when that speech enjoys First Amendment protection. The success of this intermediate approach would depend on developing a workable definition of "commercial speech" and a workable form of intermediate scrutiny. 126

As always, **the lines drawn** within one case almost **invariably** spawn further **litigation** to identify where the line falls in more ambiguous cases. 127 What [\*61] would become a long-simmering debate regarding what constitutes a "substantial government interest" (the second prong of intermediate scrutiny) arose with regard to severe restrictions on truthful and non-deceptive information undertaken for what is deemed paternalistic purposes. This Article will discuss the intermediate scrutiny standard subsequently when considering the Supreme Court's 2011 ruling in Sorrell v. IMS Health, Inc.

**Uncertainty means businesses give up on patent litigations**

**Valdes 15** (RONNY VALDES, Executive Editor, American University Business Law Review, Volume 4; American University Washington College of Law, J.D. Candidate 2015, STARE INDECISIS: THE FEDERAL CIRCUIT'S EN BANC BATTLE AGAINST ITSELF AND BUSINESS IN LIGHTING BALLAST CONTROL, LLC V. PHILIPS ELECTRONICS NORTH AMERICA CORP., 4 Am. U. Bus. L. Rev. 63, y2k)

Furthermore, businesses may be enticed to **give up** on patent litigation **all together** and instead focus on **avoiding** long litigation through **settlement**. 214 The threat of multiple en banc courts reconsidering the same issues undoubtedly creates **confusion** regarding the **true meaning of the law**, which, in turn, creates confusion for businesses because lawyers must have **consistent standards** to advise clients on litigation matters. 215 The logical question that follows is: if the law is not broken, why would the court reconsider it? **NPEs may thrive in this scenario** because businesses will **not** be enticed to challenge these small **n**on-**p**racticing patent holders with appeals to the Federal Circuit when **no prediction can be made as to how the court may rule since the law over time will become extremely muddled over time.** 216 [\*92] With patents steadily becoming a bigger and bigger part of corporate portfolios, **inconsistent applications** of law or uncertainty acts contrary to **business objectives** and **may reduce interest in patents over time**. 217

Finally, businesses facing inconsistency or uncertainty in patent law are exactly what Congress attempted to avoid when it created the Federal Circuit. 218 Congress understood the growing role of patents in the American economy and sought to make patent litigation easier because patent law would be uniform and centralized. 219 Businesses **prefer predictability** because it reduces **volatility** and **risk** both of which are important strategic considerations. 220 Congress recognized the importance of strong business strategies and the negative effects of inconsistent patent law. 221 That being said, with threats to the **uniformity** of patent law, neither the Supreme Court nor Congress have stepped up, and the confusion and uncertainty have lingered long enough.

**FTC DA**

**Perception’s thumped – Trump’s FTC tried to do exactly our affirmative and it’s been the FTC policy since the 1980s**

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**Noerr-Pennington** Yet another example of the current administration’s **seemingly** **stricter** antitrust enforcement—at least **relative to other Republican administrations**—**is the FTC’s stance on the Noerr-Pennington doctrine**. In February 2017, the FTC filed a case against Shire ViroPharma **seeking to narrow the immunity** **under Noerr**-Pennington. **36 Part of the FTC’s reason for bringing this case is to further cement the California Motor** 37 “**pattern of petitioning” exception** **to** the **P**rofessional **R**eal **E**state Investors decision’s “**objectively baseless**” **test**. 38 Narrowing the scope of immunity is very much in line with a policy objective Muris set out in the 1980s and early 2000s. With recent nominations of individuals who were at the FTC under Muris, **the case** against Shire ViroPharma **is a good indication that the future full Commission will have a similar policy objective.**

**IF the link is true, then FTC won’t enforce the aff---we still solve because states go after trolls---this is contingent on removing federal preemption**

**Feld 16** (Tara Feld, J.D. Candidate, 2016, The University of Illinois College of Law, STATES HOLD THE SWORD TO FORCE "PATENT TROLLS" BACK UNDER THEIR BRIDGES, 2016 U. Ill. L. Rev. 1123, y2k)

Further, there are limits to the effectiveness of using the FTC to combat patent trolls. The FTC cannot bring suit against a patent troll until it has actually asserted one of its patents. 190 FTC actions would be limited only to deceptive practices, such as sending threatening letters with no intent to actually bring an infringement suit, unable to get at the real crux of the patent troll problem: the coercive patent assertion itself. 191 Additionally, the FTC suffers from **limited resources**. 192 Such limitations force the FTC to "target[] its law enforcement … efforts to maximize its desired outcome," necessarily disallowing it from going after all **patent trolls**. 193

b. Executive Actions

Executive actions are less likely to succeed than even FTC litigation. Although "some points drew general praise," lawyers in the patent law community have expressed reservations as to the effectiveness of the President's legislative recommendations and executive actions. 194 One patent attorney nicely summed up the limitations of Obama's initiatives by [\*1145] labeling some as "merely aspirational," others as "ephemeral," with "the most substantive" initiatives "requiring congressional action." 195

In Executive Action No. 1, the President stated that the PTO would institute a process to make the "real party-in-interest" (that is, the true owner of the patent being asserted) more easily ascertainable. 196 The goal is to increase transparency so that target businesses "know[] the full extent of the patents that their adversaries hold," and can, in theory, better prepare for settlement negotiations or litigation. 197

Unfortunately, while the "real party-in-interest" recommendation may do its job to increase transparency, it does so at a cost. 198 This course of action can potentially burden the PTO with additional training and procedural costs which it lacks the resources to handle, thus taking resources away from patent applications and possibly leading to more improperly granted patents. 199 Further, it is unlikely to deter patent trolls from initiating litigation, a more poignant source of a patent troll's coercive power than their ability to hide behind shell companies. 200 Additionally, even if this executive action could be effective at combating patent trolls, the real teeth to the "real party-in-interest" recommendation would come from congressionally-approved sanctions for noncompliance. 201 Yet, "it's not clear that the White House has the political ammo to get Congress to pass such law in the near future." 202 These factors limit the effectiveness of the executive branch's "real party-in-interest" initiative.

The President's other executive actions similarly suffer from a low likelihood of success at curbing patent trolls' coercive behaviors. Executive Action No. 2, which provides examiners with additional training and guidelines in order to avoid granting overly broad patents, 203 will likely take time away from the examination of applications and may not lead to better patents. The USPTO is currently undergoing the Glossary Pilot Program as a result of this executive action. 204 The program is limited to certain types of software patents 205 and requires applicants to include a [\*1146] glossary of terms at the beginning of the detailed description section of their patents. 206 As of November 5, 2015, all but one petition out of one hundred sixty-seven filed under the Glossary Pilot Program had been granted. 207 The program has since ended. 208 It remains to be seen whether the program will actually inhibit the actions of patent trolls. Given the small number of petitions applied for under the program, however, it seems the initiative will have only a limited impact on the patent troll problem, if at all.

Executive Actions Nos. 3 and 4 deal with consumer education and input from patent attorneys practicing in the field. 209 Of the fifty-three attorneys quoted in Law360's article regarding the effectiveness of President Obama's executive actions, not a single one mentioned either the consumer-education or attorney-input actions. 210 This suggests attorneys practicing in the field do not believe these measures will have an impact, positive or negative, on the patent-troll problem.

Executive Action No. 5, aimed at standardizing the enforcement of exclusion orders granted by the International Trade Commission ("ITC"), does have some potential to do good for the fight against patent trolls. 211 Ensuring a uniform methodology for determining the scope of ITC enforcement orders strengthens the overall effectiveness of ITC proceedings. 212 While this is a positive outcome for the ITC in general, it will have almost no impact on the willingness of patent trolls to initiate lawsuits in the ITC, or in other U.S. courts for that matter, as "there is no evidence that [patent trolls] are bringing lawsuits at increased numbers because of lax enforcement of ITC exclusion orders." 213

Overall, President Obama's executive actions are unlikely to deter patent trolls from filing coercive lawsuits. 214 Further, a general theme throughout all of the attorneys' responses in the Law360 article was the need for legislative, rather than executive action. 215 Unfortunately, legislative [\*1147] action on this issue seems highly unlikely to occur any time in the near future. 216

3. The Judicial Branch

Some federal courts have begun to take an indirect stand against patent trolls through decisions like eBay. 217 Specifically, the eBay decision makes it more difficult for successful patent plaintiffs to be granted a permanent injunction, taking one tool out of the patent trolls' belts. The decision has been successful at eliminating the "automatic injunction" mentality that ran through the courts prior to eBay. After eBay through May 26, 2013, thirty-two percent of patent cases were denied a permanent injunction by district courts. 218 This statistic shows an increase in injunction denials, up from an estimated five percent pre-eBay. 219

While this change at the district court level certainly represents a positive step, the eBay decision has had other side effects that somewhat diminish its success at combating patent trolls. Patent trolls have shifted from using district courts to filing with the ITC. 220 Through 2011, patent troll suits before the ITC shot up from seven percent to twenty-five percent after the eBay decision. 221 The reason for this shift was that the ITC has a different standard for granting injunctions than the district courts. 222 The ITC grants injunctions in the form of exclusion orders. 223 In order to receive an exclusion order, a party must show "a widespread pattern of unauthorized use of its patented invention and certain business conditions from which one might reasonably infer that foreign manufacturers other than the respondents to the investigation may attempt to enter the U.S. market with infringing articles." 224 Because of the ITC's underlying statutory authority, 225 "certain legislative and judicial changes to patent law procedures and remedies don't apply." 226 The ITC, therefore, is not bound by the eBay decision; successful patent trolls are still almost guaranteed a permanent injunction in the jurisdiction. 227 Essentially, "the [\*1148] ITC's practices have undone many of the desirable consequences of eBay." 228

Aside from having minimal impact on patent trolls, the eBay decision has negatively affected other sectors of the U.S. economy, namely the pharmaceutical industry. 229 Such companies argued in amicus briefs before the Court in eBay "that limiting injunctions and weakening patent laws would drive up the cost of innovation." 230 Because of the highly technical nature of pharmaceuticals, courts are unlikely to arrive at the proper estimate of the reasonable royalty to award a successful pharmaceutical patent plaintiff. 231 Specifically for biotechnological tools and diagnostic products, courts are likely to find that the public interest weighs in favor of denying a permanent injunction to the plaintiff; the importance of these products to public health and safety make it unlikely that a court would limit their production through granting a permanent injunction. 232 Even if these fears have not necessarily panned out quite as the biotechnology industry feared, 233 the fact that a permanent injunction is less of a sure thing than in the pre-eBay world means that smaller biotech companies will lose out on a significant bargaining chip and will be less likely to secure favorable settlements. 234 To hedge this potential loss, companies will have to cut back on research spending, leading to a decrease in innovation. 235

Courts additionally have institutional limitations that affect their ability to make effective strides against patent trolls. Although court decisions, especially Supreme Court decisions, impact both existing and future patents, 236 they are limited only to the cases brought before them. Further, patent trolls do not even need to institute a trial in order to be successful. 237 The court system moves too slowly for the target businesses that do get all the way to trial, as such defendants "cannot wait for the appeal process to rectify the wrong decision." 238

[\*1149] Judge Rader, former Chief Judge of the Court of Appeals for the Federal Circuit, expressed concern that the Supreme Court's recent interest in patent cases has resulted in binding precedent inconsistent with the goals of the U.S. patent system. 239 Rader noted that litigating parties often want courts to do more than their job of applying the patent statutes, arguing for judges to consider consumer protection and fair competition in their application of laws not intended to tackle such issues. 240 The former Chief Judge also noted that the outcome of a trial should not be dependent upon the identities of the parties involved, meaning that courts should not be in the business of deciding against a patent troll simply because of the nature of its business model. 241 With these criticisms of the judicial branch's role in the patent troll battle, it is not a strong candidate for a swift, effective solution.

B. **The States' Responses Can Be More Effective**

The Federal Government's responses to the patent troll problem are commendable, but ultimately fall short of truly handling the impediment to innovation. The state legislatures are in a much **better position** to take on **patent trolls**. State legislation avoids many of the drawbacks and inefficiencies that plague the Federal Government's responses to the patent troll problem.

Still, one serious concern unique to relying exclusively upon state action is the "collective action" problem. Because of each state's own independent legislative body, some states will inevitably have strong anti-patent troll legislation, while others will have weak or no such legislation. 242 This could lead to a sort of "forum shopping" by patent trolls in which they strategically choose which states to send their coercive letters, frustrating the overall goal of consumer protection, especially in those targeted states. 243 Even with this drawback, states are still capable of solving the **patent troll** problem more **effectively** than the Federal Government.

1. States Can Tailor Their Laws to Specific Industries

One of the core principles of the U.S. federalist system of government is the notion that the states exist to meet the needs of their specific, diverse, and unique citizenry. 244 As Justice Black once noted, "the National Government will fare best if the States and their institutions are [\*1150] left free to perform their separate functions in their separate ways." 245 The existence of state governments allows each state to be more reactive and responsive to the specific needs of its citizenry when such needs are not homogenous from state to state. 246

Because of the states' responsive nature, they can cater their **anti-patent-troll laws** to the specific needs of the **industries** present within their **respective jurisdictions**. For example, patent trolls are not a significant problem for the pharmaceutical industry, and in fact the Big Pharma lobby pushed against anti-patent-troll reforms in Congress. 247 Yet, for the software and technology industries, patent trolls represent a substantial and growing threat. 248 Therefore, in states with a large technology industry but a smaller pharmaceutical industry (e.g. Washington), 249 the anti-patent-troll laws could be more stringent than in a state with large pharmaceutical companies (e.g. Illinois). 250 This sort of tailoring is not feasible at the federal level and represents one of the main reasons Congress has been unable to pass any further anti-patent-troll legislation in recent years. 251

2. **States Can Get the Job Done**

While states have the unique ability to tailor laws to their citizens' needs, such an advantage would be useless if states fell victim to the same impasses that have plagued Congress. States simply can get (and have gotten) **more** done to **combat patent trolls** than the federal government. 252 Aside from the questionable effectiveness of the AIA in combating patent trolls, the main frustration with Congress is its inability to come to a consensus on how to deal with patent trolls. 253 State legislatures have already proven far more amenable to agreement on this issue than [\*1151] Congress has been; in October 2014, eighteen states passed anti-patent-troll legislation, with proposed bills in at least eleven more. 254

The states do not seem to be gridlocked the same way Congress has unfortunately been on this issue. State legislatures have been far more **active** in passing **new legislation** than Congress in the last year. 255 Federally generated patent laws and policies must be uniform across the entire nation, but the industries that rely on patents are not one-size-fits-all. 256 Similar to the states' ability to tailor laws to the needs of their specific industries, the anti-patent-troll measures need not be uniform from state to state. 257 In general, state legislatures cannot play the same political games as Congress, 258 thereby avoiding, out of necessity, the industry lobbying stalemate currently going on at the federal level. 259

3. States Can Amend Existing Consumer Protection Laws

Many of the anti-patent-troll measures taken by the states have come through the use of state consumer protection laws. 260 Some state consumer protection laws are **modeled** after **the FTC's section 5 language**, 261 yet the usage of such state laws to target patent trolls has not been questioned as the FTC's similar usage has been. 262 Several courts have allowed such state consumer-protection-based claims against patent trolls, indicating that at least some courts (including federal courts) find this tactic acceptable. 263 Further, and perhaps more importantly, MPHJ thought several state consumer-protection assertions were valid enough to settle in at least two states, Minnesota 264 and New York. 265

[\*1152]

4. Other Federal Laws Have Been Successfully Supplemented by State Action

State involvement in a nationally established legal regime is not a new phenomenon in the United States. For example, states enforce the federal environmental laws promulgated by the Environmental Protection Agency ("EPA"). 266 States can step in, on their own accord, and initiate civil administrative actions, civil judicial actions, or criminal judicial actions for federal EPA violations. 267 Courts even impose state-based fines or penalties for EPA violations. 268 Additionally, state-based tort law sometimes applies in admiralty cases. 269 Admiralty law, like patent law, is reserved strictly to the federal judiciary, deriving its exclusive jurisdiction from both the Constitution 270 and Congressional law. 271

There are also areas of intellectual property law over which the state and federal governments share control. Trade secret and trademark laws involve elements of both federal and state governments. 272 Similar to the goals of patent law, trade secret law is intended to encourage innovation and the development of "valuable information." 273 Similar to the goals of anti-patent troll legislation, trademark law is focused on consumer protection. 274 For trade secret law, the state component deals with trade secret misappropriation in terms of contractual, quasi-contractual, or property law principles, 275 while the federal component handles the threats to international and national trade. 276 The states provide for private actions against misappropriation, while the federal government, though lacking private causes of action, investigates and prosecutes parties involved in trade secret theft. 277 Interestingly, state trade secret law applies even when the stolen secret ends up in a patent. 278 The successful [\*1153] interplay between state and federal trade secret law, even when involving patents, shows that such a split scheme in an intellectual property discipline can work, and affirmatively has worked, within the United States legal system.

Likewise, trademark law's state and federal components co-exist. State trademark law has its roots in the common law, and federal trademark registration affords state-registered marks with additional, supplemental benefits. 279 Both federal and state courts hear trademark causes of action. 280 Further, federal law rarely preempts state trademark law. 281 The two regimes work to offer protection to rights holders and to consumers at both the state and federal level. 282

5. The Problem of Preemption

The **looming cloud** over state-based, anti-patent-troll measures is the **federal** preemption problem. The question of preemption in the patent law context is beyond the scope of this Note, but has been covered by several other scholars. 283 There is some merit to the suggestion that federal law may not preempt state patent troll legislation. For example, in Zenith Electronics Corp. v. Exzec, Inc., the Federal Circuit held that state unfair competition laws were not preempted by federal patent law because the state cause of action requires bad faith. 284 Additionally, in Globetrotter Software, Inc. v. Elan Computer Group, Inc., the Federal Circuit held state tort liability for allegations of patent infringement were not preempted by federal patent law so long as the cause of action required the allegations to be "objectively baseless." 285 Even the current preemption law, however, once applied to state measures take against patent trolls, "will almost certainly **prohibit** the states from condemning any but the most **frivolous** **assertions** of **patent infringement**." 286