## 1AC

### Sham Litigation---1AC

#### Contention 1: Sham litigation

#### 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.

#### 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 prevents extinction

Jain 20 (Ash; 2020; Senior fellow with the Scowcroft Center for Strategy and Security; Strategic Studies Quarterly; “Present at the Re-Creation: A Global Strategy for Revitalizing, Adapting, and Defending a Rules-Based International System,” <https://www.atlanticcouncil.org/wp-content/uploads/2019/10/Present-at-the-Recreation.pdf>)

The system must also be adapted to deal with new issues that were not envisioned when the existing order was designed. Foremost among these issues is emerging and disruptive technology, including AI, additive manufacturing (or 3D printing), quantum computing, genetic engineering, robotics, directed energy, the Internet of things (IOT), 5G, space, cyber, and many others.

Like other disruptive technologies before them, these innovations promise great benefits, but also carry serious downside risks. For example, AI is already resulting in massive efficiencies and cost savings in the private sector. Routine tasks and other more complicated jobs, such as radiology, are already being automated. In the future, autonomous weapons systems may go to war against each other as human soldiers remain out of harm’s way.

Yet, AI is also transforming economies and societies, and generating new security challenges. Automation will lead to widespread unemployment. The final realization of driverless cars, for example, will put out of work millions of taxi, Uber, and long-haul truck drivers. Populist movements in the West have been driven by those disaffected by globalization and technology, and mass unemployment caused by automation will further grow those ranks and provide new fuel to grievance politics. Moreover, some fear that autonomous weapons systems will become “killer robots” that select and engage targets without human input, and could eventually turn on their creators, resulting in human extinction.

The other technologies on this list similarly balance great potential upside with great downside risk. 3D printing, for example, can be used to “make anything anywhere,” reducing costs for a wide range of manufactured goods and encouraging a return of local manufacturing industries.61 At the same time, advanced 3D printers can also be used by revisionist and rogue states to print component parts for advanced weapons systems or even WMD programs, spurring arms races and weapons proliferation.62 Genetic engineering can wipe out entire classes of disease through improved medicine, or wipe out entire classes of people through genetically engineered superbugs. Directed-energy missile defenses may defend against incoming missile attacks, while also undermining global strategic stability.

Perhaps the greatest risk to global strategic stability from new technology, however, comes from the risk that revisionist autocracies may win the new tech arms race. Throughout history, states that have dominated the commanding heights of technological progress have also dominated international relations. The United States has been the world’s innovation leader from Edison’s light bulb to nuclear weapons and the Internet. Accordingly, stability has been maintained in Europe and Asia for decades because the United States and its democratic allies possessed a favorable economic and military balance of power in those key regions. Many believe, however, that China may now have the lead in the new technologies of the twenty-first century, including AI, quantum, 5G, hypersonic missiles, and others. If China succeeds in mastering the technologies of the future before the democratic core, then this could lead to a drastic and rapid shift in the balance of power, upsetting global strategic stability, and the call for a democratic- led, rules-based system outlined in these pages.63

The United States and its democratic allies need to work with other major powers to develop a framework for harnessing emerging technology in a way that maximizes its upside potential, while mitigating against its downside risks, and also contributing to the maintenance of global stability. The existing international order contains a wide range of agreements for harnessing the technologies of the twentieth century, but they need to be updated for the twenty-first century. The world needs an entire new set of arms-control, nonproliferation, export-control, and other agreements to exploit new technology while mitigating downside risk. These agreements should seek to maintain global strategic stability among the major powers, and prevent the proliferation of dangerous weapons systems to hostile and revisionist states.

#### 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 intellectual property 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]

#### More cloud innovation begets more risk (PAE = Patent troll)

Bhattacharya 20 (Prapti Bhattacharya Asian Law College, Noida, Under the Guidance of Prof. (Dr) T. Ramakrishna, MCI Chair Professor on IPR, “Analysis of IPR Challenges of Cloud Computing and Ways to Overcome the Issues”https://iprlawindia.org/wp-content/uploads/2021/03/Prapti-Bhattacharya.pdf)

Now here we need to discuss the rising importance of PAEs (Patent Assertion Entities, businesses who litigate their patents but generally don‟t otherwise use their patented technology) because it has been observed that compensations awarded for PAEs are almost four times higher than granted for other patent claimants. Since the economic value of cloud is rising day by day, the cloud customers are preparing exclusively interesting targets for PAEs because customers usually don’t have the same level of knowledge to understand the difficulties of cloud as cloud service providers (CSPs), and also because they are less prepared to fight an IP suit, and have very less incitement to solve an IP disputes for others. This is the reason why cloud patent claim risk is being accommodated by the largest global CSPs in their cloud service agreements., and their regulators in regulated sectors in India, should take note as well.

#### Existing cloud fails to solve asteroids

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 technology 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.

### Patent Thickets---1AC

#### Contention 2: Patent Thickets

#### Brand pharma companies are amassing patents in attempts to lock out the generic market---that causes sky-rocketing prices and undermines access

Lisa Orucevic 22, JD Candidate @ Vanderbilt Law, A Machete for the Patent Thicket, 75 Vand. L. Rev. 277 (2022), https://vanderbiltlawreview.org/lawreview/2022/01/a-machete-for-the-patent-thicket/

Outrageous drug prices have dominated news coverage of the American healthcare system for years. Yet despite widespread condemnation of skyrocketing drug prices, nothing seems to change. Pharmaceutical companies can raise drug prices with impunity because they hold patents on their drugs, which give them monopolies. These monopolies are only supposed to last twenty years, and then competing lower-cost drugs like generics can enter the market, driving down the costs of pharmaceuticals for all. But pharmaceutical companies have created “patent thickets,” dense webs of overlapping patents surrounding one drug, which have artificially extended the companies’ monopolies for years or even decades after a drug’s initial patent expires. These problems will only be exacerbated as the pharmaceutical industry increasingly focuses on biologic drugs, which already provide more opportunities to acquire multiple patents on one drug than traditional small-molecule drugs.

Patent law’s weapons in the fight against patent thickets, namely litigation and inter partes reviews (an abbreviated process for challenging patent validity), have proven to be inadequate—a scalpel when the public needs a machete. Antitrust law, which polices anticompetitive behavior and corrects market failures, is the ideal weapon to fight the pharmaceutical industry’s exploitation of patent law. The Noerr-Pennington doctrine, which immunizes parties from antitrust liability when a party “petitions” the government, currently stands in the way of an antitrust solution to the patent-thicket problem. “Petitions” eligible for Noerr-Pennington antitrust immunity include patent applications and patent-infringement lawsuits, so the pharmaceutical industry can wield the Noerr-Pennington doctrine as a sword against potential antitrust challenges. The Noerr-Pennington doctrine has a narrow “sham exception,” where Noerr-Pennington antitrust immunity is pierced when a party’s petitions are “mere shams” to interfere with the operations of a competitor. Unfortunately, after two Supreme Court decisions about the sham exception, the circuit courts have disagreed on the sham exception’s operation, leaving potential antitrust plaintiffs, such as consumers and government regulators, with uncertain prospects for challenging patent thickets under antitrust law.

This Note proposes that courts adopt an approach to reconcile the Supreme Court decisions wherein courts apply a stricter standard for invoking the sham exception when an antitrust plaintiff challenges a single sham petition and a looser standard when an antitrust plaintiff challenges a pattern of sham petitions. Further, this Note proposes a general framework for analyzing patent proceedings under the looser pattern standard. This solution strikes a balance between protecting parties’ First Amendment petitioning right and discouraging abuse of the patent law system for anticompetitive effect. If successful, antitrust challenges can lead to quicker market entry for lower-cost drugs and allow more people to benefit from innovative and life-altering drugs.

#### Widely available generics prevent millions of deaths

WH 20 (West Health Citing study released today by the West Health Policy Center, “New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications”, https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/)

WASHINGTON, DC and SAN DIEGO, CA – Nov. 19, 2020 – More than 1.1 million Medicare patients could die over the next decade because they cannot afford to pay for their prescription medications, according to a new study released today by the West Health Policy Center, a nonprofit and nonpartisan policy research group. If current drug pricing trends and associated cost-sharing continue, researchers estimate cost-related non-adherence to drug therapy will result in the premature deaths of [one hundred twelve thousand] 112,000 beneficiaries a year, making it a leading cause of death in the U.S., ahead of diabetes, influenza, pneumonia, and kidney disease. Millions more will suffer worsening health conditions and run up medical expenses that will cost Medicare an additional $177.4 billion by 2030 or $18 billion a year for the next 10 years. Researchers also modeled what would happen if Medicare was allowed to bring down drug prices for its beneficiaries through direct negotiation with drug companies, as described in H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, passed by the U.S. House of Representatives last year. They found Medicare negotiation could result in 94,000 fewer deaths annually. Additionally, the model found that the policy would reduce Medicare spending by $475.9 billion by 2030. “One of the biggest contributors to poor health, hospital admissions, higher healthcare costs and preventable death is patients failing to take their medications as prescribed,” said Timothy Lash, President, West Health Policy Center. “Cost-related nonadherence is a significant and growing issue that is direct result of runaway drug prices and a failure to implement policies and regulations that make drugs more affordable.” The price of prescription medications has skyrocketed in recent years. Between 2007 and 2018, list prices for branded pharmaceutical products increased by 159% and there are few signs of it slowing.[i] According to the Centers for Medicare & Medicaid Services (CMS), spending on prescription drugs will grow faster than any other major medical good or service over the next several years.[ii]

#### Cost is key to widespread cell therapy during crisis

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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

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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.

#### Disease causes extinction

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The recent SARS-CoV-2 pandemic, which is causing COVID 19 disease, has taught us unexpected lessons about the dangers of human extinction through highly contagious and lethal diseases. As the COVID 19 pandemic is now being controlled by various isolation measures, therapeutics and vaccines, it became clear that our current lifestyle and societal functions may not be sustainable in the long term. We now have to start thinking and planning on how to face the next dangerous pandemic, not just overcoming the one that is upon us now. Is there any evidence that even worse pandemics could strike us in the near future and threaten the existence of the human race? The answer is unequivocally yes. It is not necessary to get infected by viruses of bats, pangolins and other exotic animals that live in remote forests in order to be in danger. Creditable scientific evidence indicates that the human gut microbiota harbor billions of viruses which are capable of affecting the function of vital human organs such as the immune system, lung, brain, liver, kidney, heart etc. It is possible that the development of pathogenic variants in the gut can lead to contagious viruses which can cause pandemics, leading to destruction of vital organs, causing death or various debilitating diseases such as blindness, respiratory, liver, heart and kidney failures. These diseases could result in the complete shutdown of our civilization and probably the extinction of human race. In this essay, I will first provide a few independent pieces of scientific facts and then combine this information to come up with some (but certainly not all) hypothetical scenarios that could cause human race misery, even extinction. I hope that these scary scenarios will trigger preventative measures that could reverse or delay the projected adverse outcomes.

#### Drug resistance overcomes burnout – resistance enables optimal virulence through horizontal gene transfer, which maximizes disease fitness

Schroeder et al 17 – Meredith Schroeder, PhD candidate, Department of Microbiological Sciences; North Dakota State University, Benjamin D. Brooks, PhD, Department of Electrical and Computer Engineering; North Dakota State University, and Amanda E. Brooks, PhD, Department of Pharmaceutical Sciences, North Dakota State University (“The Complex Relationship between Virulence and Antibiotic Resistance,” *Genes*, Vol. 8, No. 1, page 39, January 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5295033/)

Antibiotic resistance, prompted by the overuse of antimicrobial agents, may arise from a variety of mechanisms, particularly horizontal gene transfer of virulence and antibiotic resistance genes, which is often facilitated by biofilm formation. The importance of phenotypic changes seen in a biofilm, which lead to genotypic alterations, cannot be overstated. Irrespective of if the biofilm is single microbe or polymicrobial, bacteria, protected within a biofilm from the external environment, communicate through signal transduction pathways (e.g., quorum sensing or two-component systems), leading to global changes in gene expression, enhancing virulence, and expediting the acquisition of antibiotic resistance. Thus, one must examine a genetic change in virulence and resistance not only in the context of the biofilm but also as inextricably linked pathologies. Observationally, it is clear that increased virulence and the advent of antibiotic resistance often arise almost simultaneously; however, their genetic connection has been relatively ignored. Although the complexities of genetic regulation in a multispecies community may obscure a causative relationship, uncovering key genetic interactions between virulence and resistance in biofilm bacteria is essential to identifying new druggable targets, ultimately providing a drug discovery and development pathway to improve treatment options for chronic and recurring infection.

1. Introduction

Until recently, conventional “antibiotic wisdom” suggesting the presence of a fitness cost associated with the development of antibiotic resistance that would eventually allow susceptible species to overtake resistant species was the predominating dogma in infectious diseases [1]. However, the ever-increasing threat of antibiotic resistant bacteria contradicts dogma and insinuates that the evolution of resistance may be associated with a fitness advantage, including enhanced virulence [2,3]. Although virulence has now been directly related to multidrug resistance in several animal infection models [2], the mechanism of virulence regulation in this climate of antibiotic resistance remains elusive. This review will explore the relationship between the mechanisms of acquired antibiotic resistance and enhanced virulence, a critical link in our war on the emergence of multidrug resistant bacteria.

#### 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?

### Circuit Split---1AC

#### Contention 3: Circuit Split

#### Lower courts are currently split over how to administer the *Noerr-Pennington’s* sham exception---that undermines predictability in the existing antitrust

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Filing lawsuits to injure rivals—especially nascent competitors—is as old as the hills and as American as apple pie.1 As competition law developed in the 20th century, so did the risk of antitrust liability for dominant firms that attempted to protect their market position by burdening rivals with litigation.2 For example, in 1938, a group of radio speaker manufacturers were subjected to Section 1 scrutiny for filing at least 54 patent infringement lawsuits, along with additional letters threatening infringement suits. As the Ninth Circuit stated, “We may assume that each of those acts would be lawful, and still a conspiracy might be shown. If the agreement has an unlawful purpose, it is a conspiracy, notwithstanding that the means used to carry it out were lawful.”3 Litigation, it has been said, “can be an integral part of a scheme prohibited by the Sherman Act.”4 In the 1960s, however, the Supreme Court conferred antitrust immunity on lawsuits filed against rivals with the creation of the Noerr-Pennington doctrine. That doctrine immunizes formal requests–– such as litigation and regulatory protests––to secure government action intended to harm competitors, except when that petitioning is a “sham.”5 A sham, as the term implies, is not a legitimate effort to exercise the constitutionally protected right to petition the government to redress a grievance; rather, it is a cover for the “true” purpose of employing the courts or regulatory machinery of government in bad faith to inflict economic pain upon a competitor. That pain can take many forms, including raising rival’s costs, erecting costly entry barriers, delaying or deterring entry, or using a combination of obstacles to drive a rival out of business.6 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 Noerr Pennington 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

#### The Third Circuit recently ruled in favor of FTC in the *AbbVie* case---that thumps all DA

J. Mark Gidley 8-9, chairs the White & Case Global Antitrust/Competition practice, Third Circuit: Pharmaceutical Cases, https://www.whitecase.com/publications/article/third-circuit-pharmaceutical-cases-2021

FTC v AbbVie, Inc

The Third Circuit's highly publicized decision in FTC v AbbVie1 involves several topics of significance to antitrust litigants, including (1) interpretation of the seminal reverse-payment decision, Actavis,2 (2) application of the sham litigation exception to Noerr-Pennington immunity, which is currently before the Supreme Court on the drug manufacturers' petition for a writ of certiorari, and (3) the availability of disgorgement under section 13(b) of the Federal Trade Commission Act (the FTC Act).

Background

The FTC litigation concerns a 2011 Abbott Laboratories settlement of patent infringement suits it brought against Perrigo and Teva relating to the testosterone-replacement therapy, AndroGel.3 The FTC alleged that, on the same day as its settlement with Teva, Abbott also entered into a supply agreement with Teva for the cholesterol drug, TriCor.4 The FTC claimed that the defendants filed sham patent-infringement suits against Teva and Perrigo, and entered into an anticompetitive reverse-payment agreement with Teva.5 The FTC filed suit against Abbott, AbbVie, Unimed, Besins (collectively, the defendants), and Teva in the Eastern District of Pennsylvania pursuant to section 13(b) of the FTC Act.6

The district court granted the defendants' motion to dismiss the FTC's claims based on its reverse-payment theory.7 The district court later granted summary judgment to the FTC on the objective-baselessness prong of Professional Real Estate Investors' (PRE) sham litigation exception to the Noerr-Pennington doctrine,8 and after holding a bench trial, the district court found for the FTC on the subjective-motivation prong of the sham litigation exception and on monopoly power.9 The court awarded $448 million in disgorgement but declined to order injunctive relief.10 Both the FTC and the defendants appealed to the Third Circuit. The FTC argued that the district court erred in dismissing its reverse-payment claims, in calculating the amount of disgorgement, and in denying injunctive relief.11 The defendants argued that the district court erred in finding that the sham litigation exception applied and that the defendants possessed monopoly power.12 The defendants further argued that the district court erred in ordering disgorgement and, alternatively, in calculating the amount of disgorgement.13

Third Circuit decision

The Third Circuit held that the district court erred both in granting the defendants' motion to dismiss the FTC's reverse-payment claims, and in its summary judgment decision for the FTC that the defendants' patent-infringement suit against Teva was a sham.14 The court affirmed the district court's findings that the suit against Perrigo was a sham, and also that the defendants possessed monopoly power.15 Finally, the Third Circuit panel vacated the district court's disgorgement order, holding that the FTC lacks authority to seek disgorgement under section 13(b) of the FTC Act.16

#### Specifically, the decision eliminated one of the key components in the two-step test used for deciding immunity---that makes it impossible to administer the *Noerr* doctrine unless the Supreme Court clarifies

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

1. This Court Established a Two-Step Test for "Sham" Litigation that Requires Proof of Subjective Unlawful Intent

Under the Noerr-Pennington framework, "[a] party who petitions the government for redress generally is immune from antitrust liability." A.D. Bedell Wholesale Co. v. Philip Morris Inc., 263 F.3d 239, 250 (3d Cir. 2001) (cleaned up). An exception to the doctrine exists if a party files a "sham" lawsuit, which is what the Federal Trade Commission (FTC) alleged here. PRE, 508 U.S. at 56.

If the plaintiff succeeds in establishing that the lawsuit is "objectively baseless," as required in the first step of PRE, then a court "may ... examine the litigant's subjective motivation." Amarel v. Connell, 102 F.3d 1494, 1518 (9th Cir. 1996) (citing PRE, 508 U.S. at 60-61); see also U.S. Futures Exch., LLC v. Bd. of Trade of the City of Chicago, Inc., 953 F.3d 955, 963 (7th Cir. 2020) ("The exception requires a two-step inquiry: (1) only if challenged litigation is objectively meritless may a court (2) examine the litigant's subjective motivation ... In other words, an antitrust plaintiff must 'disprove the challenged lawsuit's legal viability' before proceeding to the second, subjective step.") (first emphasis in original, second emphasis added); CSMN Inv., LLC v. Cordillera Metro. Dist., 956 F.3d 1276, 1283 (10th Cir. 2020) ("Under the first step, a court considers whether the petitioning has an objectively reasonable basis ... If so, immunity applies ... But if not, a court proceeds to the second step, considering the subjective motivation behind the petitioning.") (citations omitted)

Where a court makes a threshold determination of objective baselessness, the second, subjective prong serves a critical purpose. It requires the court to determine "whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor...' through the 'use [of] the governmental process ... as an anticompetitive weapon.'" PRE, 508 U.S. at 60-61. Courts have described this second, subjective prong as demanding. See, e.g., Omni Res. Dev. Corp. v. Conoco, 739 F.2d 1412, 1414 (9th Cir. 1984).

2. The Third Circuit Improperly Conflated the Objective and Subjective Prongs

Despite enunciating both prongs of the exception and characterizing the analysis as a "delicate task," the Third Circuit incorrectly allowed mere satisfaction of the first prong to satisfy proof of the second: subjective intent. Pet. App. 67a. The Court held, based on a "syllogism," 2Link to the text of the note that if a reasonable person pursues a lawsuit later found, in hindsight, to be objectively baseless, subjective bad faith can be presumed from that alone. This defective reasoning effectively collapsed the objective and subjective prongs into a single element. Id. at 69a.

The Third Circuit's erroneous legal standard was necessary to its decision because--even after a 16-day trial--there was "no direct evidence of [these individuals'] subjective intent." Id. at 66a. This posture, wherein the case has gone through full discovery and a lengthy trial (but produced no evidence of subjective bad faith apart from an attenuated syllogism), illustrates the extent to which the court effectively eliminated the subjective prong.

Unquestionably, the Third Circuit's decision is at odds with this Court's decision in PRE that the "sham" litigation exception requires a discrete two-step inquiry. PRE, 508 U.S. at 60-61. The Third Circuit's opinion risks infringement of the protection afforded companies and businesses to vindicate their rights in an increasingly competitive marketplace.

Were this error to stand, it would remain unclear in many circumstances how a court can determine the line between the right to freely petition the government, which Noerr-Pennington protects, and the use of litigation as an "anticompetitive weapon," which Noerr-Pennington does not. See, e.g., Westmac, Inc. v. Smith, 797 F.2d 313, 318 (6th Cir. 1986) ("Determining whether a party who filed suit was indifferent to obtaining a favorable judgment may often be a difficult question of fact."); see also Winterland Concessions Co. v. Trela, 735 F.2d 257, 263 (7th Cir. 1984). In light of the considerable confusion displayed by courts about the "sham" litigation exception, including the mistaken view of the Third Circuit (see Part C, infra), this Court should intervene and provide much needed clarity.

#### The predictability of the antitrust regime is key to effective business planning and rule of law

Bruce Wardhaugh 20, senior lecturer in competition law @ University of Manchester, Competition, Effects and Predictability: Rule of Law and the Economic Approach to Competition. Bloomsbury Publishing

It is also clear that businesses have a significant reliance interest on the state of competition rules in planning their business development, which will include decisions concerning investment and financing, and marketing strategy. The ability to legally conduct oneself on the market in a given manner and/or to be sure that competitors or suppliers will not conduct themselves in certain ways will be a consideration in formulating and implementing these sorts of commercial decisions. If courts subsequently alter the rules due to changes in academic thinking in economics (and not as a result in the changing legal landscape), this shatters not only the reliance interests of those whose business arrangements are directly affected, but also undermines others’ confidence in their own reliance interests. The nature of these interests was raised in amici curiae briefs before the USSC in Leegin. The minority was concerned by these interests; however, the majority brushed these concerns aside.99 To the extent that US antitrust law and policy relied on the ability and willingness to overrule its earlier decisions based on a new understanding of economic theory, it creates a significant problem for antitrust advisors to give their clients clear advice of how the authorities will view their proposed (or even currently existing) business practices. This is ultimately a rule of law problem. In Europe, the rule of law problem is somewhat different. The ECJ will respect its own previous decisions, overruling them only when a development in the legal landscape has occurred. To this point, changing academic understandings of competition economics have yet to count as such a change. Rather, the European rule of law threat is from the Commission as a result of its approach of isolating competition policy from other Treaty goals.

#### Effective business planning solves extinction

Stephen Polasky 19, Fesler-Lampert Chair in Ecological/Environmental Economics, University of Minnesota, Role of economics in analyzing the environment and sustainable development, PNAS March 19, 2019 116 (12) 5233-5238, <https://www.pnas.org/content/116/12/5233>

The environmental sciences have documented large and worrisome changes in earth systems, from climate change and loss of biodiversity, to changes in hydrological and nutrient cycles and depletion of natural resources (1⇓⇓⇓⇓⇓⇓⇓⇓⇓⇓–12). These global environmental changes have potentially large negative consequences for future human well-being, and raise questions about whether global civilization is on a sustainable path or is “consuming too much” by depleting vital natural capital (13). The increased scale of economic activity and the consequent increasing impacts on a finite Earth arises from both major demographic changes—including population growth, shifts in age structure, urbanization, and spatial redistributions through migration (14⇓⇓⇓–18)—and rising per capita income and shifts in consumption patterns, such as increases in meat consumption with rising income (19, 20). At the same time, many people are consuming too little. In 2015, ∼10% of the world’s population (736 million) lived in extreme poverty with incomes of less than $1.90 per day (21). In 2017, 821 million people were malnourished, an increase in the number reported malnourished compared with 2016 (22). There is an urgent need for further economic development to lift people out of poverty. In addition, rising inequality resulting in increasing polarization of society is itself a threat to achieving sustainable development. Eliminating poverty (goal 1) and hunger (goal 2), achieving gender equality (goal 6), and reducing inequality (goal 10) feature prominently in the United Nation’s Sustainable Development Goals (23). A recent special issue in PNAS on natural capital framed the challenge of sustainable development as one of developing “economic, social, and governance systems capable of ending poverty and achieving sustainable levels of population and consumption while securing the life-support systems underpinning current and future human well-being” (24). The discipline of economics arguably should play a central role in meeting the sustainable development challenge. The core question at the heart of sustainable development is how to allocate the finite resources of the planet to meet “the needs of the present, without compromising the ability of future generations to meet their own needs” (25). A central focus of economics is how to allocate scarce resources to meet desired goals; indeed, a standard definition of economics is the study of allocation under scarcity. More specifically, economics studies the production, distribution, and consumption of goods and services, which are both a key driver of development (increasing standards of living through providing food, housing, and other basic human requirements) and a main cause of current changes in earth systems. Economics, combined with earth system sciences, is crucial for understanding both positive and negative impacts of alternatives and the trade-offs involved. Economics, combined with other social and behavioral sciences, is crucial for understanding how it might be possible to shift human behavior toward achieving sustainable development. Economics has well-developed fields in development economics, ecological economics, environmental economics, and natural resource economics, with large bodies of research relevant to the sustainable development challenge. The application of economic principles and empirical findings should be a central component in the quest to meet the aspirations of humanity for a good life given the finite resources of the earth.

### Plan---1AC

#### The United States federal government should narrow the scope of Noerr-Pennington antitrust immunity by applying a profit sacrifice test to adjudicate sham exceptions.

### Solvency---1AC

#### Solvency

#### The plan strengthens the “sham exception” standard in *Noerr-Pennington*, which brings clarity to the existing standard which caused circuit splits and a First Amendment overreach

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Courts apply the Noerr-Pennington doctrine in the litigation context to prevent competitors from turning the legal system into an anticompetitive weapon.7 Litigants who seek to abuse the judicial process do so through predatory litigation.8 The hallmark of predatory litigation is that

the litigant’s true motive is not the case’s legal success, but its anticompetitive impact.9 Identifying true motivation, however, has proven challenging for scholars and courts.10

Over the past fifty years, courts have struggled with identifying and prosecuting predatory litigation without infringing on the right to petition. The governing test for identifying a predatory is the “sham” exception, defined by the Supreme Court in its 1993 case Professional Real Estate Investors, Inc. v. Columbia Pictures (“PRE”).11 A sham lawsuit must be objectively baseless, meaning filed without probable cause, and be subjectively motivated to harm competition.12 Since PRE, the Supreme Court has been silent.

This test has resulted in numerous anticompetitive outcomes, confusion in the lower courts, and strong criticism. Antitrust scholars have proposed alternative standards rooted in logic and economic theories.13 Commentators have decried PRE’s test as overly restrictive.14 Despite these pleas for reform, lower courts remain stuck with an unworkable “sham” standard.

One area where predatory litigation has been particularly rampant is the pharmaceutical industry. Scholars have long known that the existing intellectual property scheme surrounding pharmaceuticals have made it ripe for antitrust violations.15 The intense competition between generic and brand products can drive competitors to aggressive tactics.16 Thanks to government regulation, patent holding monopolists have the power to impose delay on generic competitors.17 In recent years, Congress even investigated the impact of predatory litigation.18 Speakers at the hearing explained that the doctrine is out of balance and “effectively immunizes unfounded litigation” and that the hurdles the victimized party must overcome to pursue antitrust claims based on “predatory litigation have been set too high by the courts” and that, as a result, corporations are unaccountable.19 Professor Lao, who testified, expounded on the “murky” PRE standard and focused on the situations where the doctrine has “gone beyond the bounds of what the First Amendment is protecting.”20 Even abusive patent litigation was discussed.21 However, no complete solutions were proposed.

The difficulty with prosecuting predatory litigation is that mixed motives are often at play.22 On one hand, the predator seeks to inflict an anticompetitive injury on its competitor for its own advantage.23 On the other, it seeks to sue a competitor in court for, ostensibly, a legitimate grievance. This tension has baffled courts.24 Noerr’s uncertain foundation as a constitutional or statutory doctrine also adds confusion.25 Even though the Sherman Act is a statute, its role as the protector of the free-market heightens its importance. 26

Prior literature has focused on critiquing PRE’s broad language as the foundation for reforming the sham standard. In particular, Thomas’s inconsistent baselessness standards have been a large focus of academic debate.27 Others have written proposals using complex game- theory models designed to articulate predatory suits without considering court-usability.28 One scholar, at least, advocates for the wholesale elimination of the doctrine.29 Even the FTC is unclear about how best to resolve these ambiguities.30 As a result, existing scholarly debate has either missed the purpose of petitioning immunity or proposed a solution beyond the abilities of the courts to enact.31

This Article argues that, within the existing framework of Noerr-Pennington, a more robust standard exists that will unify the conflicting ideas of courts and economists.32 The core of predatory litigation is that whenever someone uses “the governmental process – as opposed to the outcome of that process” as an anticompetitive weapon there should be consequences.33 My proposal combines existing Supreme Court doctrine, the body of economic analysis on predatory litigation, and objective evidence to create “an enquire meet for the case” of prosecuting predatory litigation.34

#### Specifically, plan adopts what’s called a profit-sacrifice analysis to determine anticompetitive harm---it uses objective economic evidence that can accurately and fairly limit sham litigation

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In the fourth quadrant (lower-right box), lies the world of mixed motives. These cases, defined as one where “the process of petitioning is used both in hopes of obtaining governmental action and in order to impose expense and delay on competitors,” are where the courts and economists diverge.211 Under PRE, mixed motives do not impact sham analysis. If the suit has any legal merit (i.e., probable cause) the collateral anticompetitive benefits are ignored out of deference to the First Amendment. As this Article has shown, this approach is unnecessary, imprecise, and ignores the fundamental issue.

The solution is not as easy as flipping the script. One cannot expect the mere existence of a collateral anticompetitive benefit to automatically destroy any chance of antitrust petitioning immunity, either. As Professor Elhauge explains:

If a genuine hope of winning sufficed to receive immunity, then abuses of process would effectively go undeterred, and predatory litigation would flourish. If, on the other hand, a purpose of harassing opponents sufficed to lose immunity, then firms would fear to bring even meritorious litigation against their competitors. The mere existence of either motive should thus not suffice to establish immunity or non- immunity. Some weighing of the motives must be made.212

I agree. But before reaching this critical balancing test, I will address several screening techniques that courts should utilize to decrease the chances of improperly stripping a litigant of its petitioning immunity when the time to balance motives arises.

This Article’s proposal proposes a robust enquiry into whether litigation is used as an anticompetitive weapon that is mindful of protections for those who petition the government. The primary tension that my proposal resolves is the minimization of false-positives (Legitimate lawsuits that are mistakenly prosecuted as predatory) while not categorically protecting false- negatives like PRE (predatory suits lawsuits that receive petitioning immunity). To achieve this goal, I propose a three-step process. First, the case would need to be evaluated through an “antitrust screen” that would eliminate allegations of predatory litigation that are not, in fact, antitrust claims. Second, if the case successfully passed the “antitrust screen,” the case would then have to pass through the second screen that seeks to eliminate close instances of false positives. Third, if the case survives the two screens, then the case loses Noerr petitioning immunity and is analyzed under the typical predation test from antitrust law. Now, I break down each component of this test.

A. The Antitrust Screen

In Part II, I discussed several market factors that would allow courts to discern whether a predatory suit was possible from an antitrust standpoint.213 These factors are 1) market power; 2) existence of a competitive or potentially competitive relationship between plaintiff and defendant; and 3) an exclusionary externality stemming from the litigation.

The existence of these three factors establish that the case is properly filed as an antitrust claim. Most interestingly, PRE would fail this test because there was no evidence of any collateral anticompetitive benefit.

B. The Specific Intent Screen

After determining these market-factors exist, it is time to begin critically analyzing the intents and injuries stemming from the allegedly anticompetitive litigation. Recall our analysis of the multiple anticompetitive motives and injuries from Part III of this Article. There, I laid out that a predatory lawsuit could have two different motives and sources of anticompetitive injury. The difference was whether the intent to harm competition or the resulting injury arose from the outcome or the process. First, I will discuss the injury.

If an allegedly predatory lawsuit does not have a collateral anticompetitive injury, it can never be the subject of a Section 2 violation. If the only anticompetitive injury arising from an allegedly predatory case is from the relief sought by the underlying plaintiff, then this is not an instance of mixed-motives and there is no attempt to inflict injury through the litigation process. Such a case must be immunized under Noerr-Pennington.

In contrast, if the antitrust plaintiff can articulate a cognizable antitrust injury stemming from the litigation process, as opposed to the outcome, then a predatory case can exist. To establish whether a litigant possessed an anticompetitive intent to inflict that process injury, I recommend using specific intent analysis, instead of subjective intent.

Then, the question arises, how much evidence is necessary? Past proposals have included examinations of whether one motive or the other was “significant,”214 and a proposal that the collateral anticompetitive be both a “necessary and sufficient objective motivation for the allegedly strategic litigation.”215

Of these proposals, the combination of necessary and sufficient conditions appears not only to be the most robust, but also the one that most closely resembles the underlying antitrust principles in play and the abuse of process foundation of the legal test at issue. This test, proposed by Professor Elhauge, requires “the antitrust plaintiff alleging strategic litigation… to show: (1) that the antitrust defendant would not have brought the original suit but for the direct injury imposed on his competitor, and (2) that the defendant would have brought suit even without any prospect of winning in order to inflict the direct costs or delays on his competitor.”216 From an economic equation standpoint, Elhauge’s test would look like Equation 6, below.

(6) Jx < C < A Prosecutable Predatory Litigation

The expected judgment of the litigation [Jx], itself, opposed to the costs of litigation [C], makes the suit irrational. At the same time, the collateral anticompetitive benefit [A], itself, is more valuable than the cost of litigating. The predator needed the collateral anticompetitive benefit to make the suit rational and the value of that benefit alone was worth initiating the suit.

The sufficient condition, that the collateral anticompetitive benefit to the predatory litigant exceed the cost of litigating, is out of deference to the abuse of process “primary” motive doctrine.217 The necessary condition, that the expected value of the suit be less than the cost of litigating follows the profit sacrifice model used in antitrust for predatory action in Section 2 cases and Judge Posner’s Grip-Pak opinion. Under this test, “the monopolist's conduct must be irrational but for its anticompetitive effect.”218 This is precisely what Posner articulated in Grip-Pak, Stevens suggested in PRE, and economists have concluded is the proper test for predatory behavior in the antitrust realm, as described in Part III.

But, unlike Professor Elhauge’s proposal, I do not recommend requiring that both the necessary and sufficient conditions be met to lose Noerr petitioning immunity. This is because, unlike PRE “sham” litigation, strategic litigation under this test should not be treated as per se anticompetitive. Strategic litigation should only become predatory under the antitrust laws after a thorough analysis of whether the profit sacrifice test was met. Instead, I argue that the sufficient condition, whether the case would have been filed even with no chance of success, should be the threshold question that determines whether immunity should exist. If that can be established, then the necessary condition, the profit sacrifice test, should be analyzed traditionally.

C. Predatory Behavior, Profit Sacrifice Analysis

To review, to plead a proper case of predatory litigation, the plaintiff must first pass the “antitrust screen.” This requires establishing (1) “evidence of market structure” (i.e., market power and relevant markets, which are not in dispute in this case) and (2) “exclusionary effect” (i.e., foreclosure of a competitor from a market, which is also not in dispute in this case)—“both of which can ordinarily be obtained without access to the defendant's own records—[and] indicate that an antitrust violation is plausible.”219 These factors, plus evidence that the plaintiff and defendant are competitors, are the first level antitrust screens.

Then, to overcome the presumption of antitrust petitioning immunity, it would have to plausibly allege that “the defendant would have brought suit even without any prospect of winning in order to inflict the direct [anticompetitive harm] on his competitor.”220 This is the sufficient condition proposed by Professor Elhauge.

At this point, the antitrust-plaintiff has shown that the monopolist-defendant had market power, was a competitor of the plaintiff, that the litigation process caused him anticompetitive harm, and that the benefit to the monopolist of that harm was large enough to be worth filing this lawsuit, even if there was no chance of winning. Having proven this, the potentially predatory suit should not be immunized under Noerr-Pennington and should be evaluated in a way similar to other forms of allegedly predatory conduct under Section 2.

The goal would be to determine whether the primary motive was to harm competition through the litigation process, not the outcome. This would be governed by specific evidence of anticompetitive intent. The prosecuting entity would present objective evidence that the conduct was irrational but for the collateral anticompetitive benefit, as well as any subjective evidence of improper anticompetitive intent that could be useful to assist the finder of fact. Against this, the accused predator would argue that the anticompetitive impact from the process was not the driving force of the suit.

Finally, the finder of fact would be tasked with deciding the primary motive for the suit. Whether this is done via a calculation of expected benefit versus the collateral anticompetitive benefit, or is done qualitatively is not necessary to define now. The importance of this test is to provide adequate screens to prevent false positives, while still ensuring that predatory litigation can be identified and prosecuted.

As with any test, it is imperfect. If a predatory motive existed but was not sufficiently large enough on its own to justify the suit, an irrational lawsuit would still be immunized under this test. At the same time, a borderline-legitimate suit was filed alongside a coincidental anticompetitive harm could, theoretically, be improperly prosecuted. However, the fact that I am using market screens to ensure that only dominant players pursuing monopolies whose actions have imposed exclusionary effects on competitors, ensures that even if this test is incorrect, it harms someone who can afford the mistake.

CONCLUSION

When litigation is used as an anticompetitive weapon, it should be prosecuted under the antitrust laws as predatory. Under our current framework, this is only sometimes the case. Hopefully, this Article’s proposal provides a solution to this problem that is accurate, practical, and fair. While no standard is perfect, this Article may help future courts grapple with the failings of the Noerr-Pennington doctrine when mixed motives are at play. The mixed motives of strategic, predatory litigation impose great challenges on our courts, but as I have laid out here, this problem is not only solvable, but very much worth solving.

#### Only this approach solves---other proposals either go too far in eliminating the *Noerr* immunity altogether OR rely on subjective screening that is impossible to administer---the plan is easy to implement because it’s based on existing court doctrine, economic literature, and objective evidence

Hakun 21 (Nicholas E. Hakun, Adjunct Assistant Professor, Department of Legal Studies, Fox School of Business and Management, Temple University. Law Clerk, U.S. District Court for the Eastern District of Pennsylvania. J.D., cum laude, Georgetown University Law Center, Strategic Litigation and Antitrust Petitioning Immunity, 2-25, UC Irvine Law Review Forthcoming, <https://ssrn.com/abstract=3792995>, y2k)

Prior literature has focused on critiquing PRE’s broad language as the foundation for reforming the sham standard. In particular, Thomas’s inconsistent baselessness standards have been a large focus of academic debate.27 Others have written proposals using complex game theory models designed to articulate predatory suits without considering court usability.28 One scholar, at least, advocates for the wholesale elimination of the doctrine.29 Even the FTC is unclear about how best to resolve these ambiguities.30 As a result, existing scholarly debate has either missed the purpose of petitioning immunity or proposed a solution beyond the abilities of the courts to enact.31

This Article argues that, within the existing framework of Noerr-Pennington, a more robust standard exists that will unify the conflicting ideas of courts and economists.32 The core of predatory litigation is that whenever someone uses “the governmental process – as opposed to the outcome of that process” as an anticompetitive weapon there should be consequences.33 My proposal combines existing Supreme Court doctrine, the body of economic analysis on predatory litigation, and objective evidence to create “an enquire meet for the case” of prosecuting predatory litigation.34

#### That solves patent thickets---patent filings at the FDA are mechanical filings ---those filings would no longer be immunized

Marina Lao 3, Professor of Law, Seton Hall University School of Law, REFORMING THE NOERR-PENNINGTON ANTITRUST IMMUNITY DOCTRINE, 55 Rutgers L. Rev. 965

A. Generic Drug Competition

Consumers benefit greatly from the availability of generic drugs, which are far cheaper than their corresponding brand name versions. 188 Brand name drugs lose significant market share to their respective generic versions after the generics become available. 189 Because so much is at stake, it is not surprising that manufacturers of brand name drugs would do everything in their power to thwart or delay a generic drug's entry into the market. 190 The pervasiveness of government regulation of drugs, and the fact that patents are often involved, makes this a particularly attractive area for firms to claim protection under the Noerr doctrine when they misuse government processes in order to impede competition.

To understand how and why the industry is particularly susceptible to "petitioning" strategies that pose a threat to competition, a brief discussion of the relevant governmental regulatory framework is required. 191 A drug manufacturer wishing to sell a new (brand name) drug must apply to the Food and Drug Administration ("FDA") for approval by filing a "New Drug Application" ("NDA"), 192 which must include detailed clinical trial data about the drug's safety and effectiveness. 193 A 1984 law, commonly known as the "Hatch-Waxman Act," 194 requires a brand name drug manufacturer to identify all patents that "claim" a particular brand name drug and to include that patent list with the NDA filed with the FDA. 195 The FDA maintains these patent listings in what is commonly called the Orange Book. 196

The FDA's role in listing the patents in the Orange Book is purely ministerial; 197 it does not review the propriety of the patent listings. 198 Even when another company challenges the validity of a particular listing, the FDA merely asks the brand name drug manufacturer to confirm the accuracy of the information previously provided. It does not "delist" a patent from the Orange Book except at the brand name manufacturer's request. 199

A company wishing to produce and sell a generic version of a brand name drug 200 has to file an Abbreviated New Drug Application ("ANDA") with the FDA. 201 For each patent listed in the Orange Book as covering the brand name drug, the generic applicant must certify that the proposed generic will not infringe that patent or that the listed patent is invalid, 202 even if the applicant disputes the listing. 203 The brand name drug manufacturer then has forty-five days upon receipt of the generic applicant's certification 204 to file an infringement suit if it disagrees with the generic applicant's certification statements. 205 Once suit is filed, FDA approval of the generic drug is automatically stayed for thirty months. 206

A brand name drug company can trigger more than one thirty-month stay by listing additional patents in the Orange Book claiming the brand name drug after the generic applicant has filed its ANDA. 207 In that case, the generic applicant would be required to re- certify as to the new Orange Book patent listing. 208 If the brand name company, as expected, then files an infringement suit within the requisite forty-five days based on the new certification, FDA approval is stayed for another thirty months. 209 In one case, GlaxoSmithKline, a maker of the brand name drug Paxil, was able to delay FDA approval of its generic for sixty-five months. 210

Because generic versions cut deeply into the sales of brand name drugs, brand name drug manufacturers have aggressively used judicial and regulatory processes to block or delay their approval. 211 A very recent study of generic drug competition conducted by the Federal Trade Commission reveals that brand name drug manufacturers brought patent infringement suits against generic applicants for 75% of the drug products covered in the study. 212 But generic applicants prevailed in 73% of those cases that reached a judicial decision. 213

A combination of the Orange Book listing procedure and the administrative effect of that listing offers many possibilities for abuse of government processes. If the Noerr doctrine is broadly construed to protect these anticompetitive strategies, the adverse impact on competition would be immense. A recent case decided in the Southern District of New York demonstrates the type of Noerr argument that a brand name manufacturer is likely to make.

In In re Buspirone Patent Litigation, 214 Bristol-Myers Squibb allegedly made a false filing with the FDA listing a patent as claiming its brand name drug, BuSpar, when it knew that was not true. 215 The FDA included the listing in the Orange Book. 216 The generic drug applicants, as required, certified that their drugs did not infringe the listed patent. 217 Bristol-Myers then brought patent infringement suits within the requisite time frame, automatically triggering a thirty-month stay of the FDA's approval of the generic drug in question. 218 The generic drug manufacturers and others brought antitrust claims against Bristol-Myers alleging that its fraudulent Orange Book listing was an act of monopolization, and Bristol-Myers moved to dismiss on the ground that its Orange Book filing and subsequent patent litigation were protected petitioning activities under Noerr. 219

Essentially, Bristol-Myers's argument was that its Orange Book filing was a "petition" which was immunized under Noerr because it was a request made to the FDA for inclusion in the Orange Book. 220 In a well-reasoned opinion, the district court distinguished between situations where the "government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties" and those where "the government acts … only after an independent review of the merits of a petition." 221 The district court then concluded that an Orange Book filing is not a "petition" because the FDA's actions in publishing the filing "are non-discretionary and do not reflect any decision as to the validity of the representations." 222 Few cases have specifically addressed the issue of what constitutes a petition, but the court's ruling in Buspirone Patent Litigation is correct. As will be discussed in more detail in Part V, not all communications to government officials should qualify as "petitions" under the First Amendment right to petition, and Noerr protection extends only to petitions. 223 Mechanical filings acted upon by government functionaries should not be considered petitions entitled to Noerr immunity because there is no attempt to persuade any government decision-maker, and no government decision-maker ever made an evaluative decision. 224

#### Objective test is key---the current sham exception standard (“objectively baseless”) is unwinnable and unclear

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 **corrects PRE.** What is the preferred clarifying formulation? An objective test that constitutes a variant of the “objectively unreasonable” archetype seems best.

## 2AC

**2AC – Sham Litigation**

**Prefer measures of output – innovation low**

Derek **Thompson 2021** “ America Is Running on Fumes” <https://www.theatlantic.com/ideas/archive/2021/12/america-innovation-film-science-business/620858/>

Undeniably, the communications revolution has been the most significant fount of new ideas in the past half century. **But** the **vitality of the tech industry** in comparison with other industries points up that the U.S. innovation system **has devolved from variety to specialization in the past 40 years or so**. The U.S. used to produce a broad diversity of patents across many industries—chemistry, biology, and so forth—**whereas patents today are more concentrated in a single industry, the software industry**, than at any other time on record. We’ve funneled treasure and talent into the world of bits, **as the world of flesh and steel has decayed around it.** In the past 50 years, **climate change has worsened, nuclear power has practically disappeared, construction productivity has slowed down, and the cost of developing new drugs has soared.**

**2AC – Patent Thickets**

**R&D doesn’t cause innovation – here’s a 4-decade longitudinal study**

**Mazzucato 13** (Mariana, Professor in the Economics of Innovation and Public Value and Director of the Institute for Innovation and Public Purpose at University College London (UCL), The Entrepreneurial State: Debunking Public vs. Private Sector Myths, Anthem Other Canon Economics, Anthem Press, p 37-45)

Myth-busting 1: R&D is not enough

The literature on the economics of innovation, from different camps, has often assumed a direct causal link between R&D and innovation, and between innovation and economic growth. Yet, surprisingly, there are very few studies which prove that innovation carried out by large or small firms actually increases their growth performance — the macro models on innovation and growth do not seem to have strong empirical ‘micro foundations’.34 Some company level studies have found a positive impact of innovation on growth35 while others no significant impact.36 And some studies have found even a negative impact of R&D on growth, which is not surprising: if the firms in the sample don’t have the complementary characteristics needed, R&D becomes only a cost.37 It is thus fundamental to identify the company specific conditions that must be present to allow spending on innovation to affect growth. These conditions will no doubt differ between sectors. Demirel and Mazzucato, for example, find that in the pharmaceutical industry, only those firms that patent five years in a row (the ‘persistent’ patenters) and which engage in alliances achieve any growth from their R&D spending.38 Innovation policies in this sector must thus target not only R&D but also attributes of firms. Coad and Rao found that only the fastest growing firms reap benefits from their R&D spending (the top 6 per cent identified in Nesta’s report ‘The vital 6 per cent’).39 And Mazzucato and Parris find that this result, of the importance of high growth firms, only holds in specific periods of the industry life-cycle when competition is particularly fierce.40 Myth-busting 2: Small is not necessarily beautiful This finding that the impact of innovation on growth is indeed different for different types of firms has important implications for the commonly held assumption that ‘small firms’ matter (for growth, for innovation), and hence for the many different policies that target SMEs. The hype around small firms arises mainly from the confusion between size and growth. The most robust evidence is not on the role of small firms in the economy but the role of young high growth firms. Nesta, for example, claims that the most important firms for UK growth have been the small number of fast growing businesses that between 2002 and 2008 generated the highest amount of employment growth in the UK.41 And while many high growth firms are small, many small firms are not high growth. The bursts of fast growth that promote innovation and create employment are often staged by firms that have existed for several years and grown incrementally until they reach a take-off stage. This is a major problem since so many government policies aim to target tax breaks and benefits to SMEs, with the aim of making the economy more innovative and productive. Although there is much talk about small firms creating jobs,42 this is just a myth because while by definition small firms will cause jobs to increase, in fact many small firms also destroy a large number of jobs when they go out of business. Haltiwanger, Jarmin and Miranda find that there is indeed no systematic relationship between firm size and growth.43 Most of the effect is from age: young firms (and business start-ups) contribute substantially to both gross and net job creation. Productivity should be the focus, and small firms are indeed often less productive than large firms. Recent evidence has suggested that some economies that have favoured small firms, such as India, have in fact been punished. Hsieh and Klenow, for example, suggest that 40–60 per cent of the total factor productivity (TFP) difference between India and the USA is due to misallocation of output to too many small and low productivity SMEs in India.44 As most small start-up firms fail, or are incapable of growing beyond the sole owner-operator, targeting assistance to them through grants, soft loans or tax breaks will necessarily involve a high degree of waste. Bloom and Van Reenan argue that small firms are less productive than large ones because they are less well managed, and subject to provincial family favouritism.45 Furthermore, small firms have lower average wages, fewer skilled workers, less training, fewer fringe benefits and are more likely to go bankrupt. They argue that the UK has many family firms and a poor record of management in comparison with other countries such as the USA and Germany.46 Among other reasons, this is related to the fact that the tax system is distorted to give inheritance tax breaks to family firms. Some have interpreted the result that it is high growth rather than size that matters to mean that the best that governments can do is to provide the conditions for growth innovation. Bloom and Van Reenan argue that instead of having tax breaks and benefits target SMEs, the best way to support small firms is to ‘ensure a level playing field by removing entry barriers to firms of all sizes, reducing barriers to growth, enforcing competition policy and strongly resisting the lobbying efforts of larger firms and their agents’.47 But as we will see in chapters 3 and 5, often the most innovative firms are precisely those that have benefitted the most from direct public investments of different types, making the case much more complex. Myth-busting 3: Venture capital is not so risk-loving If the role of small firms and R&D is overstated by policy makers, a similar hype exists in relation to the potential for venture capital to create growth, particularly in knowledgebased sectors where capital intensity and technological complexity are high. Venture capital is a type of private equity capital focused on early-stage, high-potential, growth companies. The funding tends to come either as seed funding or as later growth funding where the objective is to earn a high return after the IPO of the company or sale. Venture capital fills a void of funding for new firms, which often have trouble gaining credit from traditional financial institutions such as banks and thus often have to rely on other sorts of funding such as ‘business angels’ (including family and friends), venture capital and private equity. Such alternative funding is most important for new knowledge-based firms trying to enter existing sectors or new firms trying to form a new sector. Risk capital is so scarce in the seed stage because there is a much higher degree of risk in this early phase, when the technological and demand conditions are completely uncertain. The falling risk in the different phases falls dramatically with the seed financing occurring when there is the most uncertainty about the potential of the new idea (table 1). Figure 2 shows the usual place that it is assumed that venture capital will enter the stage of the invention-innovation process. In reality the real picture is much more non-linear and full of feedback loops. And many firms die during the transition between a new scientific or engineering discovery and its successful commercial transformation and application. Thus the third phase shown in figure 2 of commercial viability is often referred to as the valley of death. Figure 2 does not illustrate how time after time it has been public rather than privately funded venture capital that has taken the most risks. In the USA, government programmes such as the Small Business Innovation Research (SBIR) programme and the Advanced Technology Program (ATP) in the US Dept of Commerce have provided 20–25 per cent of total funding for early stage technology firms. Thus government has played a leading role not only in the early stage research illustrated in figure 2, but also in the commercial viability stage. Auerswald and Branscomb claim that government funding for early stage technology firms is equal to the total investments of ‘business angels’ and about two to eight times the amount invested by private venture capital.50 Venture capital funds tend to be concentrated in areas of high potential growth, low technological complexity and low capital investment since the latter raises the cost significantly. Since there are so many failures in the high risk area, venture capital funds tend to have a portfolio of different investments with only the tails earning high returns—a very skewed distribution. Although most venture capital funds are usually structured to have a life of ten years, because of the management fees and the bonuses earned for high returns, venture capital funds tend to prefer to exit much earlier than ten years, in order to establish a track record and raise a followon fund. This creates a situation whereby venture capital funds therefore have a bias towards investing in projects where the commercial viability is established within a three to five year period.51 Although this is sometimes possible (eg Google) it is often not. And surely, in the case of an emerging sector like biotech or green tech today, where the underlying knowledge base is still in its early exploratory phase, such a short term bias is damaging to the scientific exploration process, which requires longer time horizons and more willingness to risk failure. The role of US venture capital that worked was to provide not only committed finance, but also managerial expertise and ensure the building of a viable organisation.52 The problem has been not only the lack of venture capital investment in the most needed early seed stage, but also its objectives in the process. This has been strongly evidenced in the biotech industry where an increasing number of researchers have criticised the model of venture capital in science, indicating that significant investor speculation has a detrimental effect on the underlying innovation.53 The fact that so many venture-capital-backed biotech companies end up producing nothing, yet make millions for the venture capital firms that sell them on the public market, is highly problematic for the role of venture capital in the development of science and its effect on the growth process. The increased presence of patenting and venture capital is not the right one for allowing risky and long term innovations to come about. Pisano in fact claimed that the stock market was never designed to deal with the governance challenges of R&D entities.54 Mirowski describes the venture-capital–biotech model as: commercialized scientific research in the absence of any product lines, heavily dependent upon early-stage venture capital and a later IPO launch, deriving from or displacing academic research, with mergers and acquisitions as the most common terminal state, pitched to facilitate the outsourcing of R&D from large corporations bent upon shedding their previous in-house capacity.55 The problem with the model has been that the ‘progressive commercialisation of science’ seems to be unproductive, with few products, and damage to long-run scientific discoveries and findings over time. Myth-busting 4: A patent doesn’t necessarily mean progress A similar misunderstanding exists in relation to the role of patents in innovation and economic growth. For example, when policy makers look at the number of patents in the pharmaceutical industry, they presume it is one of the most innovative private sectors in the world. This rise in patents does not however reflect a rise in innovation, but a change in patent laws and a rise in the strategic reasons why patents are being used. This has caused their importance to be greatly hyped up—mythologised. The exponential rise in patents, and the increasing lack of relationship this rise has had with actual ‘innovation’ (eg new products and processes), has occurred for various reasons. First, the types of inventions that can be patented has widened to include publicly funded research, upstream research tools (rather than only final products and processes) and even ‘discoveries’ (rather than only inventions) of existing matter such as genes. The 1980 Bayh-Dole Act, which allowed publicly funded research to be patented rather than remain in the public domain, encouraged the emergence of the biotechnology industry as most of the new biotech companies were new spin-offs from university labs with heavy state funding. Furthermore, the fact that venture capital often uses patents to signal which companies to invest in means that patents have increased in their strategic value to companies that need to attract financing. All these factors have caused the number of patents to rise, with most of them being of little worth (eg very few citations received from other patents) and without resulting in a high number of innovations, eg new drugs in pharma (figure 5).

Chart, line chart

Description automatically generated

\*\*\*\*\*CAPTION BEGINS

Economists measure productivity by comparing the amount of input into production with the amount of output that emerges. In this sense the large pharmaceutical companies have been fairly unproductive over the last few years in the production of innovations. As figure 5 shows there has been an exponential rise in R&D spending by members of the Pharmaceutical Research and Manufacturers of America (PhRMA) with no corresponding increase in the number of new drugs, commonly known as new molecular entities (NMEs). Figure 6 shows that this also holds for patenting: while the number of patents has skyrocketed since the Bayh-Dole Act (1980) allowed publicly funded research to be patented, most of these patents are of little value. When patents are weighted by the amount of citations they receive (the common indicator of ‘important’ patents), the figure is relatively flat—there are few important patents. Between 1993 and 2004, of the 1,072 drugs approved by the FDA, only 357 were NMEs rather than just variations of existing ‘me too’ drugs. The number of important ‘priority’ new drugs is even more worrying: only 146 of these had priority rating (NME with P rating). In figure 7 we see that only 14 per cent were seen as important new drugs. For the sake of the argument being made in this pamphlet, what is important is that 75 per cent of the NMEs trace their research not to private companies but to National Institutes of Health (NIH), publicly funded labs in the USA or other public labs across the globe, such as the MRC in the UK. So while the state-funded labs have invested in the most risky phase, the big pharmaceutical companies have preferred to invest in the less risky variations of existing drugs (a drug that simply has a different dosage than a previous version of the same drug). All a far cry, for example, from the recent quote by UK based GlaxoSmithKline 76 CEO Andrew Witty**: ‘The pharmaceutical industry is hugely innovative...** If governments work to support, not stifle, innovation, **the industry will deliver the next era of revolutionary medicine.’** 7 \*\*\*\*CAPTION ENDS Thus directing too much attention to patents, rather than to specific types of patents, such as those that have high citations, risks wasting much money (as argued below for the patent box case). Researchers have argued that many of the recent trends in patents, such as the increase in upstream patents (eg patenting of ‘research tools’), has caused the rate of innovation to fall rather than increase as it blocks the ability of science to move forwards in an open exploratory way.56 The effect has been especially deleterious to the ability of scientists in the developing world to repeat experiments carried out in the developed world, before undertaking their own developments on those experiments, thus hurting their ability to ‘catch up’.57 Notwithstanding the fact that most patents are of little value, and the controversial role that patents play in innovation dynamics, the UK Government insists that patents have a strong link to ongoing high-tech R&D and must thus be incentivised in order for the UK to have innovation-led growth. Thus in October 2010 Osborne announced a patent box policy, due to begin in 2013, which would reduce the rate of corporation tax on the income derived from patents (to 10 per cent). This of course fits with the current government’s belief that investment and innovation can be easily nudged via taxes. The Institute for Fiscal Studies (IFS) has argued against this policy, claiming that the only effect it will have is to reduce government tax revenue (by a large amount) without affecting innovation. It is argued that R&D tax credits are enough to address the market failure issue around R&D, and that the patent box policy is instead poorly targeted at research, as the policy targets the income that results from patented technology, not the research itself (a similar claim we make around R&D tax credits when they are not subject to control). A recent report by the IFS claims: Once a patent is in place, a firm has a monopoly on the use of those ideas, and so can capture all of the returns and therefore faces the correct incentives to maximise the related income stream. In addition, to the extent that a Patent Box reduces the tax rate for activity that would have occurred in the absence of government intervention, the policy includes a large deadweight cost.58 Furthermore, the authors claim that the patent box policy will also add complexity to the tax system and require expensive policing to ensure that income and costs are being appropriately assigned to patents. They claim that the great uncertainty and time lags behind creating patentable technologies will counteract the incentives, and since international collaborations are increasingly common, there is no guarantee that the extra research that is incentivised will be conducted in the UK.59 This chapter shows that many of the assumptions that underlie growth policy should not necessarily be taken for granted. Over the last decade or so, policy makers searching for proxies for economic growth have alighted on things they can measure such as R&D spend, patents, venture capital activity, and the number of small firms that are assumed to be important for growth. We have attempted to demystify these assumptions and now turn to the largest myth of all: the limited role for government in producing entrepreneurship, innovation and growth.

**Patent thickets eviscerate competition and innovation**

**PCMA 21**—Pharmaceutical Care Management Association. ("“Patent Thickets” are Anti-Competitive and Lead to Higher Drug Costs," May 17, 2021, from https://www.pcmanet.org/patent-thickets-are-anti-competitive-and-lead-to-higher-drug-costs/)

What is a patent thicket? Even for a health care data wonk like me, sometimes Wikipedia is a helpful resource. Wikipedia describes a patent thicket as “a concept with negative connotations that has been described as ‘a dense web of overlapping **i**ntellectual **p**roperty **r**ights that a company must **hack** its way through in order to actually **commercialize** new technology…’” This is a pretty apt description in the prescription drug field, where patent thickets are **thorny** and **obstructive**, just like a “dense web” might look.

Brand drug manufacturers extend the exclusivity of their drugs beyond the end of their initial exclusivity period by filing multiple additional patents on the same drug, thus creating “patent thickets.” For **Humira**, **Enbrel**, **Keytruda**, **Revlimid**, and **Imbruvica**, five of the top-10 selling drugs in the U.S., a total of **584 patent app**lication**s** have been filed after their initial Food and Drug Administration approval. For example, on Humira there are additional patents on the autoinjector device and a separate patent for the “firing button” on the device. These added patents mean additional years – in the case of one of these drugs, **an added 28 years** – with **monopoly pricing power protected from competition**.

For pharmacy benefit managers (PBMs), patent thickets are **anti-competitive** and **obstruct** the ability to negotiate for savings, which ultimately means patients are not paying the lowest cost possible for medications. We’ve said this before because it’s **very important**: the key to lower prescription drug costs is **adequate competition** in the marketplace.

For brand drugs, the ability of PBMs to lower drug costs hinges on the availability of sufficient alternatives, which creates negotiating leverage through competition. Once drug manufacturers set drug prices, PBMs negotiate with those manufacturers for rebates, which are a key tool in helping to reduce prescription drug costs for consumers. Rebates reduce the overall costs for prescription drugs, thereby generating billions of dollars in savings every year. If there is no competitor on the market for a drug, PBMs lack the leverage to negotiate rebates on brand drugs.

That’s why the drug manufacturer strategy known as patent thickets is so **pernicious** – it intentionally keeps direct competitor products off the market, sometimes for years or even decades. I’ll leave you with the result: patent extensions for just those same five drugs **led to over $500 billion in additional net sales**.

Patent abuses hurt everyone, especially patients. Let’s hope the committee’s hearing leads to a broader conversation on drug manufacturers’ schemes that **block competition**, **increase** their **profits**, and lead to **higher drug costs** for everyone.

**2AC – Advantage CP**

**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.

**Unfair patent use standard is too vague and links to the net benefit**

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

C. Challenges to the Implementation

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

**They’re misreading guglizzia – he’s saying that you CANT distinguish because the precedent is grounded in the first amendment**

Paul R. **Gugliuzza** **16**. 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 "Regulating Patent Assertions" https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2833548

6.3 Constitutional Limits on Regulating Patent Assertions **Under current law, opponents of the TROL Act may be correct that the bill violates the First Amendment**. The Federal Circuit has held that **patent holders are immune from liability** based on their enforcement actions **unless** the patent holder’s allegations of **infringement were objectively baseless** and the patent holder knew those allegations were objectively baseless. This broad immunity rule, however, misinterprets the relevant constitutional provisions and wrongly vitiates courts’ long-standing power to condemn acts of patent enforcement that are undertaken, simply, in bad faith. 6.3.1 Judicially Created Immunity for Patent Holders **For decades**, **persons** accused of patent infringement **have tried to assert civil claims** against overzealous patent holders. Those claims are sometimes grounded in state law (for example, claims for unfair competition or for tortious interference with business relations) and other times grounded in federal law (for example, claims for unfair competition under the Lanham Act or for violations of the civil RICO statute). **The Federal Circuit, however, has held that patent holders are mostly immune from civil liability for their enforcement behavior**. According to the Federal Circuit, to strip a patent holder of immunity, the plaintiff must prove not only the elements of its claim, it must also prove, by clear and convincing evidence, (1) that the patent holder’s infringement allegations were “objectively baseless,” meaning that no reasonable litigant could have expected to succeed, and (2) that the patent holder made its infringement allegations with knowledge of their inaccuracy or with reckless disregard for their accuracy (Globetrotter 2004, 1377). Courts and commentators sometimes call the immunity enjoyed by patent holders a matter of “preemption” because it is most frequently invoked when an alleged infringer relies on state law, such as the law of torts or unfair competition, to challenge a patent holder’s behavior in enforcing a federal patent (see, e.g., Hunter Douglas 1998, 1338; Johnson 2014, 2027). The term “preemption” suggests that the source of the immunity doctrine is the Constitution’s Supremacy Clause, which limits only the power of state governments, not the federal government. In more recent cases, however, **the Federal Circuit has made clear that its immunity doctrine stems not from the Supremacy Clause alone,** **but also from the First Amendment,** **which does limit the power of the federal government**. In Globetrotter, for instance, the court wrote: “Our decision to permit state-law tort liability for only objectively baseless allegations of infringement rests on both federal preemption and the First Amendment” (Globetrotter 2004, 1377). The Federal Circuit’s two-element test for stripping patent holders of immunity is drawn from U.S. Supreme Court decisions on the Noerr-Pennington doctrine of antitrust law. That doctrine protects the First Amendment right to petition the government by immunizing defendants from antitrust liability based their pursuit of litigation unless the litigation was a “sham” (Noerr 1961; Pennington 1965). To establish that litigation was a sham, the plaintiff must show that the defendant’s lawsuit was both objectively baseless and filed with the subjective intent to impair competition (Professional Real Estate Investors 1993, 60–61). **The Federal Circuit has explicitly cited the Supreme Court’s test for establishing sham litigation as the basis of its test for stripping a patent holder of immunity from civil liability for patent enforcement activities** (Globetrotter 2004, 1376).

**Clarifying in favor of objectively baseless doesn’t solve because unifying under objectively baseless is still unclear! We’re saying we need to get rid of the two prong altogether!**

**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

B. The PRE “Objectively Baseless” Objective Test – An Ambiguous Test 1. Evidence of Ambiguity from the PRE Decision Itself As stated, the first problem with the objective test established by the Court in PRE is that it is ambiguously framed. **The court’s opinion features multiple, and** materially **inconsistent**, **formulations** for its test for “objective baselessness.” The reader is directed to the express language of the objective test as stated in PRE (the location of that exact text, in this paper, being indicated in the margin).45 Even in these short passages, one can begin to recognize linguistic formulations that might not entirely overlap. However, the trouble doesn’t stop there. **There are actually several different**, **substantially varying, formulations** of the objective baselessness test **that appear in the Court’s decision.** Consider the following formulations, **all taken from the majority opinion:**  The lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. 46  The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation. The notion of probable cause, as understood and applied in the common law tort of wrongful civil proceedings, requires the plaintiff to prove that the defendant lacked probable cause to institute an unsuccessful civil lawsuit and that the defendant pressed the action for an improper, malicious purpose.47  Probable cause to institute civil proceedings requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication. 48  When a court has found that an antitrust defendant claiming Noerr immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant’s position could realistically expect success on the merits of the challenged lawsuit.49  Even though it did not survive PRE’s motion for summary judgment, Columbia’s copyright action was arguably “warranted by existing law” or at the very least was based on an objectively “good faith argument for the extension, modification, or reversal of existing law.” Fed. R. Civ. P. 11.50 As we have held, PRE could not pierce Columbia’s Noerr immunity without proof that Columbia’s infringement action was objectively baseless **or frivolous.** 51  We hold that an objectively reasonable effort to litigate cannot be sham regardless of subjective intent.52  If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail.53  A court could reasonably conclude that Columbia’s infringement action was an **objectively plausible** effort to enforce rights. 54 **Thus, one sees no less than nine (9) separate linguistic formulations** purporting to distinguish “genuine” versus “sham” litigations for the purpose of Noerr-Pennington immunity. If the formulations were all closely correlated, they could be viewed as mere restatements. However, it is difficult to see how one can equilibrate “a reasonable belief that there is a chance that a claim may be held valid” with a “realistic expectation of success on the merits” with “an objectively plausible effort to enforce rights” with a suit “reasonably calculated to elicit a favorable outcome.” **How does one decide upon the appropriate legal test in such a case**? The author posits that the PRE objective test is likely either: (a) an “objectively baseless” type of test; or (b) an “objectively unreasonable” type of test. Arguably, when read in context, the first six of the nine bulleted PRE formulations listed above are of the “objectively baseless” variety.55 However, the three “objectively unreasonable” formulations appearing in the opinion use language that is compelling.56 The experienced practitioner will appreciate that case law interpretation is infrequently resolved by resort to arithmetic tallies, so it makes sense to evaluate major appellate decisions penned after PRE to see how the lower courts themselves have interpreted the decision and whether they too report or evidence ambiguity.

**ITC fails – tiny number of cases**

Matthew **Duescher 14** Lawyer @ Foster, Murphy, Altman, & Nickel, PC, Controlling the Patent Trolls: A Proposed Approach for Curbing Abusive Section 337 Claims in the ITC, 96 J. Pat. & Trademark Off. Soc'y 614, 96 J. Pat. & Trademark Off. Soc'y 614, 96 J. Pat. & Trademark Off. Soc'y 614

Although some NPEs are widely considered to be desirable contributors to society, Congress and the ITC are taking steps to stem the tide of abusive litigation filed by a category of NPEs known as Patent Assertion Entities ("PAEs"), commonly referred to as patent "trolls." A patent troll is an entity that acquires and asserts patents in order to extract licensing fees without concern for whether the patented material is manufactured or practiced. 5 With the well-documented, meteoric rise in the number of patent infringement suits filed by PAEs, the practice of patent trolling has become a point of concern for policymakers. 6 Although **the number** of **patent infringement cases** being heard in the ITC is **dwarfed** by the number heard in **federal courts**, several factors and recent changes in the way such cases are evaluated have now made the ITC a fertile ground for suits filed by PAEs. 7

**Trolls will troll the ITC**

Joe **Mullin 20** is a policy analyst at EFF, where he works on encryption, platform liability, patents, copyright, and free expression online, It’s Time to Kick Patent Trolls Out of the International Trade Commission, 10-29, <https://www.eff.org/deeplinks/2020/10/its-time-kick-patent-trolls-out-international-trade-commission>

The International Trade Commission, or **ITC**, is a federal agency in Washington D.C. that investigates unfair trade practices. Unfortunately, in recent years, it has also become a **magnet** for some of the **worst abusers** of the U.S. patent system. Now, there’s a bill in Congress, the Advancing America’s Interest Act (H.R. 8037), that could finally get patent trolls out of the ITC—a place they never should have been allowed in the first place. Patent owners can ask the Commission to investigate an allegation of infringement, in addition to their right to bring a patent infringement case into federal court. The ITC can’t award damages like a district court can, but the ITC can grant an “exclusion order,” which bans importation of the excluded item, and orders customs agents to seize products at the border. Not everyone is entitled to ask the ITC for an exclusion order; the complainant must be part of a “domestic industry.” But over the years, **administrative law judges** at the ITC have **lowered the bar** for **what** that requires. Engaging in patent licensing and litigation—without more—is enough to establish a “domestic industry” in this country, in the eyes of ITC judges. That means **patent trolls**, which produce **no goods** or **services**, can **qualify**.Even patent assertion entities based in other countries are using the ITC. For example, last year, the ITC took up a case in which an **Ireland-based patent troll** sought to stop **80% of U.S. imports** on Android tablets, 86% of Windows tablets, and more than 50% of Android smartphones. The ITC was never intended to be a forum for raising costs on domestic companies based on allegations of patent infringement. But that’s exactly what it has become. Since 2006, the ITC’s **own data** show that between 6 and **33 percent** of the venue’s patent cases are brought by entities that **don’t** practice the patent, which are, more often than not, **patent trolls**. The **fast pace** of ITC litigation, which has an 18-month time limit, makes it **more expensive** and **less fair** to **defendants** than district court litigation. When U.S. companies are forced to pay **huge legal fees**, and big settlements, to avoid threatening their product lines, **prices go up** and **consumers are the losers**.

### 2AC – States CP

**The federal circuit has explicitly said it will strike down or substantially narrow the counterplan**

**Hrdy 2019**. Camilla A. Hrdy. Assistant Professor, University of Akron School of Law. “"Getting Patent Preemption Right" https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3332528

Perhaps precisely because it makes little doctrinal or policy sense, the Federal Circuit has abandoned its conflict preemption approach and supplemented it with the First Amendment. As Professor Paul Gugliuzza has discussed, **the Federal Circuit has** **supplemented its patent preemption** **decisions** **with** **an analysis** **of whether state laws that restrict patent enforcement violate the First Amendment’s Petition Clause.**84 **Drawing on** the so-called **Noerr-Pennington doctrine**, used to limit antitrust liability for certain anticompetitive actions taken in the course of “petitioning” the government,85 **the Federal Circuit has derived a rigid two-part test** that requires assessing both the objective merits of the patentee’s assertion of infringement and the patentee’s subjective motives in making the assertion.86 In Globetrotter Software, Inc. v. Elan Computer Group, Inc.,87 the Federal Circuit cited antitrust law cases, including the Supreme Court’s holding in Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., which immunized a copyright plaintiff from antitrust liability under NoerrPennington. 88 **The Federal Circuit explained** its rule that **state laws** that seek to penalize blameworthy conduct taken in the course of enforcing a patent **would not be upheld as applied unless the patent is “obviously invalid” o**r “plainly not infringed.”89 **This outcome, the court stated**, **was** **required by** “**both federal patent preemption and the First Amendment**.”90 In sum, the Federal Circuit’s reading of Petitioning Immunity essentially preempts any state law that creates liability for enforcing a patent that is not “obviously invalid” or “plainly not infringed.”91 The upshot for patentees is robust protection from state law liability. “[S]ince Globetrotter,” Gugliuzza recounts, “the Federal Circuit has barred the state law claims in all but one case raising the issue.”92 So what is the problem? The Federal Circuit is not entirely unreasonable in its usage of this Petitioning Immunity doctrine as applied to state anti-patent law. The First Amendment Petition Clause obviously applies to states. That said, there are some legal problems here. The first is that **Noerr-Pennington immunity**, like antitrust law’s state action doctrine, **comes from the Supreme Court’s interpretation of the Sherman Act,** which in the Court’s view must be construed narrowly to avoid a conflict with the Petition Clause.93 There is no inherent reason this doctrine could not be applied to state laws as well—assuming bringing a patent suit is a “petition,” which the Supreme Court case law suggests it is.94 But the Federal Circuit has not explicitly performed this narrowing construction of state law or at least has not been particularly clear about what it is doing. Second, the Federal Circuit seems to have an exceptionally strong idea about how much protection the Petition Clause provides to a petitioner— something the Supreme Court recently pointed out in Octane Fitness, LLC v. Icon Health & Fitness, Inc, where it addressed the Federal Circuit’s protective rule for awarding damages against a losing patent plaintiff. 95 Third, the focus of Petitioning Immunity analysis is ill-suited to this situation—where a state (or federal) law seeks to impose liability for pre-litigation conduct, partly in order to save potential defendants the costs of going to court. The test asks courts to assess the objective merits of a patent assertion claim. Courts simply cannot reasonably do this prior to infringement. Lastly, relying on the First Amendment rather than patent preemption raises a significant policy issue, clearly identified by Gugliuzza— that the First Amendment would limit federal regulation of patents as well.96 The irony here is that the impact of Noerr-Pennington immunity—stricter preemption of state law—is not dissimilar to the impact of applying the historic preemption rule under the Intellectual Property Clause. In effect, the Federal Circuit has unwittingly displaced the Intellectual Property Clause’s preemptive effect with Petitioning Immunity under the First Amendment.97 Again, there is no inherent reason the Federal Circuit cannot use the First Amendment to address this issue instead of the Intellectual Property Clause. But along with the legal and policy issues stated above, my larger problem with Noerr-Pennington is that it is simply unnecessary. The court should just be using preemption under the Intellectual Property Clause instead.

**2AC – Pharma DA**

**Turn outweighs the link---welfare loss from monopolies are much larger**

Marlee P. **Kutcher 13** Loyola University Chicago School of Law, J.D, Illinois Symposium: Comment: Waiting is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit's Analysis of Pay-for-Delay Settlement Agreements, 44 Loy. U. Chi. L.J. 1093

B. Policy Arguments: **Balancing** Settlement and **Innovation** with Judicial Testing and Competition While courts applying the **scope** of the **patent** test have found support in public policy arguments for innovation and settlements, they have not properly weighed the public policy arguments for challenging invalid patents and promoting competition. 234 Even though the underlying reason courts generally give to support settlement is cost efficiency, 235 these courts overlook that **antitrust law** **also** saves the public money by **protecting** the **basic rules of competition** to keep prices **low**, production **efficient**, and **innovation robust**. 236 Specifically, **early** competition benefits consumers because it **lowers** drug prices **sooner**. 237 Reverse payment settlements merely **transfer** "wealth from consumers to **drug makers**, in the form of continued high pharmaceutical prices, with brand-name firms sharing a portion of that transfer with the generic firm." 238 Although settling patent litigation cases may save major pharmaceutical companies substantial sums of money, 239 consumer **welfare losses** from delayed generic drug market entry are **eighty-five times greater** than the loss the public suffers from **costly litigation**. 240 Even though courts favor settlements because they benefit the public, the courts found that settling parties owe no duty to "preserve the public's interest in lower prices." 241 In essence, these courts reason that cost efficiency matters at the courts, but not at the pharmacy. 242 Similarly unpersuasive, the Second, Eleventh, and Federal Circuits have warned that scrutinizing patent settlements could hinder patent innovation, the foundation of patent law. 243 The Supreme Court has declared that patent law also strongly supports the public interest in testing patents as a way to promote innovation and prevent invalid patent holders from maintaining monopolies. 244 The Court also has explained that patent laws must recognize that "**imitation** and **refinement** through imitation are both necessary to **invention** itself and **the very lifeblood of a competitive economy**." 245

**Generic competition causes brand-level innovation**

**Li 21** (Xuelin Li, Assistant Professor of Finance at the University of South Carolina's Darla Moore School of Business, Paying off the Competition: Market Power and Innovation Incentives, <https://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/2021-04/Competition%20Generics%20Draft%20v8.pdf>, y2k)

How does a firm’s market power in existing products affect its incentives to innovate? We explore this question using **granular project-level** and **firm-level data** from the **pharma**ceutical industry, and focus on a particular mechanism through which incumbent firms may maintain their market power: “reverse payment” or “pay-for-delay” agreements to delay the market entry of competitors. We first show that when firms are **unfettered** in their use of “**pay-for-delay**” agreements, they **reduce** their **innovation activities** in response to the potential entry of direct competitors. We then examine a legal ruling that subjected these agreements to antitrust litigation, thereby reducing the incentive to enter them. After the ruling, incumbent firms increased their net innovation activities in response to competitive entry. These effects center on firms with products that are more directly affected by competition. However, at the product therapeutic area level, we find a reduction in innovation by new entrants after the ruling in response to increased competition. Overall, these results are **consistent** with firms having **reduced incentives to innovate** when they are able to **maintain** their market power, highlighting **a particular channel** through which this takes place. 1 Introduction The effect of competition among firms on innovation is a critical issue for policymakers, given the importance of innovation as a driver of economic growth. However, the relationship between increased competition and innovation is not clear-cut in the literature (e.g. Aghion, Bloom, Blundell, Griffith, and Howitt (2005)). On the one hand, measures such as greater patent protection to reward firms for innovation by limiting competition may encourage further innovation in order to reap monopoly profits. On the other hand, an incumbent firm with an existing product under such protection may feel no need to innovate further if it can already rely on a guaranteed revenue stream from the product. Understanding the interaction between these forces is crucial for ascertaining the effect of policies aimed at increasing innovation by changing the degree of competition in a market, such as antitrust enforcement and patent policy. In this paper, we explore this issue by providing evidence from a legal mechanism through which innovative firms may maintain their market power, and its ramifications for innovation. We do so in the setting of a particular sector known for its research and development (R&D) activities that spur innovative products, the pharmaceutical industry. In this industry, firms that are first to pass clinical trials and obtain Food and Drug Administration (FDA) approval for their drugs enjoy marketing exclusivity for a number of years, during which no other firm can directly compete against that drug. However, after marketing exclusivity expires, other firms may enter the market by launching generic versions of the specific drug through what is known as a Paragraph IV filing. In order to continue their **monopoly** over marketed drugs, incumbent pharmaceutical firms have regularly entered into “pay-for-delay“ agreements—also known as “reverse payment”—**settlements** with entering generic manufacturers, whereby the generic firm agrees to delay product launch in exchange for a cash amount. These agreements effectively provide an endogenous tool through which incumbent firms can reduce the competition that they face. Using detailed data on public pharmaceutical firms and their drug development portfolios from 2005 to 2016, we construct a firm-specific measure of the amount of competition that each incumbent faces through Paragraph IV generic drug entry filings. We show that unconditionally over our sample period, incumbent firms responded to potential entry from direct competitors by reducing their innovation activity and initiating a smaller number of new drug trials.1 The results suggest that firms appear to reduce their levels of innovation when faced with increased competition. We then explore the **effect** of a Supreme Court ruling in 2013, ***FTC v. Actavis***, which increased the **legal risk** of engaging in pay-for-delay agreements. The ruling stated that under **antitrust law**, the Federal Trade Commission (FTC) could target such agreements, and granted the FTC broader bargaining power in these types of antitrust settlements. Consistent with the increased legal risk, we document a sharp decline in the number of pay-for-delay agreements after the ruling, a stark reversal of the previous trend. Furthermore, we show that the ruling did not appear to change the incentives of generic entrants, which filed at the same rate both before and after the ruling.2 We therefore interpret the ruling as an unexpected regulatory change that reduced the ability of incumbent firms to enter into agreements to impede new competition. Our initial result, that incumbent firms reduce their levels of innovation when faced with increased competition, **reverses itself following this ruling**. Put differently, pharma firms **after** the ruling increase their **number of new drug trial initiations** and **decrease** their number of **suspensions of existing projects** in response to **generic entry filings**. This suggests that the initial negative relationship between generic competition and innovation is driven primarily by the ability of incumbent firms to protect their monopoly power through pay-for-delay agreements. Such agreements allow firms to resolve the uncertainty of product competition and reduce the need to maintain their competitive edge with novel drugs. However, after this channel becomes legally risky, firms need to **rely** on **innovation activities** to escape **neck-to-neck competitions** (e.g. Aghion et al. (2005)).

**Existing innovations are not “innovative”**

David **Blumenthal 21**, MD, is president of the Commonwealth Fund, The U.S. Can Lower Drug Prices Without Sacrificing Innovation, 10-1, <https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation>

The **C**ongressional **B**udget **O**ffice estimated that reducing the pharmaceutical industry’s revenues would result in **two fewer drugs** in the next decade, 23 fewer in the following decade, and 34 fewer drugs in the third decade. Predictions 20 to 30 years out are necessarily imprecise, **but** in any case, many of those **projected new therapies** would likely be **neither novel** nor **more valuable** than existing drugs. That is, **they wouldn’t be innovative.**

**Clarifying in favor of objectively baseless doesn’t solve because unifying under objectively baseless is still unclear! We’re saying we need to get rid of the two prong altogether!**

**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

B. The PRE “Objectively Baseless” Objective Test – An Ambiguous Test 1. Evidence of Ambiguity from the PRE Decision Itself As stated, the first problem with the objective test established by the Court in PRE is that it is ambiguously framed. **The court’s opinion features multiple, and** materially **inconsistent**, **formulations** for its test for “objective baselessness.” The reader is directed to the express language of the objective test as stated in PRE (the location of that exact text, in this paper, being indicated in the margin).45 Even in these short passages, one can begin to recognize linguistic formulations that might not entirely overlap. However, the trouble doesn’t stop there. **There are actually several different**, **substantially varying, formulations** of the objective baselessness test **that appear in the Court’s decision.** Consider the following formulations, **all taken from the majority opinion:**  The lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. 46  The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation. The notion of probable cause, as understood and applied in the common law tort of wrongful civil proceedings, requires the plaintiff to prove that the defendant lacked probable cause to institute an unsuccessful civil lawsuit and that the defendant pressed the action for an improper, malicious purpose.47  Probable cause to institute civil proceedings requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication. 48  When a court has found that an antitrust defendant claiming Noerr immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant’s position could realistically expect success on the merits of the challenged lawsuit.49  Even though it did not survive PRE’s motion for summary judgment, Columbia’s copyright action was arguably “warranted by existing law” or at the very least was based on an objectively “good faith argument for the extension, modification, or reversal of existing law.” Fed. R. Civ. P. 11.50 As we have held, PRE could not pierce Columbia’s Noerr immunity without proof that Columbia’s infringement action was objectively baseless **or frivolous.** 51  We hold that an objectively reasonable effort to litigate cannot be sham regardless of subjective intent.52  If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail.53  A court could reasonably conclude that Columbia’s infringement action was an **objectively plausible** effort to enforce rights. 54 **Thus, one sees no less than nine (9) separate linguistic formulations** purporting to distinguish “genuine” versus “sham” litigations for the purpose of Noerr-Pennington immunity. If the formulations were all closely correlated, they could be viewed as mere restatements. However, it is difficult to see how one can equilibrate “a reasonable belief that there is a chance that a claim may be held valid” with a “realistic expectation of success on the merits” with “an objectively plausible effort to enforce rights” with a suit “reasonably calculated to elicit a favorable outcome.” **How does one decide upon the appropriate legal test in such a case**? The author posits that the PRE objective test is likely either: (a) an “objectively baseless” type of test; or (b) an “objectively unreasonable” type of test. Arguably, when read in context, the first six of the nine bulleted PRE formulations listed above are of the “objectively baseless” variety.55 However, the three “objectively unreasonable” formulations appearing in the opinion use language that is compelling.56 The experienced practitioner will appreciate that case law interpretation is infrequently resolved by resort to arithmetic tallies, so it makes sense to evaluate major appellate decisions penned after PRE to see how the lower courts themselves have interpreted the decision and whether they too report or evidence ambiguity.

### 2AC – CSR DA

**We just stop worst lies – they still have first amendment if they prove it was protected speech**

Tim **Wu 20**. 9-20-20. Tim Wu is an Isidor and Seville Sulzbacher Professor of Law at Columbia Law School. “Antitrust and Corruption: Overruling Noerr” https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3670&context=faculty\_scholarship

As the first step suggests, an important doctrinal tool in a First Amendment defense of Noerr like conduct is the speech / conduct distinction. **The speech / conduct distinction** is a familiar First Amendment trope most famously associated with Holmes’ example of shouting “fire” in a crowded theater. As implied by that example, the Court has never taken everything that might, in some sense be called “speech” to be protected expression under the First Amendment. Many so-called “speech acts,” such as true threats, criminal conspiracy, harmful lies and most procedural court filings are not granted protection as speech under the First Amendment.74 **Hence, a defendant who claims that their conduct**, **otherwise illegal under the Sherman Act, is** **in fact protected speech**, would need to demonstrate that what is claimed as speech enjoys protection at all.75 **Much anticompetitive speech would still be protected.** The railroad company that expresses its passionate support for climate change laws, knowing that such laws will disadvantage the trucking industry, is protected by the First Amendment. In fact, even if the industry supports such measures because emission requirements might hurt its competitors would still be engaged in protected speech — the premise being that it is participating in the debate. **But a company that issues false statements in a government proceeding to hurt a competitor or competition is not protected**, as in the example of the oil company that lies about its patents to a state agency formulating a regulation,76 or the filing of false claims to the FDA to try and extend the life of a patent.77 That kind of claim could be decided by United States v. Gilliland, 78 which affirmed that intentionally false declarations to the government are unprotected by the First Amendment. The Court held that it was legitimate to protect “agencies from the perversion which might result from the deceptive practices described”79 and prosecutions for such lies are now routine. A similar analysis obtains for bribery. Bribery can be thought of as a form of expressive conduct, in the same way that the assassination of a political figure might be. But if the courts sometimes take a very narrow view of bribery, they have not been willing to afford a Constitutional defense to those convicted of bribery.80 **It is important to understand how this analysis would differ from the invoking of Noerr’s sham exception. A**s it stands, the sham exception has been limited by the Supreme Court to a form of conduct unprotected by the First Amendment (purely baseless abuse of process). **The court using existing First Amendment analysis would necessarily be forced to consider whether other forms of expressive conduct, like bribery or deceit, were protected or not**.81 Even if they are not engaged in protected speech, antitrust defendants might argue, alternatively, that they were engaged in petitioning, which is separately protected by the First Amendment. But to invoke this defense, the defendant would have to demonstrate that what they were doing was actually petitioning. As the FTC puts it, petitioning is not “all activity involving communication with the government;” but is limited to a “request to a government decision maker to exercise its discretion to decide in a certain way.”82 Consequently, the manufacturer who petitions the Commerce department for an exception to a steel tariff is protected by the Constitution. (Many forms of lobbying would likely be protected as well; though strictly speaking the Court has yet to explicitly rule that lobbying amounts to protected petitioning. 83 ) But there are such a thing as a communication with government that is not a petition. 84 For example, purely ministerial or procedural filings, over which the government exercises no discretion, are not good faith efforts to persuade the government of anything.85 Similarly, the party who lies to the patent office in a patent application has indeed tried to influence government in their favor, but in a form that cannot be termed a legitimate petition.86 The First Amendment protections afforded litigation would remain a slightly complex matter. The Supreme Court has, under the First Amendment, protected the activities of lawyers, at least when “resorting to the courts to seek vindication of Constitutional Rights.” The Court has also said that “the Petition Clause protects the right of individuals to appeal to courts and other forums established by the government for resolution of legal disputes.”87 That, and the protection granted litigation under existing Noerr doctrine, would tend to suggest a baseline of constitutional protection for suits that are allegedly filed for anticompetitive purposes. That said, the Constitutional protection afforded litigation is obviously limited. **Courts have long felt themselves free to punish lawyers who bring frivolous suits, lie to the court during litigation, or induce perjury.** **Hence, baseless or repetitive litigation brought purely for harassment purposes would be unprotected.**

**You could still lobby just can’t lie**

Tim **Wu 20**. 9-20-20. Tim Wu is an Isidor and Seville Sulzbacher Professor of Law at Columbia Law School. “Antitrust and Corruption: Overruling Noerr” https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3670&context=faculty\_scholarship

IV The First Amendment as a Replacement for Noerr **In the absence of Noerr, the defendant who claims to be petitioning government or expressing political views would not be left helpless**. Instead, such a defendant would raise the First Amendment as a defense, as is typical in other areas of the law. 73 This section considers, briefly, what such a defense might look like in practice. A defendant engaged in concerted anti-competitive activities that involve the government would defend itself by asserting that it is engaged in either political speech, petitioning, or both. Faced with such a defense, the main two questions before the court would be this: was the defendant in fact engaged in speech or petitioning, or, instead, in some category of conduct, such as bribery, deception of an agency, abuse of process, or other such categories? Second, if the defendant was engaged in protected speech or expressive conduct, do the governments’ interests — understood as preventing monopolistic corruption of the political process — outweigh those interests?

**Unchecked Noerr immunity sanctions dirty climate advocacy**

Tim **Wu 20**. 9-20-20. Tim Wu is an Isidor and Seville Sulzbacher Professor of Law at Columbia Law School. “Antitrust and Corruption: Overruling Noerr” https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3670&context=faculty\_scholarship

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 polluting as widely believed, promoting the concept of “clean coal.” And it might formally petition government with economic arguments for abandoning the subsidization of wind power.

These activities are all within the core of First Amendment protection. By providing information to government and the public relevant to an important debate, they serve the process of democratic self-government, both through the formation of public opinion and the provision of information necessary to making important public decisions. 41. See Alexander Meiklejohn, Free Speech and Its Relation to Self-Government (1948); Vincent Blasi, Learned Hand and the Self-Government Theory of the First Amendment: Masses Publishing Co. v. Patten, 61 U. Colo. L. Rev. 1 (1990).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 better in that context.42. Whitney v. California, 274 U.S. 357, 375 (1927) (Brandeis, J., dissenting) (“[T]he fitting remedy for evil counsels is good ones.”); Buckley v. Valeo, 424 U.S. 1, 48–49 (1976) (“[T]he concept that government may restrict the speech of some elements of our society in order to enhance the relative voice of others is wholly foreign to the First Amendment[.]”); accord Citizens United v. Fed. Election Comm’n, 558 U.S. 310, 350 (2010).

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, at some point, they disappear entirely. This 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. Industry might also publish demonstrably **false** or even defamatory information, such as the suggestion that wind turbines are highly **harmful** to human health (“wind power syndrome”). 43. Jeffrey Ellenbogen et al., Wind Turbine Health Impact Study: Report of Independent Expert Panel (2012) (“There is insufficient evidence that the noise from wind turbines is directly [...] causing health problems or disease.”).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. At the extreme, it might 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 the point of being nonexistent. 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.44. United States v. Halloran, 821 F.3d 321, 340 (2d Cir. 2016) (holding that the First Amendment does not protect bribery); United States v. Yermian, 468 U.S. 63 (1984) (never suggesting that 18 U.S.C. §1001, which makes it a federal crime to knowingly lie to the government, poses First Amendment issues). See also Bill Johnson’s Restaurants, Inc. v. NLRB, 461 U.S. 731, 732 (1983) (“A baseless lawsuit with the intent of retaliating against an employee for the exercise of rights protected by the [NLRA is] ... not within the scope of First Amendment protection[.]”).

**On the antitrust side of the ledger**, the strength of the government’s interests would similarly seem to depend on 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 by case law condemning intentional monopolization, 45. Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985).deception, 46. United States v. Microsoft Corp., 253 F.3d 34 (D.C. Circuit 2001); Walker Process Equip., Inc. v. Food Mach. & Chemical Corp., 382 U.S. 172 (1965). See also In re Union Oil Co. of Cal. (Unocal), FTC Dkt. No. 9305, slip op. at 16 (2004).and other tortious conduct like fraud or sabotage.

What is needed, is something that courts do regularly, namely, balance the respective interests protected by the First Amendment and antitrust laws, **respectively**.

And that is what is completely **lacking** in **Noerr**: any consideration of the relative strengths 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 defensible boundary**.

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### 2AC – EPA Court Ptx DA

**Vaccine strike down kills the DA**

**Wehle 1/14** “Opinion | The Supreme Court Just Made an Incredible Power Grab” KIMBERLY WEHLE, 01/14/2022, https://www.politico.com/news/magazine/2022/01/14/vaccine-mandates-supreme-court-biden-regulations-527154

Thursday’s Supreme Court decision blocking the federal government’s mandate that large businesses require vaccinations or tests of their employees is being seen as a blow to the Biden administration’s efforts to combat the Covid-19 pandemic. It is certainly that, despite the court’s split decision allowing the same mandate to remain in force for medical facilities that accept money under the Social Security Act.

But the biggest loser coming out of these decisions is not the president’s reputation as a problem solver but decades of constitutionally established power-sharing between the legislative and executive branches. And the winner, if that’s the right term, is the Supreme Court itself, which has executed an unprecedented power grab and masked it as an act of judicial restraint.

How did the court’s conservative 6-3 majority pull this off?

Here’s the key passage with the court’s unsigned opinion: “Although Covid– 19 is a risk that occurs in many workplaces, it is not an occupational hazard in most. Covid–19 can and does spread at home, in schools, during sporting events, and everywhere else that people gather.” Because the statute gives the Occupational Safety and Health Administration authority to enact standards “reasonably necessary or appropriate to provide safe or healthful employment,” it reasoned, and Covid-19 doesn’t just spread in the workplace, OSHA acted outside its lane of authority. The vaccine-or-test mandate “draws no distinctions based on industry or risk of exposure to Covid-19,” and thus cannot be enforced. “[M]ost lifeguards and lineman face the same regulations as do medics and meatpackers,” for example.

The logical flaw in the majority’s reasoning is that this line-drawing isn’t required by the actual 1970 law (the Occupational Safety and Health Act) that established OSHA. Back in 1979, the Court recognized in Industrial Union Department v. American Petroleum Institute that OSHA has “broad authority … to promulgate different kinds of standards.” Justice Stephen Breyer in his dissenting opinion thus explained: “The Standard falls within the core of the agency’s mission to ‘protect employees’ from ‘grave danger’ that comes from ‘new hazards’ or exposure to harmful agents,” as set forth in the relevant part of the OSH Act.

What the majority is really saying, then, is that it doesn’t like how much power Congress gave to OSHA in the first place. The question of whether Congress can delegate its lawmaking powers to executive branch agencies has been debated for decades. But since the 1930s, the court has basically allowed Congress to give agencies rulemaking power under Article I’s “Necessary and Proper” clause, in part on the theory that courts lack the kind of expertise that agencies have. Moreover, even though they are not elected, agency employees answer to someone who is accountable to voters: the president.

This is known as the delegation of legislative power. Instead of keeping its lawmaking power for itself, Congress gives the executive branch the power to fill in the inevitable blanks it leaves in legislation. When executive branch agencies respond, the resulting laws are often known as “regulations.” But they function with virtually the same force of law as an act of Congress itself. The legal critique of the practice of handing off lawmaking power to agencies has not garnered traction in the Supreme Court for nearly a century. Only a tiny handful of court decisions in the New Deal era struck down Congress’ decisions to delegate legislative authority under the so-called non-delegation doctrine.

The court’s majority opinion signals that this Supreme Court is poised to strike down an undisclosed segment of federal regulations that don’t follow express, detailed authority from Congress. And even more troubling, the court’s conservatives have apparently determined that Congress may do so only if the subject matter of the law implicates what the court deems a “major question,” a nebulous and undefined term that has no textual support in the Constitution. Because our polarized Congress is shockingly dysfunctional when it comes to substantive policy, it doesn’t bode well for the country’s legislative needs.

**OR, EPA could still target co-pollutants**

Lexi **Smith 11/7**—BA from Harvard in nvironmental science and public policy. ("Supreme Court to weigh EPA authority to regulate greenhouse pollutants » Yale Climate Connections," 11/7/2021, from Yale Climate Connections, https://yaleclimateconnections.org/2021/11/supreme-court-to-weigh-epa-authority-to-regulate-greenhouse-pollutants/)

Finally, **even if EPA** – **and** therefore the **executive branch agencies as a whole** – **were to lose authority to regulate** **g**reen**h**ouse **g**ase**s** **directly under the** **C**lean **A**ir **A**ct**, it could still indirectly reduce greenhouse gas** **emissions by targeting co-pollutants** **that fall more squarely under** **C**lean **A**ir **A**ct **authority.** For instance, **greenhouse gas emissions are** often **accompanied** **by particulate matter, nitrogen oxides, sulfur oxides, volatile** organic **compounds, and air toxics. By regulating those co-pollutants, EPA can** **bring down** **greenhouse gas emissions without exercising any direct regulatory authority** over them. Of course, if the Court fully embraces the nondelegation doctrine, EPA’s authority to regulate those other pollutants could also be jeopardized. But, as mentioned above, some Justices may stop short of such a decision in light of concerns about the Court’s legacy and risks of a backlash.

## 1AR

**1AR – Sham Litigation**

**Ignore all innovation high arguments. No answer to our internal link that trolls devastate cloud security and privacy—that dooms the success of any potential solution.**

**Ahmad 22** (Ahmad,W. Department of Cyber Security, Air University, Islamabad; Rasool, A.; Javed, A.R.; Baker, T.; Jalil, Z. Cyber Security in IoT-Based Cloud Computing: A Comprehensive Survey. Electronics 2022, 11, 16. https://doi.org/10.3390/ electronics11010016)

The success of any cloud-based solution is heavily **reliant on providing the best experience** to cloud administrators, software developers, and end-users. There are specific barriers to the adoption of clouds, such as complexity, compliance, **security, reliance, privacy**, control, and cost [17]. Security in cloud computing **is considered a crucial barrier** since data and applications may reside at multiple layers depending on the chosen cloud service model. This uncertainty led researchers to consider security as the number one concern with cloud computing [18]. Gartner [19] mentioned four trends impacting cloud adoption in January 2020, where distributed multi-cloud scenarios are more commonly used. Handling associated security and privacy issues are one of them.

Cloud offers the distribution of heterogeneous data and resources along with virtual environments. In a traditional software infrastructure of businesses, a user can only use the resources available to them (i.e., storage space, computation capabilities, and hardware), whereas in cloud computing, a user can enjoy unlimited storage space and more server resources when required. Traditional approaches for user identification, authentication, access management are not adaptable for the cloud in their current form. External data storage, less user control, integrated models, and architectures are significant areas of security concern. The most significant concern for security and privacy in cloud-based systems **is protecting data**. If this is compromised, then the private information of each user will be at risk, resulting in an increasing number of **cybercrimes** affecting individuals, organizations, and states.

**Expert consensus agrees they’re existential**

**Sandberg ’18** - Ph.D. in computational neuroscience from Stockholm University, and is currently a James Martin Research Fellow at the Future of Humanity Institute at Oxford University

Anders Sandberg, “Human Extinction from Natural Hazard Events,” *Oxford Research Encyclopedia of Natural Hazard Science*, February 26, 2018, <https://doi.org/10.1093/acrefore/9780199389407.013.293>.

Impacts

Earth is subject to impacts of Near Earth Objects (NEOs) and long-periodic comets. While the possibility of impacts causing disasters was suggested early by Halley, Laplace, and others, the serious possibility of global risk was first convincingly brought up in 1980 when Luis Alvarez suggested a link between an asteroid impact and the Cretaceous–Tertiary mass extinction event (Alvarez et al., 1980). Since then much research has tried to establish a causal role of impacts in past mass extinctions. While conclusive proofs have not yet been found, **there is consensus that a large impact could cause a mass extinction and hence human extinction.**

The effects of impacts depend to a large degree on impactor mass (although velocity and impact site can have relevant effects [Walkden & Parker, 2008]). For smaller (<1.4 km diameter) impactors the effects are local or transmitted through tsunamis. Beyond this size the **main hazard is global cooling** due to stratospheric ejecta and soot from wildfires, as well as harm the ozone layer through nitrous oxides. Ejecta from larger impactors may cause **globally distributed fires** and darken the sky enough to **prevent photosynthesis for months**, and injections of sulphate aerosols and water vapor into the stratosphere would change the climate over years (Toon et al., 1997; Pierazzo & Artemieva, 2012; Brugger, Feulner & Petri, 2017). At this scale infrastructure and agricultural collapse is to be expected (Chapman, 2003). Human mortality has been modeled as scaling linearly from 0% at 1.6 km to 100% for 10 km impactors (Stokes et al., 2003), although this is at best an educated guess. **The most extreme impacts** (440 km and upward) **would sterilize the biosphere** (Sleep et al., 1989); such events may have occurred in the early solar system but today only a handful of such bodies remain and are all in stable orbits.

The population of potential impactors has a roughly power-law size distribution (Malamud, 2004), with globally risky asteroids impacting once every few million years and multi-megaton locally devastating impacts such as the 1908 Tunguska explosion every 1,000 years (Brown et al., 2002; Harris & D’Abramo, 2015). At present the NASA Space Guard has mapped an estimated 90% of 1 km or larger NEOs, significantly reducing the remaining risk for the next century. The handful of known 10+ km NEOs are in safe orbits. All remaining risk is from undiscovered large NEOs. The residual human risk is dominated by tsunamis rather than global disaster or extinction (Harris, 2008; NRC, 2010). However, “new” long-periodic comets add a badly characterized risk that may be on the order of one 2+ km impactor per 5 to 10 million years. This is based on estimates from observed comet fluxes, correcting for observational incompleteness, rough models of comet size distributions, and the possibility of brief (2–3 Myr) comet showers due to gravitational interactions with passing stars (Chapman, 2003; Weissman, 2006).

**1AR – Patent Thickets**

**Models demonstrate patent thickets substantially deck innovation**

Bronwyn **Hall et al. 16**—Professor Emerita of Economics, UC Berkeley; Christian Helmers, Georg von Graevenitz. ("Patent thickets and first-time patenting: New evidence," 4/1/2016, from VoxEU, https://voxeu.org/article/patent-thickets-and-first-time-patenting-new-evidence)

Patent thickets can lead to **hold‐up of innovations**, increases in the **complexity of negotiations** over licenses and increases in litigation, and can also create incentives to add **more and weaker patents** to the patent system. All these phenomena increase **transaction costs**, reduce profits that derive from the commercialisation of **innovation**, and ultimately **reduce incentives to innovate**.

One worry is that patent thickets may stop companies large and small from even entering those technologies in which patent thickets are widespread. To investigate this question, in a recent paper we analyse the effect of **patent thickets on entry** into technology areas by firms in the UK (Hall et al. 2015). We present a theoretical model that describes incentives to enter technology areas that differ in the degree of technological opportunity, complexity of technology, and the potential for hold-up in patent thickets.

We derive a number of predictions regarding the effects of complexity (positive), opportunity (positive), and expected hold up (negative) on entry from the model. The predictions are tested using data on patenting activity of UK firms where we define entry into a new technology as first-time patenting in a given technology class by a company. We distinguish empirically between complexity and hold-up potential and control for technological opportunity in several different ways.

As shown in Figure 2, the measure of hold-up potential (Triples density coefficient)1 is associated with a reduction of first time patenting in a given technology area, controlling for the level of technological complexity and opportunity. The figure also shows that this relationship is independent of firm size in our data. Technology areas characterised by more technological complexity (Network density coefficient)2 and opportunity (Aggregate patenting coefficient,3 and 5-year growth NPL coefficient),4 in contrast, see more entry. This is in line with the predictions we derive from the theoretical model. Our evidence indicates that patent thickets raise **entry costs**, which leads to less entry into technologies. It is important to emphasize that this result is not due simply to very active patenting in a technology nor to citation density in general, as these have been controlled for.

Figure 2. The effect of thickets on technology entry

Chart

Description automatically generated

These results indeed support the view that many patents are filed in technologies in which there is a lot of technological change, as well as the view that some of these technologies are associated with patent thickets.

We show that patent thickets reduce entry (first time patenting in an area) by **20**%, which is **substantial** bearing in mind that the average probability of entry into a technology area is only about 1.5% in our sample.

This effect is **surprisingly strong** and suggests that measures to reduce patent thickets might allow more entrants to compete in important technology areas.

**Specifically, in pharma**

Olga **Gurgula 17**—Lecturer in IP Law, Brunel Law School, Brunel University London, Visiting Fellow, Oxford Martin School, University of Oxford. (Strategic accumulation of patents in the pharmaceutical industry and patent thickets in complex technologies - two different concepts sharing similar features," June 2017, from - International Review of Intellectual Property and Competition Law, https://bura.brunel.ac.uk/bitstream/2438/17417/1/Fulltext.pdf)

As was mentioned previously, the phenomenon identified by the Commission shares some common features with the patent thickets concept: it also has a dense web of overlapping patents, which occur due to the institutional gaps described above. However, it is different from patent thickets in a number of ways. Firstly, this dense web of patents is created by and belongs to a single firm, the originator, as opposed to the multiple participants in complex technology patent thickets. Secondly, this dense web is created by the originator in order to protect its basic patent, which covers a commercially valuable product, as well as to extend the protection beyond the basic patent A substantial difference here is in the nature of a product – it is discrete, i.e. consists of an active ingredient that is protected by a basic patent. In order to protect this active ingredient, the originator company builds up multiple layers of defence by means of applying for numerous incremental patents. Therefore, the classic model of strategic accumulation of patents in the **pharma**ceutical industry is: (1) multiple **secondary patents** on a (2) **basic compound** (3) held by a single originator company. Thirdly, unlike in complex technologies, the originator maintains exclusive rights over its patent portfolio. Therefore, the originator does **not need to cooperate** with its competitors and is free to operate in the field, protected by its numerous patents. Fourthly, with respect to **patent thickets**, business strategies of patent holders are not aimed at the creation of patent thickets per se. On the contrary, in the **pharma**ceutical industry the creation of a web of patents is an **intentional action** of the originator for the **sole purpose** of **protecting** valuable products from generic **market entry**. It is a strategic **exclusionary behaviour** of a pharmaceutical company intended to block **or delay generic entry**. Fifthly, the aim of such a dense web of patents in the pharmaceutical sector is not to strengthen bargaining and licensing position, as is normally the case in complex technologies industries, but to block the competitor from entering the market for as long as possible.

**Broad consensus agrees**

Jonas **Frank &** Wolfgang **Kerber 16**—University of Marburg, School of Business & Economics. ("Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective," 3 May 2016, Dewenter, Haucap, Kehder, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2277508)

In the last decade, the insight has **increased** that the patent law regime (both in the U.S. and the EU) suffers from **serious defects**.15 In the meantime, there is a **broad consensus** that often patent claims are not precisely defined, leading to the **problem** of overlapping patents and **patent thickets** (Shapiro 2001, Gilbert 2009, p. 2). In addition to that, experience shows that the requirements, e.g., in regard to the necessary "**inventive step**", have been lowered (Harhoff et al. 2007, p. 250). Therefore, too many patents for often only **minor inventions** have been granted, which **endangers competition** and **stifles innovation**. Part of the problem is that the patent offices lack sufficient resources to carry out solid and well researched examinations of patent applications (Gallini 2002, p. 150, Shapiro 2003b, p. 392, Farrel/Merges, 2004, pp. 944). In the meantime, both economic and legal scholars of patent issues are well aware of these problems. Therefore, the assumption that all patents granted by the patent offices are justified and should be deemed as unquestionably valid, cannot be upheld any more.

**1ar –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.

**Courts are afraid to strike the down the patents---couching in terms of antitrust is key**

**Rose 14** (COLLIN A. ROSE, Managing Editor, COLUM. J. L. & SOC. PROBS., 2014-15. J.D. Candidate 2015, Columbia Law School. A Match Made for Court: Patent Assertion Entities and the Federal Trade Commission, 48 Colum. J.L. & Soc. Probs. 95, y2k)

1. Limits on Judicial Actors

For **judicial actions**, recent cases demonstrate **the limits** courts face in **affecting change** to the **patent system** and, by extension, the **business model of PAEs**. The case that most directly targets PAEs, eBay, 179 is almost eight years old, and PAE activity has only increased in its wake. 180 The rule that eBay instituted has been partially circumvented by those PAEs turning to the ITC to recreate the problem of patent holdup. 181 Furthermore, both KSR Technology and Bilski demonstrate that the Court has identified [\*125] aspects of the patent system it finds intolerable--for example, a rigid TSM test or patenting a commodity-hedging process 182--but that it has also struggled to delineate the future of those limits. In both cases, the Court left significant guesswork for **lower courts** to **interpret** its holdings. 183 Moreover, i4i Limited Partnership emphasizes the Court's continued belief in **the strictest presumption of validity for patents**, 184 even when it comes at the **expense** of those targeted by **patent infringement** suits. 185 All four of these cases highlight the **Court's difficult position** in adjudicating **patent cases** as it walks the line of **staying true** to the principles of the **patent system** while simultaneously adapting to modern needs. **Most disturbingly**, these episodes cast doubt that courts will soon provide **an effective remedy** to the **systematic patent issues** that have allowed PAEs to **thrive**.

**1AR – Pharma DA**

**The “objectively basis” standard is too high**

Karen **Roche 2013**. \* J.D. Candidate, May 2013, Loyola Law School Los Angeles. 2-8-2013. “Deference or Destruction? Reining in the Noerr-Pennington and State Action Doctrines” <https://digitalcommons.lmu.edu/cgi/viewcontent.cgi?article=2809&context=llr>

Is the Sham Exception Itself a Sham? The Court could have used the sham exception as a tool to narrow the reach of Noerr immunity.178 However, the exception has grown increasingly confusing and has been narrowed to the point where **it is almost impossible to claim that something is a sham**.179 As such, **it is ineffective as a limit to Noerr**. 180 **The result** of such a narrow exception **is the immunization of too many petitions** **that**, whether or not successful, **give petitioners room to overcharge consumers and eliminate competitors**. 181 Petitioners are able to use the petitioning process to raise costs for their competitors or to delay the entry of competitors into the market. **Even if the petition is eventually unsuccessful,** **the effect of the petition itself may eliminate competition** **and allow the petitioner to raise prices** **without competing products or services to bring those prices down**.182 a. The PRE test raises the bar too high and fails to protect the consumer While the language of the PRE test may seem straightforward,183 it is unclear how the test should be applied in practice. Much of this confusion was caused by the language Justice **Thomas** used in PRE. 184 He **did not** clearly **explain what “objectively baseless” meant**, but instead defined an objectively baseless lawsuit as one in which “no reasonable litigant could realistically expect success on the merits”; one that lacked probable cause, as in the tort of malicious prosecution; and one that was not warranted by existing law or based on a good faith argument for the modification of the law, as in Federal Rule of Civil Procedure 11 (“Rule 11”).185 Justice Thomas borrowed the language of Rule 11 and the requirements for malicious prosecution to define objectively baseless, but, as Justice Souter pointed out in his concurrence, the Rule 11 test and the requirements for malicious prosecution are not the same.186 **Thus, what it means for a petition to be objectively baseless is unclear at best**. As one commentator pointed out, “Many cases may be sufficiently weak that a reasonable litigant could not realistically expect success and yet not be so devoid of merit as to lack probable cause.” 187 Moreover, while most people read PRE as a narrowing of the Court’s earlier application of the sham exception, the Ninth Circuit views the PRE and California Motor Transport tests as inconsistent and attempts to “reconcile these cases by reading them as applying to different situations.” 188 The Ninth Circuit applies the two-part PRE analysis to cases in which a single action may be sham petitioning but applies California Motor Transport to cases where a whole series of legal proceedings may constitute sham petitioning.189 In the latter situation, the court does not look at whether any of the proceedings had merit but instead looks at whether collectively they are brought for the purpose of harming or harassing a market rival.190 The lack of clarity surrounding the PRE test makes it much more difficult for those harmed by petitions to claim an antitrust violation since it is unclear what will be enough to prove a sham. **Additionally**, the test that Justice **Thomas** articulated, **which equates objectively baseless petitions with a lack of probable cause, is far too broad**.191 The PRE Court said that a winning lawsuit precludes a finding that the suit is objectively baseless.192 Further, the court must not assume that a losing lawsuit was unreasonable or without foundation.193 Thus, from the outset, it will be difficult to find that a petition is objectively baseless.194 The current test “allows [an antitrust defendant] to present a sufficiently weak citizen petition with no reasonable expectation of success” and protects that petition because it is “not so devoid of merit as to lack probable cause.” 195 This sets the bar too high for proving a sham petition and often results in increased cost to the consumer, who without the sham exception has no tools to prove an antitrust violation.196 For example, in Louisiana Wholesale Drug Co. v. Sanofi-Aventis, 197 the court held that a petition to the FDA was not a sham, even though the defendant petitioner may have had no reasonable belief that the petition was viable.198 Instead, the court believed that the petitioner’s arguments were “arguably warranted by existing law or at the very least [ ]based on an objectively good faith argument for the extension, modification or reversal of existing law.” 199 Using this language to determine whether the petition was objectively baseless allowed the court to conclude that the petition was not a sham, **regardless of the fact that the petition seemed to have little merit and was clearly harmful to the plaintiff and other consumers**.200 **The PRE test’s high bar allowed the defendant to submit its petition without antitrust liability and protected the petitioner’s activity at the expense of the consume**r.201

**Kills R&D**

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**Patent thickets** also create **troublesome incentives** to wage **meritless litigation**. 164 Some bad faith litigants have **overwhelmed** practicing entities by acquiring thousands of patents regardless of the patents' quality. This type of action allows an entity to essentially weaponize their own patent thickets: Their **scale** often enables them to license **without litigation** because defendants are **reluctant** to challenge an entire portfolio of patents. The patent aggregation model depends on patent intensity in an industry; it works because the patent aggregator has so many patents that read on a particular target that a challenge to the validity of the patents makes little sense. 165 And because patent infringement is a strict liability tort, the question of whether an inventor accused of infringement was aware of the pre-existing patent, or made a good faith effort to find it, has no exculpatory value. 166 As a result, patent thickets can **ex ante** and **ex post** raise the **costs of innovation**, thereby **discouraging** R&D investment. 167 The countries with the **most patents** in force are the most likely to be **burdened** by patent thickets. Historically, the United States has issued the most patents, which is attributable to the size of the American market; since both domestic and foreign inventors sell their technologies in the United States, inventors have sought to guard their market share by obtaining U.S. patents. Indeed, there are no requirements - in the United States, China, Japan, Europe, Korea, and most other nations - that a patent applicant reside in the country where the applicant seeks protection. As one may imagine, firms have not been bashful in applying for patents in their non-resident jurisdictions. 168 Despite the alarm expressed in some corners that the United States no longer receives the most patent applications, there are substantially more patents currently in force in the United States than anywhere else, sitting at a little over 2.5 million. 169