## 1AC

**1AC—Citizen Petitioning**

**Advantage 1 is Citizen Petitions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

\*footnotes omitted\*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**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

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

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

**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.

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

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

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

**Cultivated meat solves extinction**

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

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

CULTIVATED MEAT IS MUCH BETTER FOR THE ENVIRONMENT

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

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

CULTIVATED MEAT CONSERVES LAND & WATER RESOURCES

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

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

**The judicial revision of the sham litigation doctrine solves---it’s key to make regulations effective**

**Avery 13** (Associate at Pearson, Simon & Warshaw, LLP in San Francisco, The Antitrust Implications of Filing Sham Citizen Petitions with the FDA, 65 Hastings L.J. 113, y2k)

B. **JUDICIAL GUIDANCE**

A **judicial approach** to overseeing the **citizen petition** process should come from both **judicial deference** and **a new look at the sham exception** in light of the abuse of the petition process.249 The courts should generally defer to the FDA,50 which has broad discretion to establish and apply rules for public participation in Agency matters.25' This discretion gives the FDA broad authority to create and enforce its procedural rules on citizen petitions. The courts should also defer to the FDA when reviewing its factual determinations related to evaluating citizen petitions.

i. Reduce Judicial Participation

Courts may set aside agency action, findings, and conclusions if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. ' 52 In order to avoid such arbitrary and capricious rulings, the FDA should issue guidelines on the meaning of the terms "main purpose of delaying ANDA approval," "intent to delay," or "delaying petition," as discussed previously in Part VI.A.4. 53 Absent clear guidelines, any FDA decision would likely need to define the meaning of "intent to delay" in order to avoid being found arbitrary or capricious. Such guidelines would streamline FDA decisions and create a baseline for the courts to review citizen petitions under the antitrust laws.

Nonetheless, courts should not, in the interim, analyze such determinations to see whether they should be set aside. Agencies are granted broad deference because they are considered best equipped to respond to "changing circumstances."25' 4 **Recent cases** suggest, however, that courts have come to **ad hoc conclusions** regarding the merits of **eleventh-hour citizen petitions** and that **the sham exception is not consistently applied to Noerr-Pennington cases**. 55 It is possible that the current legal climate for citizen petitions consists of those "**changing** circumstances." ' 5

6 The fact that the **FDA** issued **a new rule** suggests that the Agency has been taking **notice** of the hole it needs to plug.5 7 Both judges and academics have pointed out the failings of the legislation currently in place."' If the **FDA** or **the legislature** pays greater attention to sham petitions and **delineates** the **difference** between what constitutes "**sham**" and "**not sham**," it could **speed up** the process in which **meritless petitions are deemed a sham**. Allowing the FDA to determine whether a petition constitutes a sham would shift the responsibilities to the **better-suited entity** and increase the efficiency and certainty of labeling petitions as sham. Given the FDA's greater expertise in evaluating scientific methodologies, **judicial deference** to FDA's determination of whether a petition is a sham creates **an effective system of deterrence**. 59 Alternatively, the FDA could promulgate clear guidelines regarding the definition of "sham," and courts could rely on those guidelines in their analysis of alleged sham petitions. Another possible policy would be to create **a rebuttable presumption** in **antitrust** disputes that a petition is a sham if the FDA finds any of the claims to be **late** or **suspicious**. This rule could be especially relevant in claims that include fraudulent or misleading concerns.' Such an approach would work in concert with the pre-screening processes proposed above in Part VI.A.i.

2. Define the Court's Role

Courts can **contribute** by **clarifying** the second step of the **P**rofessional **R**eal **E**state test, which looks at the subjective intent of the filer. The Professional Real Estate standard has been the subject of scholarly debate,26' and critics argue that the second prong is redundant and should be eliminated.62 The argument is that the subjective prong arose out of early cases discussing the sham exception in a legislative setting and was then folded into the general test for the sham exception. It is arguably redundant because if a claim is objectively baseless, then the act of filing a lawsuit or citizen petition already demonstrates a lack of good faith and improper purpose64 Until the courts can **manifest** a **clear** standard, **judicial guidance could lead to better regulation of sham petitions**. Similar to the FDA's rebuttable presumption proposed in Part VI.B.i, courts could develop a standard imposing strict liability on sham petitioners. For example, any citizen petition that fails to convince the FDA that it contains any scientifically valid arguments could be deemed a per se sham. **This rule would remove the courts from making actual determinations** as to the technical details contained in the petitions. **Incentives** like this will encourage petitioners to **back up** their submissions with **valid scientific** data, or not file them at all.

**1AC—Patent Federalism**

**Advantage 2 is Patent Federalism**

**The strictness of Noerr-Pennington has created a rigid patent system that has an overly expansive definition of free speech. The plan returns the courts to the previous standard of good faith, striking the right balance**

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

In recent years, a small number of patent holders, often called “bottom feeder” patent trolls, have been abusing the U.S. patent system. These **patent holders blanket the country** **with thousands of letters** demanding that the recipients purchase a license for a few thousand dollars or else face an infringement suit. The letters are usually sent to small businesses and nonprofits that do not have the resources to defend against claims of patent infringement. And the letters often contain false or misleading statements designed to scare the recipient into purchasing a license without investigating the merits of the allegations. In response to this troubling behavior, legislatures in over thirty states have enacted statutes that outlaw assertions of patent infringement that are deceptive, false, or made in bad faith. **These statutes, however, may be unconstitutiona**l. The U.S. Court of Appeals for the Federal Circuit, which **has exclusive jurisdiction over appeals** **in** **patent** cases, has held that patent holders are immune from civil claims challenging acts of patent enforcement unless the patent holder knew its infringement allegations were objectively baseless. **This rule provides patent holders with nearly complete immunity from liability under the new statutes**. In fact, the rule has already immunized two notorious bottom feeders, Innovatio IP Ventures and MPHJ Technology Investments, from liability under state consumer protection and deceptive trade practices laws. Although the Federal Circuit has sometimes called the immunity afforded to patent holders a matter of the federal Patent Act’s “preemption” of state law, the court’s immunity doctrine also appears to limit the ability of the federal government to regulate patent enforcement behavior. This is because the Federal Circuit’s decisions are not grounded in the Constitution’s Supremacy Clause, which is the usual source of preemption doctrine, but in the First Amendment right to petition the government. Unlike the Supremacy Clause**, the First Amendment restricts the power of the federal government, not just state governments**. Accordingly, the Federal Circuit’s immunity doctrine also limits the ability of the **F**ederal **T**rade **C**ommission to bring unfair competition proceedings against patent trolls **and may thwart Congress’s efforts to outlaw** false or **misleading statements** made in patent demand letters. This chapter makes two main arguments. First, the Federal Circuit’s immunity doctrine is wrong as a matter of law, policy, and historical practice. Until the Federal Circuit adopted its “objective baselessness” requirement, **courts had, for nearly a century**, held that patent **enforcement conduct could be declared unlawful if it was simply “in bad faith.”** That flexible, equity-based immunity **standard struck an appropriate balance** between the goals of punishing extortionate schemes of patent enforcement and respecting patent holders’ rights to make legitimate allegations of infringement**. But the Federal Circuit has abandoned** **that standard** in the misguided belief that letters between private parties, such as demand letters sent by patent holders to alleged infringers, are protected by the First Amendment right to petition the government. **If the Federal Circuit reversed course in future cases**, both state governments and the federal government would be able to regulate letters that use deceptive or false statements to intimidate recipients into purchasing a license, even if the infringement allegations in the letters are not objectively baseless. **Second, state governments and the federal government should share responsibility for regulating patent demand letters**. Although patents are usually thought to be a matter for the federal government, not the states, the states have long regulated unfair and deceptive trade practices resembling the demand letters sent by bottom-feeder trolls. State governments also offer critical enforcement resources. They are more accessible to the small businesses, nonprofits, and local governments likely to be targeted by deceptive campaigns of patent enforcement, and the quantity of enforcement actions that could be pursued by numerous states’ attorneys general likely dwarfs what the federal government could do. At the same time, federal legislation on patent demand letters would provide a uniform standard for assessing the legality of patent enforcement conduct. Federal legislation could also clarify difficult jurisdictional issues that arise in disputes over the lawfulness of patent assertions.

**Returning to good faith solves state innovation**

Paul R. **Gugliuzza 15**. Professor of Law at Temple University. Professor Gugliuzza has testified before both the U.S. Senate and the U.S. House of Representatives on the topic of patent law, and his scholarship has been cited in over a dozen judicial opinions across all levels of the state and federal courts.“Patent Trolls And Preemption” <https://www.virginialawreview.org/wp-content/uploads/2020/12/Gugliuzza_Online.pdf>

V. RETHINKING PETITIONING IMMUNITY IN PATENT CASES Although state governments and the federal government are increasingly interested in regulating patent enforcement, **the Federal Circuit has left them powerless**. Yet the court has offered no persuasive justification for extending the broad antitrust immunity conferred by Noerr to all civil claims challenging patent enforcement conduct. Accordingly, the Federal Circuit en banc or the Supreme Court should **force a return to a narrower, more flexible immunity standard** that accommodates the courts’ historical practice of condemning unfair and deceptive acts of patent enforcement. A. Returning to Good Faith Some scholars have argued that Noerr should never protect litigation conduct as petitioning activity. 355 They contend that Noerr immunity should be limited to its original context of petitions directed toward the legislative and executive branches. Under that view, the Supreme Court erred in cases such as California Motor Transport and Professional Real Estate Inventors, which immunized defendants from antitrust claims based on the pursuit of litigation. If that position is correct, then the Federal Circuit is almost certainly wrong in applying Noerr to claims that seek to impose civil liability based on patent enforcement activity. If documents that are actually filed in court are not protected by Noerr, then surely patent demand letters, which are ostensibly a precursor to the filing of litigation, should likewise not be entitled to Noerr immunity. But even if Noerr does protect litigation or litigation-related conduct as petitioning activity, there is, as discussed above, a reasonable argument that defendants should not be able to invoke Noerr as a defense against claims not grounded in antitrust.356 The holding in Noerr was “a construction of the Sherman Act” adopted to avoid “important . . . questions” about the right to petition, informed by the Sherman Act’s purpose to regulate “business activity,” not “political activity.”357 Most civil claims challenging patent enforcement are not asserted under the antitrust laws, however. And the purpose behind laws on wrongful civil proceedings and abuse of process—unlike antitrust law—is plainly to regulate litigation conduct. Likewise, laws governing unfair competition are designed to ensure the accuracy of information in the marketplace,358 and so are plausibly aimed at eliminating false or deceptive allegations of patent infringement that influence the market. Disparagement claims similarly target false statements intended to cause pecuniary harm,359 so it is conceivable that false allegations of patent infringement come within the purpose of that tort. And the intent of the new state patent assertion statutes is obviously to regulate litigationrelated conduct. Thus, the statutory justification for Noerr immunity, that is, that regulation of litigation conduct is outside the purpose of the Sherman Act, is absent in the context of many civil claims used to challenge patent enforcement, leaving defendants reliant solely on the First Amendment rights to petition and to free speech. Case law under those constitutional provisions—unlike the Noerr doctrine—permits courts and legislatures to condemn false and deceptive statements,360 even if those statements are attached to plausible legal claims.361 When it comes to claims based on statements made in pre-litigation communications, such as demand letters, the case for conferring Noerr immunity is even weaker. The basic reasoning for extending Noerr to pre-litigation communications has been clearly articulated by the Fifth Circuit: Given that petitioning immunity protects . . . litigation, it would be absurd to hold that it does not protect those acts reasonably and normally attendant upon effective litigation. The litigator should not be protected only when he strikes without warning. If litigation is in good faith, a token of that sincerity is a warning that it will be commenced and a possible effort to compromise the dispute.362 Although pre-filing communications make it possible to resolve a dispute without calling on the public resources of the courts, there are reasons to pause before extending Noerr immunity to all pre-litigation communications. To begin with, there is the constitutional text. Assuming that Noerr immunity is based on the First Amendment, as the Federal Circuit has indicated,363 it is absurd to say that a letter between private parties is a “petition” to “the government” within the meaning of the Petition Clause.364 The Tenth Circuit, in a decision that represents a minority view, has held that “[a] letter from one private party to another private party simply does not implicate the right to petition.”365 But ignoring the constitutional text is usually justified based on the policy argument, embraced by the Fifth Circuit in the passage quoted above, that immunizing threats to sue encourages out-of-court settlement, saving the courts’ time and effort.366 If, however, the sender is using the threat itself to extract a payment and has no intention to actually file suit, then it is not clear that the threat should be protected.367 Similarly, even if the infringement allegations made in a demand letter are considered to constitute petitioning activity protected by the First Amendment, ancillary statements that have nothing to do with the infringement claim seem less worthy of immunity, particularly when those ancillary statements are false or misleading or are designed to induce the recipient to purchase a license without retain ing an attorney to investigate the infringement allegations.368 Punishing patent holders who send those types of letters will not discourage or inhibit patent holders who make assertions of patent infringement in a legitimate attempt to avoid going to court. **This is not to say that patent holders should have no leeway when making infringement allegations.** Indeed**, the law should protect patent holders who make plausible but unsuccessful allegations of infringement**, so long as the allegations are made in a way that is neither unfair nor deceptive. Fortunately, those goals can be attained without granting patent holders the **broad immunity** that Noerr confers on antitrust defendants. Rather, **courts can and should return to** first principles: **the flexible, equitable good faith standard** to which the Federal Circuit’s current immunity doctrine traces its roots. As discussed, pre-Federal Circuit decisions allowed patent holders to make legitimate assertions of patent infringement while also permitting injunctions against patent holders based on their bad faith. **That bad faith standard included both subjective considerations** (such as the patent holder’s lack of intent to file a threatened infringement suit) **and objective considerations** (such as the weakness of the infringement claim on the merits). **Returning to this flexible standard would allow governments**, both state and federal, **to condemn the assertions of infringement that are most troublesome**. For example, a patent holder who threatens numerous end users with an infringement suit, with no intent to actually file suit, could be subjected to civil liability. An illustrative pre-Federal Circuit case is Adriance, Platt & Co. v. National Harrow Co., in which the patent holder sent letters to the plaintiff’s customers, claiming that it would “sue all dealers” who purchased the allegedly infringing goods manufactured by the plaintiff and that it was “constantly bringing suits wherever these dealers are found” when, in fact, it had never actually filed an infringement suit.369 The Second Circuit enjoined the patent holder from sending additional letters, noting that the previous letters “were inspired by a purpose to intimidate the [plaintiff’s] customers, and [to] coerce the [plaintiff], by injuring its business, into becoming a licensee of the defendant.”370 “In view of its failure to bring an infringement action,” the court wrote, “the defendant cannot shelter itself behind the theory that its circulars and letters were merely legitimate notices of its rights.”371 Similarly, a patent holder who makes allegations of infringement without having investigated the supposed acts of infringement—as is almost certainly the case when a patent holder sends letters to thousands of alleged infringers—would not be entitled to immunity under the traditional bad faith standard. As the Federal Circuit noted in Mallinckrodt, under that standard, courts had enjoined infringement notices “when the patentee sent notices indiscriminately to all members of the trade.”372 **In more recent cases**, however, the Federal Circuit has prohibited plaintiffs from relying on the patent holder’s lack of investigation into the alleged infringement to prove bad faith.373 Furthermore, a return to the traditional standard would free courts from the Noerr-based principle, embraced in Innovatio and Activision, that any false statement must relate to the issues of validity or infringement to strip a patent holder of immunity. Pre-Federal Circuit decisions, for example, condemned patent holders who circulated notices that “falsely stated and pretended that certain patents owned by the [patent holder] ha[d] been adjudicated and sustained in contested cases.”374 **This change in the law would enable** private **plaintiffs and government law enforcers**, such as the FTC and state attorneys general, **to impose civil liability on unscrupulous patent holders without** having to take the difficult additional step of **disproving** **the merits of the underlying infringement claim.**

**Innovation now is a sham! Narrowing immunity is essential to patent federalism. Dynamic IP innovation requires a state experimentation in a cooperative regulatory regime**

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

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

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

A. The Flawed Federal Patent System

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

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

1. THE PATENT-QUALITY CRITIQUE

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

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

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

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

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

2. THE PATENT-TROLL CRITIQUE

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

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

Moreover, there are reasons to think that trolls can be socially beneficial. The troll label applies when a patent holder does not practice the claimed invention, but there is no reason to expect those who are good at inventing new technologies to also be good at commercializing those technologies. Just as specialization in the broader economy leads to gains from trade, patent trolls may efficiently separate invention from commercialization. Universities are the classic example: universities are very good at inventing new technologies, but they lack the expertise in operations, manufacturing, sales, and management to build those technologies into viable businesses. So they routinely license their intellectual property to others to commercialize, and they routinely assert those intellectual-property rights against nonlicensees. 99 And the same story can be told about other non-practicing entities. When an inventor develops a new technology but fails to commercialize it, she may nevertheless have created significant potential value—value that may be realized when others succeed in commercializing the invention.100

3. THE NUISANCE-LITIGATION CRITIQUE

A variant of the patent-troll critique focuses on the most problematic troll behavior: bringing nuisance litigation that is designed to exploit litigation costs and asymmetric bargaining power to extract nuisance settlements.

As I have discussed in previous work, a combination of features of the patent system encourages applicants to seek patents even when their primary value is nuisance value.101 Patent litigation is extraordinarily expensive—defending a case can cost hundreds of thousands or millions of dollars even in relatively simple cases.102 And because much of this cost comes from discovery, which can include wide-ranging discovery both into the technical details of the defendant’s products (for the merits of the patent case) and into the defendant’s sales, profitability, and licensing practices (for damages), it usually cannot be avoided through dismissal or summary judgment.103 So almost any patent lawsuit— including even a nakedly unmeritorious suit—has a nuisance settlement value in the tens or hundreds of thousands of dollars; even such a settlement would cost far less than litigating the case.104 At the same time, in general, it can cost $20,000 to $30,000 to prosecute a patent application, far less than the nuisance settlement value of a typical patent.105 So it is worth getting even a low-quality patent, and given the quality problems discussed in the last subsection, it is readily possible to do so.106

Empirical evidence suggests that nuisance litigation plays a role in the patent system, though it is hard to tell how significant that role is. One indicator that nuisance suits may represent a large fraction of patent cases is the number of cases that settle quickly, within 180 days of filing. Between 2000 and 2013, 33.3% of the 43,166 patent lawsuits filed were terminated in PACER within 180 days of filing.107 This is notable because six months is practically instantaneous in the time scale of high-stakes commercial litigation; patent cases that are resolved on the merits typically take two, three, or more years just to be resolved in the district court. So these quickly resolved cases generally represent settlements, walk-away agreements, or unilateral dismissals by plaintiffs. And the more quickly a case is settled, the more likely it is to be a nuisance settlement, since settlements that occur before significant discovery has taken place are more likely designed to avoid litigation costs and since the parties are less likely before discovery to have enough information to evaluate the merits of the case. The more cases that settle quickly, then, the more we should expect to see nuisance cases.

Another indicator of the role that nuisance suits play in the patent system comes from surveys of frequent patent defendants. For instance, RPX Corp., a firm that buys patents to prevent them from being asserted against corporate clients, has found in surveys of its clients that more than half of lawsuits brought by non-practicing entities were settled within six months.108 And in another RPX study, this one of patent settlements, the firm found that attorney fees and litigation costs exceeded settlement payments in all but the most expensive category of cases.109

4. THE END-USER-LITIGATION CRITIQUE

A related critique that has recently been made of the patent system is that **it is too easy for patent holders to sue end users** of a product rather than the company that makes and sells the product. Under American patent law, a patent holder has the choice of whom to sue, since making, using, selling, offering to sell, and importing a patent invention all constitute infringement.110 In the scanner-troll cases, for instance, the patent holders could have targeted the companies that made the scanners, or the stores that sold them; instead, they targeted the small businesses that used them to scan documents.111 As a matter of doctrine, there is nothing wrong with this; if the scanners embodied a patented invention, then using them is just as infringing as making and selling them would be.112

Even though it is perfectly legal, we should still be wary of enduser patent litigation because it should be less efficient than pursuing upstream manufacturers and sellers. If a patent holder has to sue thousands of small businesses that use networked scanners, for instance, that requires wasteful duplication of demand letters, complaint drafting, filing fees, and so forth. When a patent holder nevertheless elects to sue end users, we should ask why it is voluntarily taking on higher costs. And the likely answer is not good: suing end users suggests that the patent holder relies less on the underlying merits of the claim and more on asymmetric bargaining power to extract settlements. If the legal merits of the claim were strong, then a patent holder should be able to get the same damages suing the manufacturer as suing end users, since the usual measures of patent damages, lost profits and a reasonable royalty, generally scale linearly with the number of units sold.113 But if the goal is to use the threat of attorney fees to extract an early settlement, then measures that drive up those fees—like suing end users—work to a patent holder’s advantage. So does targeting defendants, like small businesses, who are more sensitive to those fees.114 And end-user defendants are likely to be easier targets for weak claims because they are often one-time players in the patent game and have less technical knowledge of the accused products or the asserted patents, and so are less equipped to defend suits on the merits.115

B. The Corresponding Benefits of State Anti-Patent Laws

Several of the state anti-patent laws that have been enacted are well tailored to address some of these critiques of the federal patent system. In particular, the laws may address portions of the patent-quality critique and are quite well suited to addressing the nuisance-litigation and end-user-litigation critiques. They are more poorly suited, however, to addressing the patent-troll critique, to the extent patent trolls are a problem independent of the other critiques.

First, the state laws help respond to the patent-quality critique by making it harder to enforce low-quality patents. They do this in several ways. Some state laws specifically consider the quality of the patent. The Vermont law, for instance, asks whether “[t]he claim or assertion of patent infringement is meritless, and the person knew, or should have known, that the claim or assertion is meritless”116 and whether the patent holder “offers to license the patent for an amount that is not based on a reasonable estimate of the value of the license.”117 If so, that weighs in favor of a bad-faith finding. State laws can also impose due diligence requirements that are hard to satisfy with a low-quality patent.

Vermont again, for instance, asks whether the patent holder “fails to conduct an analysis comparing the claims in the patent to the target’s products, services, and technology,” or when such an analysis was done, whether it “does not identify specific areas in which the products, services, and technology are covered by the claims in the patent.”118 It is difficult to provide a good-faith analysis of conduct infringing a lowquality patent. And state laws can ban false threats to sue, as Illinois has done; this has a disproportionate impact on low-quality patents, since patent holders who realize that their patents are vulnerable are much less likely to follow through on litigation threats.119

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

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

State anti-patent laws are well suited to combatting these end-user and nuisance-litigation strategies. The scanner-troll cases that inspired states to get involved were classic end-user cases, for instance, brought against small businesses that had no role in designing or producing the allegedly infringing products. The state laws would make it significantly harder to bring such cases, since they would disproportionately raise the cost of bringing end-user cases. This is so because the pre-suit requirements imposed by the state laws impose costs—of investigating the defendant’s infringing activity, preparing infringement allegations, and so forth—that are essentially fixed per case. But end-user cases are likely to be smaller in scale, so these costs reflect a greater portion of the overall burden of bringing a patent case. If the scanner trolls had to satisfy the pre-suit requirements for each of their 16,000 end-user lawsuits, that would impose a much greater burden than if they sued a half dozen scanner manufacturers. So the state laws would make end-user litigation harder without formally targeting those cases. At the same time, state anti-patent laws only do so much to combat end-user litigation; they cannot ban it outright, or impose additional requirements on it, **without clearly conflicting with federal law**.

Nuisance litigation is similarly targeted. Because the settlement pressure of a nuisance suit is driven by litigation costs, a nuisance case can be brought without regard to the underlying merits, so long as the complaint can pass muster under Rule 11. So a nuisance plaintiff has no need to carefully analyze the defendant’s products, develop claim charts, or perform other extensive pre-litigation investigation. But failure to perform such an investigation is precisely the conduct targeted by most states. Vermont’s law, for instance, considers whether a patent holder identifies “factual allegations concerning the specific areas in which the target’s products, services, and technology infringe the patent or are covered by the claims in the patent,”122 or has “conduct[ed] an analysis comparing the claims in the patent to the target’s products, services, and technology.”123 Other laws target failure to inform a defendant of specific infringement allegations—which is only possible with a pre-suit investigation. So to the extent state antipatent laws have any effect on litigants’ behavior, they should affect the behavior of plaintiffs bringing nuisance cases. State anti-patent laws, then, are well suited to targeting the two **most troubling kinds of patent litigation**—the ones designed to extract undeserved settlements, not to enforce legitimate patent rights.

**Increasing patent validity solves every existential risk**

**Rando 16** (Robert J. Rando, Founder and Lead Counsel of The Rando Law Firm P.C., Fellow of the Academy of Court-Appointed Masters, Treasurer for the New York Intellectual Property Law Association, Chair of the Federal Bar Association Intellectual Property Law Section, “America’s Need For Strong, Stable and Sound Intellectual Property Protection and Policies: Why It Really Matters”, IP Insight, June 2016, p. 12-14 [language modified] [abbreviations in brackets])

Robert F. Kennedy’s speech, which includes his reference to the oft-quoted “interesting times” curse, applies throughout history in many contexts and, indeed, with both negative and positive connotation. While he focused on the struggles for freedom and social justice, the requisite ascendancy of the individual over the state, and the institution and integration of those ideals for the greater good, he also promoted the goals of **greater global unity, cooperation and communication**, which were, and could be, achieved by advances in **tech**nology. And, as noted in the excerpt, he championed “the creative energy of men.”

Intellectual Property in “Interesting Times”

It is beyond question that starting with the last decade of the twentieth century and throughout the first two decades of the twenty-first century, when it comes to matters relating to intellectual property, we have been living in “interesting times.” Some may interpret these interesting times as defined by the curse and others may view it by the ordinary meaning of “interesting.” In either case, those of us that toil in the fields of patents, copyrights, trademarks, trade secrets, and privacy rights have experienced an unprecedented sea change in the way those rights are procured, protected and enforced. Likewise, and perhaps more importantly, even those of us that do not practice in these areas of law, as well as the general public, have been, and continue to be, impacted by the consequences of these changes (both positive and negative).

The Changes In Intellectual Property Law

Examples of some of the changes in intellectual property law are: the sweeping 2011 legislative changes to the patent laws under the America Invents Act (AIA), which impact is only beginning to be fully appreciated; the various proposals for patent law reform, on the heels of the AIA, beginning with the 113th and 114th Congress; the copyright laws Digital Millennium Copyright Act (DMCA) and numerous 114th Congressional proposed copyright law changes; the recently enacted federal trade secret law (Defend Trade Secrets Act of 2016 (DTSA))2; the impact of the internet, domain names and globalization on Trademark law; the intellectual property law harmonization requirements included in various global/regional trade agreements; and the proliferation of devices (both invasive and non-invasive) that defy any rational basis for believing we can still adhere to the republic’s libertarian understanding of the right to privacy.

Without engaging in “chicken and egg” analysis, it is sufficient to observe that **technological advancement**, **societal needs**, **globalization**, **existential threats**, **economic realities**, and **political imperatives** (or what James Madison referred to in the Federalist Papers No. 10 as factious governance), have combined to create the “interesting times” for the United States [IP] intellectual property laws.

What was said by Bobby Kennedy in 1966 remains true today. We live in dangerous and uncertain times. Many of the existential threats remain the same (**nuclear war** and proliferation, **[genocides]** ~~genocidal maniacs~~ and **natural disease**) and some are new ([hu]manmade disease, greater awareness of **environmental changes** and possibly human interrelationship factors, and the unintended consequences of **genetic manipulation** and **robotic technologies**). The danger and uncertainty that pervades changes in intellectual property laws, though not an existential threat of the same manner and kind, correlates with the threat and remains “more open to the creative energy of man than any other time in history.”

Apropos the creative energy of man, there is a non-coincidental congruence and convergence of activity across and among the three branches of government, occurring almost simultaneously with the congruence and convergence of the rapid developments of technological innovation across various scientific disciplines and the information age, reflected in the transformation of the [IP] intellectual property laws in the United States.

Patents

The passage of the AIA was a culmination of efforts spanning several years of Congressional efforts; and the product of a push by the companies at the forefront of the twenty-first century new technology business titans. The legislation brought about monumental changes in the patent law in the way that patents are procured (first inventor to file instead of first to invent) and how they are enforced (quasi-judicial challenges to patent validity through inter-party reviews at the Patent Trial and Appeals Board (PTAB)).

The 113th and 114th Congress grappled with newly proposed patent law reforms that, if enacted, may present additional tectonic shifts in the patent law. Major provisions of the proposals include: fee-shifting measures (requiring loser pays legal fees - counter to the American rule); strict detailed pleadings requirements, promulgated without the traditional Rules Enabling Act procedure, that exceed those of the Twombly/Iqbal standard applied to all other civil matters in federal courts, and the different standards applicable to patent claim interpretation in PTAB proceedings and **district court litigation** concerning patent **validity**.

The Executive and administrative branch has also been active in the patent law arena. President Obama was a strong supporter of the AIA3 and in his 2014 State Of The Union Address, essentially stated that, with respect to the proposed patent law reforms aimed at patent troll issues, we must innovate rather than litigate.4 Additionally, the USPTO has embarked upon an energetic overhaul of its operations in terms of patent quality and PTO performance in granting patents, and the PTAB has expanded to almost 250 Administrative Law Judges in concert with the AIA post-grant proceedings’ strict timetable requirements.

The Supreme Court, not to be outdone by the Articles I and II branches of the U.S. government, has raised the profile of patent cases to historical heights. From 1996 to the 2014-15 term there has been a steady increase in the number of patent cases decided by the SCOTUS5. The 2014-15 term occupied almost ten percent of the Court’s docket. Prior to the last two decades, the Supreme Court would rarely include more than one or two patent cases in a docket that was much larger than those we have become accustomed to from the Roberts’ Court6.

While the SCOTUS activity in patent cases is viewed by some as a counter-balance to the perceived Federal Circuit’s pro-patent and bright line decisions, it can just as assuredly be viewed as decisions rendered by a Court of final resort which does not function in a vacuum devoid of the social, economic and political winds of the times. In recognition of the effect new technologies have on the patent law, the politicization of intellectual property law matters, especially patent law (through factious governing principles of the political branches of the government), and the maturation of the Federal Circuit patent law jurisprudence, the SCOTUS has rendered opinions in cases that impact, and perhaps are/were intended to mitigate the concerns regarding, some of the vexing issues confronting the patent community today (e.g., non-practicing entities or in the politicized parlance “patent trolls,” the intersection of patent and antitrust laws in Hatch-Waxman so called “pay-for-delay” settlements between Branded and Generic pharma companies, and the fundamental tenets that comprise the very heart of what is patent eligible subject matter).

Copyrights

The advent and ubiquity of the internet, social media and digital technologies (MP3s, Napster, Facebook, YouTube, and Twitter) represents the impetus for changes in the Copyright laws. The DMCA addressed the issues presented by these advances or changes in the differing media and forms of artistic impressions. The proliferation of digital photos, graphic designs and publishing alternatives, as well as adherence to globalization harmonization have given rise to changes in the statutory law and jurisprudence in this area of intellectual property law. Additionally, there is an overlap of patent rights and copyrights for software driven by the ebb and flow of the strength of each respective intellectual property protection.

Notably, the Patent and Copyright Clause7, in addition to Author’s writings, has been viewed as discretely applying to two different types of creativity or innovation. When drafted the “sciences” referred not only to fields of modern scienctific inquiry but rather to all knowledge. And the “useful arts” does not refer to artistic endeavors, but rather to the work of artisans or people skilled in a manufacturing craft. Rather than result in ambiguity or confusion, perhaps the Framers were either quite prescient or, just coincidentally, these aspects of the Patent and Copyright Clause have converged.

For example, none other than the famous Crooner, Bing Crosby, benefited from both protections. Well-known as a prolific and popular recording artist he also benefited from his investments in the, then innovative, recording technologies. Similarly, the Beatles, Beach Boys, as well as many other rock and roll artists, experimental efforts in music performance, recording and production, helped to transform the music industry in both copyrightable artistic expression and patentable inventions. Similarly, film, literary and digital arts reap benefits at the crossroads of both copyright and patent protections.

Trademarks

Trademark laws have been impacted by numerous changes in the business landscape. They include the internet, Domain names, international rights in a global economy, different venues and avenues for branding, marketing and merchandising, global knock-offs from nations that have a less than stellar respect for intellectual property rights, and international trade agreements. More recently, politicization (or perhaps political correctness) has creeped into the trademark law arena pitting branding rights and protections against first amendment rights.

Trade Secrets

As with Copyright and Trademark law, trade secrets law includes some of the same issues related to trade agreements. TRIPS required members to have trade secret protection in place. Initially, the United States compliance with this requirement has relied upon the trade secret law of the individual states. That compliance may be supplanted by the recently enacted DTSA. Similarly, the Trans Pacific Partnership (TPP) trade agreement contains intellectual property rights provisions that will trigger required changes to United States statutory Intellectual Property Laws.

The proposed trade secret legislation also gives rise to several concerns. For instance, there is an absence of a specific definition for trade secret, as well as potential issues of federalism, conflict with state law precedent (despite no preemption), remedies, and the impact on employer/employee relations.

There is also a real concern that the strengthening of trade secret protection **in conjunction with the perceived weakening of patent protection** (e.g., high rate of invalidating patents in post-grant proceedings before the PTAB and strict limitations on what is patent eligible subject matter) may very-well have the unintended consequence of contravening the purpose behind the Patent and Copyright Clause: “to promote the progress of the sciences and the useful arts.” Moreover, the incentive to innovate may very well be usurped by the advantage of withholding patent law disclosure of highly beneficial scientific advancements that directly affect the human condition, alter life expectancies and the evolution of the human species (rather than by mere “natural selection”), and what is the very essence of a human being (for better or worse). Thus, crippling innovation and the progress of the sciences and useful arts.

Privacy Rights

It is increasingly more difficult to function “off the grid.” The invasive and non-invasive attributes of the internet, the reliance upon the multitude of devices, social media, and information age technologies, and access to big data, all contribute to the decrease in and dilution of the right to privacy. Wittingly or otherwise, the strong libertarian roots of the republic have been replaced by dependence upon these modes of an information-age life. Commentary on the benefits and deficits of this reality are beyond the subject and purpose of this writing. Suffice to acknowledge that the right to privacy has been significantly reduced. The laws that protect these rights are in a constant struggle to maintain those rights while yielding to the demands of the lifestyle and security concerns. Laws that relate to cybersecurity in the global and domestic space create interplay with privacy rights. Legislation, trade agreements and jurisprudence all impact this area of intellectual property. Cross-border theft of trade secrets, competitor espionage, and loss of control over personal data are all implicated in the intellectual property law arena.

America’s Need For Strong Intellectual Property Protection

The need for strong protection of intellectual property rights is greater now than it was at the dawn of our republic. Our Forefathers and the Framers of the U.S. Constitution recognized the need to secure those rights in Article 1, Section 8, Clause 8. James Madison provides insight for its significance in the Federalist Papers No. 43 (the only reference to the clause). It is contained in the first Article section dedicated to the enumerated powers of Congress. The clause recognizes the need for: uniformity of the protection of IP rights, securing those rights for the individual rather than the state; and, incentivizing innovation and creative aspirations.

Underlying this particular enumerated power of Congress is the same struggle that the Framers grappled with throughout the document for the new republic: how to promote a unified republic while protecting individual liberty. The fear of tyranny and protection of the “natural law” individual liberty is a driving theme for the Constitution and throughout the Federalist Papers. For example, in Federalist No. 10, James Madison articulated the important recognition of the “faction” impact on a democracy and a republic. In Federalist No. 51, Madison emphasized the importance of the separation of powers among the three branches of the republic. And in Federalist No. 78, Alexander Hamilton, provided his most significant essay, which described the judiciary as the weakest branch of government and sought the protection of its independence providing the underpinnings for judicial review as recognized thereafter in Marbury v. Madison.

All of these related themes are relevant to the Patent and Copyright Clause and at the center of the intellectual property protections then and now. The Federalist Papers No. 10 recognition that a faction may influence the law has been playing itself out in the halls of congress in the period of time leading up to the AIA and in connection with the current patent law reform debate. The large tech companies of the past, new tech, new patent-based financial business model entities, and pharma factions have been the drivers, proponents and opponents of certain of these efforts. To be sure, some change is inevitable, and both beneficial and necessary in an environment of rapidly changing technology where the law needs to evolve or conform to new realities. However, changes not premised upon the founding principles of the Constitution and the Patent and Copyright Clause (i.e., uniformity, secured rights for the individual, incentivizing innovation and protecting individual liberty) run afoul of the intended purpose of the constitutional guarantee.

Although the Sovereign does not benefit directly from the fruits of the innovator, enacting laws that empower the King, and enables the King to remain so, has the same effect as deprivation and diminishment of the individual’s rights and effectively confiscates them from him/her. Specifically, with respect to intellectual property rights, effecting change to the laws that do not adhere to these underlying principles, in favor of the faction that lobbies the most and the best in the quid pro quo of political gain to the governing body threatens to undermine the individual’s intellectual property rights and hinder the greatest economic driver and source of prosperity in the country.

It is also important to recognize that the social, political and economic impact of strong protections for **i**ntellectual **p**roperty **cannot be overstated**. In the social context, the incentive for disclosure and **innovation is critical**. Solutions for **sustainability** and **climate change** (whether natural, man-made or mutually/marginally intertwined) rely upon this premise. Likewise, as we are on the precipice of the ultimate convergence in technologies from the hi-tech digital world and life sciences space, capturing the ability to **cure many diseases** and fatal illnesses and providing the true promise of extended longevity in good health and well-being, that is meaningful, productive, and purposeful; this incentive **must be preserved**.

In similar fashion, advancements in **tech**nologies related to the global economy and communications will enhance the possibilities for **solutions to political and cultural conflicts that arise around the globe**. Likewise, the **U**nited **S**tates economy has always benefited when it is at the forefront of innovation and achieves prosperity from its **leadership role in technological advancements**.

Conclusion

As was the case in 1966, how we move forward today, **to solve the many problems facing our country and the broader global community** in these “interesting times,” both within and without the laws affecting intellectual property rights, **depends upon** the “creative energy of man” which must prevail. An achievable goal, dependent on **the strong, stable and sound protection of intellectual property rights**.

**Strong patent protections key to US ag**

**Moscona 21** (Jacob Moscona, Harvard University, “Flowers of Invention: Patent Protection and Productivity Growth in US Agriculture”, http://economics.mit.edu/files/18687)

Institutions that protect **i**ntellectual **p**roperty are potentially **of central importance** for economic growth and development. The role of patent protection in spurring innovation features prominently in growth theory. However, since patent regimes are endogenously determined, our understanding of the impact of patent rights on technological progress or—of perhaps greater interest—the impact of patent rights on downstream productivity and profits, is limited. This paper investigates the impact of the introduction of patent rights on technological progress and productivity by exploiting unique features of plant biology and intellectual property protection in agricultural biotechnology. A plant having imperfect flowers facilitates the development of hybrid plant varieties, which have de facto intellectual property protection even in the absence of formal patent rights. This physiological difference across crop species, combined with the extension of patent rights to crop varieties in 1985, makes it possible to estimate the causal impact of patent rights on technology development and productivity in US agriculture. I find that the introduction of patent protection led to a **substantial increase in novel variety development** in treatment relative to control crops. This was driven predominantly by an increase in private research investment, had positive spillover effects on innovation in certain non-biological crop technologies, and increased crop yields. Patent rights were thus successful at providing ex ante incentives for technology development and growth in physical productivity. Patent rights, however, can come with significant trade-offs for consumers of technology, and an increase in technological progress is a necessary but insufficient condition for downstream benefits. I show, however, that counties that were more exposed to the change in patent law due to their crop composition experienced a large increase in agricultural land values and profits. The idea that patent rights are a source of productivity growth has been challenged in recent years, both in academic writing and across other outlets. While the costs of the patent system have been extensively reported, perhaps nowhere more than in the context of biotechnology, its benefits are more challenging to observe and the counterfactual level of technology in a world without patent rights more difficult to quantify. The present study stands in contrast to claims that patent rights are inconsequential by documenting that the **extension of patent protection** to plant biotechnology led to a dramatic increase in technology development and shaped **patterns of productivity and profits across the US**. Understanding the effects of patent protection outside of a high-income, research intensive country like the US, as well as the impact of patent protection on the characteristics and diversity of new technology, which could shape the longer-run consequences of patent incentives, are important goals for future research

**Ag innovation stops nuclear war**

John **Castellaw 17**, National Security Lecturer at the University of Tennessee, Founder and CEO of Farmspace Systems LLC, Former President of the Crockett Policy Institute, Retired Lieutenant General in the United States Marine Corps, “Food Security Strategy Is Essential to Our National Security”, Agri-Pulse, 5/1/2017, https://www.agri-pulse.com/articles/9203-opinion-food-security-strategy-is-essential-to-our-national-security

The United States faces many threats to our National Security. These threats include continuing wars with extremist elements such as ISIS and potential wars with rogue state **North Korea** or regional nuclear power **Iran**. The heated economic and diplomatic competition with **Russia** and a surging **China** could spiral out of control. Concurrently, we face threats to our future security posed by growing civil strife, famine, and refugee and migration challenges which create incubators for extremist and anti-American government factions. Our response cannot be one dimensional but instead must be a nuanced and comprehensive National Security Strategy combining all elements of National Power including a Food Security Strategy.

An American Food Security Strategy is an imperative factor in reducing the multiple threats impacting our National wellbeing. Recent history has **show**n that reliable food supplies and **stable prices** produce more stable and secure countries. Conversely, food insecurity, particularly in poorer countries, can lead to **instability**, unrest, and violence.

Food insecurity drives mass migration around the world from the Middle East, to Africa, to Southeast Asia, destabilizing neighboring populations, generating conflicts, and threatening our own security by disrupting our economic, military, and diplomatic relationships. Food system **shocks** from extreme food-price volatility can be **correlate**d with protests and riots. Food price related protests toppled governments in **Haiti** and **Madagascar** in 2007 and 2008. In 2010 and in 2011, food prices and grievances related to food policy were one of the major drivers of the **Arab Spring** uprisings. Repeatedly, history has taught us that a strong agricultural sector is an unquestionable requirement for inclusive and sustainable growth, broad-based development progress, and long-term stability.

The impact can be remarkable and far reaching. Rising income, in addition to reducing the opportunities for an upsurge in extremism, leads to changes in diet, producing demand for more diverse and nutritious foods provided, in many cases, from American farmers and ranchers. Emerging markets currently purchase **20 percent of U.S. agriculture exports** and that figure is expected to **grow** as populations boom.

Moving early to ensure **stability** in strategically significant regions requires long term **planning** and a **disciplined, thoughtful strategy**. To combat current threats and work to prevent future ones, our national leadership must employ the entire spectrum of our power including diplomatic, economic, and cultural elements. The best means to prevent future chaos and the resulting instability is positive engagement addressing the causes of instability before it occurs.

This is not rocket science. We know where the instability is most likely to occur. The world population will grow by 2.5 billion people by 2050. Unfortunately, this massive population boom is projected to occur primarily in the most fragile and food insecure countries. This alarming math is not just about total numbers. Projections show that the greatest increase is in the age groups most vulnerable to extremism. There are currently 200 million people in Africa between the ages of 15 and 24, with that number expected to double in the next 30 years. Already, 60% of the unemployed in Africa are young people.

Too often these situations **deteriorate into shooting wars** requiring the deployment of our military forces. We should be continually mindful that the price we pay for committing military forces is measured in our most precious national resource, the blood of those who serve. For those who live in rural America, this has a disproportionate impact. Fully 40% of those who serve in our military come from the farms, ranches, and non-urban communities that make up only 16% of our population.

Actions taken now to increase agricultural sector jobs can provide economic opportunity and stability for those unemployed youths while helping to feed people. A recent report by the Chicago Council on Global Affairs identifies agriculture development as the core essential for providing greater food security, economic growth, and population well-being.

Our active support for food security, including agriculture development, has helped **stabilize key regions** over the past 60 years. A robust food security strategy, as a part of our overall security strategy, can mitigate the growth of terrorism, build important relationships, and support continued American economic and agricultural prosperity while materially contributing to our Nation’s and the **world’s security**.

**Clarity of the legal framework is key—solves water shortages**

**Esper 09** (Mark Esper, Executive Vice President of the U.S. Chamber of Commerce’s Global IP Center, “CLIMATE FOR INNOVATION: TECHNOLOGY AND INTELLECTUAL PROPERTY IN GLOBAL CLIMATE SOLUTIONS”, Hearing Before the Select Committee on Energy Independence and Global Warming House of Representatives, 7/29/2009, https://www.gpo.gov/fdsys/pkg/CHRG-111hhrg62451/html/CHRG-111hhrg62451.htm)

The Global IP Center and its members believe that strong **i**ntellectual **p**roperty rights are **integral** to driving the innovation and creativity necessary to create jobs, save lives, advance economic growth and development around the world, and generate **breakthrough solutions to global challenges** such as climate change.

Our Nation's Founders recognized the link between strong IP rights and innovation more than 200 years ago and explicitly gave Congress the power to protect IP rights in the constitution. As a result, America has led the world in innovation for generations.

Today, the **U**nited **S**tates IP is worth between $5 and $5.5 trillion. IP accounts for more than half of all U.S. exports, helping drive 40 percent of the **U**nited **S**tates economic growth; and, as of 2008, IP-intensive industries employed more than 18 million Americans. But beyond driving job creating and economic growth, strong IP rights have created a **secure framework for investment in research** that led to **solving some of the world's most difficult problems**, from **disease** and **famine** to **water scarcity** and **energy security**, just to name a few.

In addition to **protecting** and **incentivizing** inventors, strong IP rights are also **integral to promoting technology deployment and diffusion** by providing a **clear legal framework** by which companies can transact business.

**Water shortages go global AND nuclear**

**Wake 21** Bronwyn, Chief Editor, Nature Climate Change at Springer Nature, “Water Wars,” Nature Climate Change, vol. 11, no. 2, 2, Nature Publishing Group, 02/2021, pp. 84–84

Anthropogenic-driven changes to the hydroclimate will impact on water resources. For example, rainfall changes will affect **crop** yields and **food** production; **snow** and **ice**, which melt to feed major **river** system**s**, are at risk with warming. More than **one-sixth of the global population** rely on melt-fed river catchments, and this resource is **at risk** as climate change is likely to cause greater seasonal variability — higher winter flows, because of earlier melt, and reduced summer and autumn flows. Additionally, higher temperatures, and resultant increased biological activity, could lead to decreased water quality. All these changes could occur alongside increased **populations** and **economic development**, creating greater demand for a diminishing resource.

The potential for **water** resource **scarcity** to lead to **conflict**, particularly between **nations**, is the question Michael T. Klare of Hampshire College, Amherst, USA, considers by examining the available research. While within-country water conflicts have been considered and identified as climate change risk, international conflict has received less attention. Globally, many nations **share** river catchments, and these may not be covered by an agreed cooperative management framework. Conflict between nations over water could trigger **secondary** engagement from **additional** nations in an attempt to **resolve** the conflict.

Klare focuses on **South Asia** — where major river systems flow through a number of countries — as a significant risk. The region is **highly populated**, and the populations rely on the transboundary river systems for freshwater resources. Melt from the Himalayan glaciers feeds many of Asia’s major rivers, including the Indus, Ganges, Brahmaputra and Mekong rivers, in the dry season.

From any transboundary river system, high extraction by an **upstream** nation can result in reduced availability to **downstream** nations, with the potential for **conflict over** water **rights**. Pakistan is one example that Klare considers. It is a nation reliant on agriculture, fed by water from the Indus River, which is also used for electricity generation. The Indus originates in China with additional feeds from India, placing Pakistan as a downstream nation, with tensions previously arising over water rights.

If river flows reduce with climate change, and upstream extractions remain the same or upstream nations divert additional flow for their own benefit, there is the potential for conflict **between Pakistan and India**, as well as conflict **within Pakistan**. Syria is an example of where climate and water have contributed to domestic conflict (Weather Clim. Soc. 6, 331–340; 2014).

India and Pakistan have a history of dispute over the **Kashmir** region, and there have been threats to dam the tributaries of the Indus, which India has control over, in the past during tense periods. Both nations have **nuclear capacity**, and Klare outlines how any sign that **nuclear weapons** could fall into **hostile** parties’ **possession** (as a result of domestic conflict or coup) would invoke a **response from the US**A to prevent this outcome.

**1AC—Solvency**

**United States federal government should restrict Noerr-Pennington antitrust immunity.**

**Good faith standard is essential to clarity.**

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

By looking to history, the Federal Circuit could better balance the goals of protecting patent holders from liability when they make legitimate allegations of infringement and punishing patent holders when they employ unfair or deceptive tactics. At the time the Federal Circuit was created in 1982, **the lower federal courts had, for nearly a century, been addressing the precise question** of when a patent holder could be held liable for its enforcement conduct. **Those courts enjoined patent holders from making infringement assertions “in bad faith**” (see, e.g., Emack 1888) – precisely the behavior many of the new state statutes condemn. But **the Federal Circuit has largely ignored that long line of decisions**, instead demanding that anyone challenging patent enforcement conduct prove that the infringement allegations were objectively baseless (Gugliuzza 2015, 1624–27). Historically, the courts treated bad faith as a flexible standard with both subjective and objective components (Bicks 1977, 303–304). **Under this equity-based immunity standard – as opposed to the rigid “objective baselessness**” test mandated by the Federal Circuit – **the government could impose reasonable restrictions on patent enforcement**, enjoining enforcement campaigns when, for instance, the patent holder conducted no investigation into the alleged acts of infringement (e.g., Besser Manufacturing 1951), failed to follow its threats with actual lawsuits (e.g., Adriance, Platt 1903), or falsely claimed that a patent’s validity had previously been confirmed in court or in reexamination (e.g., A.B. Farquhar Co. 1900). At the same time, cases in which courts enjoined enforcement conduct under the bad faith standard **were usually egregious and often involved claims that were objectively weak on the merits** (e.g., Emack 1888). Accordingly, a bad faith immunity standard, as opposed to the Federal Circuit’s “objective baselessness” rule, would protect patent holders’ ability to provide legitimate notice of their patent rights while also offering the government some leeway to punish unfair or deceptive behavior.

**Immunity standard gaps undermine overall confidence in IP protections**

Paul R. **Gugliuzza 15**. Professor of Law at Temple University. Professor Gugliuzza has testified before both the U.S. Senate and the U.S. House of Representatives on the topic of patent law, and his scholarship has been cited in over a dozen judicial opinions across all levels of the state and federal courts.“Patent Trolls And Preemption” <https://www.virginialawreview.org/wp-content/uploads/2020/12/Gugliuzza_Online.pdf>

B. **Objections and Responses** One might reasonably be concerned that allowing governments more leeway to regulate assertions of patent infringement would compromise the rights of patent holders with legitimate claims. **But**, to be clear, **the cases in which courts should find bad faith are exceptional**. In the past, those cases often involved statements by patent holders that were plainly false,375 legal claims that were objectively weak on the merits,376 or both. **Thus, a good faith immunity standard would provide ample protection** **for** patent holders to provide **legitimate** notice of their patent **rights**. One might also object that state laws regulating unfair or deceptive patent enforcement are unnecessary because shake-down settlements are not particularly common. For instance, a draft complaint prepared by the FTC as part of its investigation into MPHJ claimed that, of the over 16,000 businesses that received a letter, only seventeen purchased licenses.377 If few people are in fact harmed by this activity, then it may not be worth rewriting the law. That said, MPHJ’s campaign is an extreme example because its dubious enforcement tactics were so heavily publicized, making it less likely that recipients would feel compelled to purchase a license. Many patent holders target relatively unsophisticated organizations on a smaller scale,378 and some of those patent holders actually pursue litigation in court as a source of further leverage.379 Data about patent settlements is hard to come by, in part because targets are usually not eager to publicize the fact that they have been accused of infringement or that they have paid to make the allegations go away.380 Furthermore, for patent disputes that are resolved out of court, there is no threat of judicial sanction for frivolous or abusive tactics,381 and legislative proposals to award prevailing parties their attorneys’ fees provide little help.382 **Thus, allowing governments to condemn unfair or deceptive enforcement practices fills a regulatory gap**, even if it is difficult to quantify the harm from those practices.383

**All CPs will be struck down.**

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

6.5 Conclusion Under the Federal Circuit’s current case law, **no government body – state or federal; legislative, administrative, or judicial – will be able to meaningfully police unfair or deceptive patent enforcement**. As this chapter has shown, however, the broad immunity the Federal Circuit has conferred on patent holders provides too much leeway for manipulation and harmful tactics. **Returning to the equitable, good faith immunity standard would respect a patent holder’s right to make legitimate allegations of infringement** **while not shielding the extortionate schemes recently deployed by bottom-feeder trolls.** Under a good faith standard, both the states and the federal government could play a useful role in regulating patent assertions. **An ideal regime would allow states** (and private parties) **to capitalize on their superior enforcement capabilities**, with the federal government providing a uniform substantive standard and clarifying the vexing jurisdictional matters that arise in legal challenges to patent enforcement conduct.

**US tech innovation prevents nuclear wars**

**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 **U**nited **S**tates 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 **U**nited **S**tates and its democratic allies need to work with other major powers to develop a framework for **harness**ing emerging **tech**nology 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.

**Uncertainty exists now**

**Joseffer 4-19-21**. Daryl Joseffer. Daryl Joseffer is senior vice president and chief counsel at the U.S. Chamber Litigation Center, the litigation arm of the U.S. Chamber of Commerce. 4-19-21“Brief Of The Chamber Of Commerce Of The United States Of America As Amicus Curiae In Support Of Petitioners” <https://www.supremecourt.gov/DocketPDF/20/20-1293/176027/20210419132645500_Chamber%20of%20Commerce%20of%20the%20United%20States%20of%20America%20Amicus%20Curiae%20Brief.pdf>

C. **This Court Should Clarify The “Sham” Exception** **To The Noerr-Pennington Doctrine**. The Third Circuit’s decision is but one example of the difficulty courts have exhibited over the application of the “sham” litigation exception. Some courts, like the Third Circuit, articulate the correct standard but nonetheless err in its application. Take the Ninth Circuit. In Rickards v. Canine Eye Registration Foundation, it was alleged that a veterinary group violated the Sherman Act by engaging in a conspiracy to monopolize the market and by bringing a lawsuit which was baseless and a sham. 783 F.2d 1329, 1334 (9th Cir. 1986). Affirming that the “sham” litigation exception applied, the Ninth Circuit acknowledged that “[t]he application of the sham exception to single lawsuits may have a chilling effect on those who in good faith seek redress in the courts. The threat of treble damages may discourage the filing of meritorious claims, or preclude plaintiffs from asserting novel or cutting-edge theories of liability.” Id. However, despite its appreciation that courts “must apply the sham exception with caution,” the court nonetheless determined that the litigation before it presented the exceptional case despite “no evidence” the challenged conduct “cause[d] any cognizable [] injury.” Id. The Ninth Circuit’s reasoning evidences an appreciation that in certain contexts, such as “bet the business” litigation or attempts to advance or alter the jurisprudential landscape, “novel” or innovative does not necessarily mean “sham.” Yet, like the Third Circuit here**, the court nonetheless failed to faithfully apply these principles and mishandled the subjective intent inquiry**. As explained in the dissent, where “[t]he district court made no factual findings on the issue ... simply [holding] that the lawsuit was ‘baseless and a sham,’” Noerr Pennington immunity applies. Id. at 1336. The dissent rightly recognized that the majority opinion relied solely on “the concerted refusal to deal which showed the group’s ‘anticompetitive motivation[,]’ [b]ut the desire to harm a competitor does not make a lawsuit a sham.” Id. **Other courts have expressed dismay at the lack of clarity in the Noerr-Pennington doctrine** and the “chilling effect” on the exercise of First Amendment rights. See Mercatus Group, LLC v. Lake Forest Hosp., 641 F.3d 834, 846 (7th Cir. 2011). As the Court in Mercatus observed, “the greater the uncertainty, the more likely that laypeople will hesitate to seek redress, out of fear that their petitioning activity will subject them to legal liability.” Id.; see also Puerto Rico Tel. Co., Inc. v. San Juan Cable LLC, 874 F.3d 767, 771 (1st Cir. 2017) (“We find ourselves quite skeptical of the notion that a defendant’s willingness to file frivolous cases may render it liable for filing a series of only objectively reasonable cases.”). **Even the FTC itself acknowledged the lack of clarity** around the sham exception in a 2006 report: “[w]hat is not clear, however, are the exact boundaries of Noerr[-Pennington’s] protection ... and neither the Supreme Court case law nor federal appellate decisions provide a firm guide.”5 The FTC issued this 2006 report to “attempt[] to interpret the doctrine,” and provide “the viewpoint of FTC staff, who have grappled with these issues when faced with anticompetitive conduct in the form of communications with the government.” Id. **In light of lower courts’ and the FTC’s difficulty in interpreting and uniformly applying the “sham” exception, this Court’s intervention is necessary not only to correct the Third Circuit’s error, but also to clarify the boundaries of the First Amendment rights protected by Noerr-Pennington immunity**.

**Plan is net-better for enforcement---**

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

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

**We’ve been trying to do this for years**

**Harkrider 18** (John D. Harkrider is a partner at Axinn, Veltrop & Harkrider LLP, Antitrust in theTrump Administration: A Tough Enforcer That Believes in Limited Government,” Antitrust, Vol. 32, No. 3, Summer 2018, https://nysba.org/NYSBA/Meetings%20Department/2019%20Annual%20Meeting/Coursebooks/Antitrust%20Section/Panel%202%20Summer18-Harkrider%C2%A9.pdf)

**Noerr-Pennington**

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

## 2AC

**2AC – T Private**

#### ‘Private sector’ means parts of the economy not controlled by government---thanks michigan

**Gale ’18** [Gale Encyclopedia of U.S. Economic History; May 17; Online encyclopedia offering comprehensive coverage of American economic history; Gale Encyclopedia, “Private Sector,” <https://www.encyclopedia.com/social-sciences-and-law/economics-business-and-labor/economics-terms-and-concepts/private-sector>]

The **private sector** is the **part** of a country’s **econ**omy that is **not controlled directly** by the **government**; it is a term that combines households and businesses in the economy into a single group. The resources of production owned by the private sector are owned in the form of private property. The private sector includes entities such as households and individuals, for-profit enterprises, sole traders, partnerships, corporations, **nonprofit**-making **org**anization**s**, charities, and **n**ongovernmental or**g**anizatio**ns** (NGOs). Private sector is **contrasted** with **public sector**, which is a comparable term for the **governmental** sector. In 2004 the private sector share of gross domestic product (GDP) in current prices in countries of the Organisation of Economic Co-operation and Development was: Australia 85.85 percent, Canada 87.72 percent, Finland 81.48 percent, France 80.73 percent, Germany 85.32 percent, Greece 87.54 percent, Italy 85.68 percent, Japan 84.38 percent, Norway 82.31 percent, Sweden 78.17 percent, the United Kingdom 83.65 percent, and the United States 89.46 percent. In contrast, in developing countries and transition economies the 2004 private sector share of GDP in current prices was lower: the Bahamas 73.29 percent, Botswana 70.50 percent, the Democratic Republic of Congo 69.07 percent, Nicaragua 76.61 percent, South Africa 75.92 percent, Bulgaria 70.36 percent, Croatia 75.36 percent, the Czech Republic 71.98 percent, Georgia 51.44 percent, and the Slovak Republic 75.69 percent (Heston, Summers, and Aten 2006). Dani Rodrik (2000) argues that the reason for the private sector’s low share in developing countries is due to the fact that for governments in low-income countries, creating additional public-sector jobs is administratively easier than establishing an unemployment insurance scheme or subsidizing job security in the private sector.

The distinction between private sector and public sector reflects the two alternative methods of solving the allocation of resources in an economy: markets or government. Markets utilize private ownership of resources—thus the term private sector—for voluntary allocation decisions. In contrast to the public sector, the private sector—with the exception of nonprofit-making organizations, charities, and nongovernmental organizations—mainly searches for profit opportunities. Private companies and organizations produce goods and services in response to supply-and-demand forces in the market, with the final goal of making a profit for the owners and shareholders of the private enterprise.

The private sector plays a key role in accelerating economic growth in market capitalist economies. The private sector is the foundation of the market capitalist economic system. Without the private sector the capitalist market cannot exist, and vice versa. For example, the development of the private sector in transition economies was vital, and the final goal of transition was associated with the private sector being converted into the dominant sector in the economy. In all industrialized or advanced capitalist economies, the absolute and relative size of the private sector is very high. Hence, in a capitalist market economy the private sector is mostly responsible for most of the country’s investments, for the generation of new job opportunities, and for the improvement of standards of living, and it is the source of most technological developments.

The government in market capitalist economies undertakes the following responsibilities to promote and support the private sector:

1.       creating proper legal environment for the private sector to function, through private property rights and contract law;

2.       introducing customs and tax laws that should encourage private investment;

3.       often providing basic infrastructure produced by public enterprises such as water, power, land, transport and communication services, and other necessities;

4.       initiating macroeconomic policies and expenditure to increase the demand for the private sector produced goods.

The private sector increases into two ways: through privatization of state-owned enterprises (SOEs) and through the creation and establishment of new firms. In this way, the share of the private sector in the economy grows. Privatization represents the transfer of state-owned assets to private ownership, alongside the creation and fostering of private businesses. Privatization is an alternative way of distributing and choosing the means of generating wealth (Marangos 2004). Consequently, it also may be considered a distribution of political and economic power in the economy. The increase of the private sector further implies the abandonment of government control over economic activity, as well as the abandonment of state monopoly in certain sectors. However, as the private sector increases, both income and wealth inequality increase, and intergenerational mobility decreases:

It is true, however, that America was once a place of substantial intergenerational mobility: Sons often did much better than their fathers.... [However,] over the past generation upward mobility has fallen drastically. Very few children of the lower class are making their way to even moderate affluence.... In modern America, it seems, you’re quite likely to stay in the social and economic class into which you were born. (Krugman 2004)

Supporters of the private sector mistrust government-initiated economic activities because they believe that the private sector is both efficient and enterprising. This further increases efficiency because of the increase in macroeconomic productivity due to the adoption of new technology. Critics of the private sector argue that the private sector does not produce public goods, that it creates private monopolies, enhances income and wealth inequality, and discourages intergenerational mobility. Public goods are commodities where the exclusion principle breaks down, and they are nonrivalrous. Such goods include, for example, lighthouses, national defense, police, fire brigades, and traffic lights. In nearly all industrialized or advanced market-capitalist economies, public goods are provided by the government and funded through the collection of state revenues.

Private Sector

Private individuals and organizations in the United States generate most economic activity involving the production of goods and services. Independent ownership and control define the private sector. Independently owned firms, ranging from large corporations to single individuals within a household, manage their privately owned capital resources to make a profit. Examples include all Fortune 500 corporations such as General Motors and IBM, the local flower shop and a small retail clothing store, the vineyard owner and peanut farmer, the consultant working from a home office and the neighborhood babysitter. Also included in the **private sector** are **non-profit organizations** including private colleges and universities and the Catholic **Church**. In **contrast**, the public sector includes all governmental activities and local, state, and federal government employees such as postal workers and public school teachers.

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**2AC – T Per Se**

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

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

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

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

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

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

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

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

**2AC – Intrastate CP**

**The counterplan hands the keys to the first amendment to the states – that destrosy patent ceteranty**

**Hrdy 18** (Camilla A. Hrdy, Assistant Professor, University of Akron School of Law, THE REEMERGENCE OF STATE ANTI-PATENT LAW, 89 U. Colo. L. Rev. 133, y2k)

Following the **Federal Circuit's** lead, courts **currently** rely on either implied conflict preemption analysis 381 or on the Federal Circuit's **expansive interpretation** of the **First Amendment Petitioning Immunity Doctrine**. 382 There are several reasons to prefer the historic approach.

1. Rooted in History and Relevant Supreme Court Precedent

First, the historic approach is not only rooted in history, but in accordance with Supreme Court precedent. This cannot be said for implied conflict preemption, which comes from Supreme Court case law addressing state patent-like rights, not state anti-patent laws. As explained in the prior section, these two fields of law are distinct and should not be assessed using the same preemption standard. 383 Nor can it be said for Petitioning Immunity, which is imported from case law involving federal antitrust liability. No Supreme Court case has said that the Petition Clause should apply to state laws that regulate patents, or that the Petition Clause represents a particularly high level of immunity for patentees.

[\*211]

2. Recognizes a Constitutional, as Opposed to Merely a Statutory, Barrier to State Anti-Patent Laws

Second, implied conflict preemption analysis wrongly assumes that congressional intent to preempt a state anti-patent law is required. Congress's implied intention to preempt a state anti-patent law is not required. Rather, the mandate to preempt a local law that interferes with the patentee's exclusive right comes from the Intellectual Property Clause itself. 384 The historical Intellectual Property Clause analysis recognizes that the true limit to state authority to pass anti-patent laws is the Intellectual Property Clause.

3. Preserves a Slice of State Authority to Regulate Patents

Third, the Intellectual Property Clause analysis preserves a not-insignificant slice of state authority to regulate patent assertions and other activity involving patents. So long as the state anti-patent law does not impose an "unreasonable" burden on the patentee's exclusive right, it is not preempted. In Allen, the Court found a registration statute that sought to ensure patents were genuine (not expired or revoked) was not unreasonable. Several other state regulations can avoid preemption under this reasonableness standard, so long as they survive the balancing test described above, i.e., the burden on the patentee does not outweigh the state's valid interest in passing the law.

The reasonableness assessment thus avoids one of the major problems with the Federal Circuit's utilization of First Amendment Petition Clause Immunity to address state restrictions on patentees' ability to enforce their patents: the standard is arguably overly strict and weighs in favor of preemption in most conceivable cases. 385 As discussed above, one of the problems may be that it is simply too difficult to determine whether a patent assertion is "objectively baseless" or not, especially before litigation commences. Thus, the safe route may simply be to lean towards finding the patentee was [\*212] not wrong to bring a potentially meritorious claim.

Notably, the Petitioning Immunity analysis is not the only place we see the courts erring on the side of preemption. When applying conflict preemption analysis, the Federal Circuit has been quite patentee-protective. For instance, in Biotechnology Industry Organization v. District of Columbia, the Federal Circuit held that a state law restricting the prices patentees could charge for their patented drugs was preempted merely because it limited the pecuniary reward patentees could make from their patents. 386 Plaintiffs urged that the District of Columbia's Prescription Drug Excessive Pricing Act, which prohibited charging "excessive" prices for patented prescription drugs, conflicted with "Congress's intention to provide [pharmaceutical patent holders] with the pecuniary reward that follows from the right to exclude granted by a patent." 387 The Federal Circuit agreed, determining that a major boon of the "right to exclude" is the "opportunity to obtain above-market profits during the patent's term." 388 "By penalizing high prices - and thus limiting the full exercise of the exclusionary power that derives from a patent" the Act conflicted with the congressional "purpose and objectives" of the patent laws. 389 "The underlying determination about the proper balance between innovators' profit and consumer access to medication, though, is exclusively one for Congress to make." 390

Such pronouncements comport with many nineteenth-century courts' views about the allocation of power between Congress and the states. 391 However, under the rule of Allen, the true test should be whether the burden on the exclusive right is one of "reasonableness." A state price restriction law that does not significantly affect patentees' incentive to invent and commercialize should not be preempted.

[\*213]

4. Asks the Right Question

Fourth, the Intellectual Property Clause standard asks precisely the right question. By balancing the burden on patentees' exclusive rights against the state's legitimate interests, such as its interest in regulating fraud, this rule directly addresses what we actually care about at a policy level: Namely, does the state law make it so difficult to enforce or profit from a patent that it effectively undermines the federal patent incentive? If the law's burden or compliance cost is high, then (as Justice Kent observed long ago) the law should be preempted because otherwise the state is essentially taking away what Congress has given through the patent. 392 If there is little or no cost to the patentee, and there is a high payoff for the state, then we should not care that the state law imposes a minimal compliance cost on patentees in order to achieve its legitimate purpose. 393 This singular focus on the burden to the patentee's Intellectual Property Clause rights contrasts with both obstacle preemption's open-ended balancing test and the Petition Clause's futile efforts to assess the merits of the patentee's cause of action prior to determining the validity of the patent and of the infringement claim. 394

5. More Practical to Apply

Fifth, the historic approach is a far more practical standard for courts to apply. As explained, purposes and objectives analysis is unwieldy and circuitous, and it wrongly relies on congressional intent to preempt. Meanwhile, the Petitioning Immunity analysis is not workable for the majority of state laws to which it is presently applied. Petitioning Immunity requires determining whether a patentee has been prevented from making an "objectively reasonable" patent assertion. 395 This is not a workable rule for adjudging patent assertions brought early in a patent dispute's lifetime. Except [\*214] in the most egregious cases, no court - state or federal - can know before at least claim construction whether a patent is valid or infringed. 396 In contrast, assessing the compliance cost of a local law on patentees is at least something that courts (even state courts) can do, and that they can do even before a patent lawsuit has been filed. As explained, courts can order parties, including private parties as well as state attorneys general who bring public actions against patentees, to collect evidence on a state law's compliance cost on patentees in order to get a sense of whether the exclusive right has been unreasonably burdened by the law.

6. Applies Only to State, Not to Federal, Regulation of Patents

Lastly, returning to the Intellectual Property Clause as the benchmark for assessing the constitutionality of state anti-patent laws avoids the issue noted by Gugliuzza, if the Federal Circuit uses an **expansive notion** of Petitioning Immunity under the First Amendment equivalently with preemption, this case law would apply to **both** state regulation of **patents** and **federal regulations**. 397 This is **highly** problematic. Historically, courts that struck down state anti-patent laws were clear that they were not prohibiting regulation of patents entirely; rather, they were holding that this regulation could only be imposed by a federal body. 398

**No net benefit – commerce clause is dead already**

**Hildabrand 14** (Clark L. Hildabrand, Assistant Solicitor General, Tennessee Attorney General's Office, Interactive Antitrust Federalism: Antitrust Enforcement in Tennessee Then and Now, 16 Transactions: TENN. J. Bus. L. 67, y2k)

On one hand, some critics of state antitrust enforcement focus on the interstate character and impact of state antitrust litigation. 28 Due to the **nationalization** and increased interconnectivity of the country's economy, a **broader** reading of the **I**nterstate **C**ommerce **C**lause and other federal antitrust laws, that at one time simply precluded state enforcement of activities with interstate effects, would, today, effectively render state antitrust laws useless.29 **However**, the U.S. Supreme Court has **consistently** held that federal antitrust laws do not **preclude** or **preempt** application of similar or **more far-reaching state antitrust statutes**.30 As long as the state law or policy in question reflects a **legitimate state public interest** and is not **excessively** discriminatory or protectionist, state antitrust enforcement does **not** run afoul of the **D**ormant **C**ommerce **C**lause. 31 State antitrust enforcement thus overcomes one potential barrier for situations in which the regulated activity has **interstate** effects

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

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

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

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

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

#### Both CPs get struck down because they both rely on state action

Paul R. **Gugliuzza 15**. Professor of Law at Temple University. Professor Gugliuzza has testified before both the U.S. Senate and the U.S. House of Representatives on the topic of patent law, and his scholarship has been cited in over a dozen judicial opinions across all levels of the state and federal courts.“Patent Trolls And Preemption” <https://www.virginialawreview.org/wp-content/uploads/2020/12/Gugliuzza_Online.pdf>

II. PREEMPTION AND PETITIONING IMMUNITY The constitutional barrier that immediately comes to mind, given the federal nature of substantive patent law, is preemption under the Supremacy Clause. Some states that have passed statutes regulating patent enforcement appear to be aware of preemption concerns. The preamble to the Vermont statute, for instance, states that the legislature “recognizes that Vermont is preempted from passing any law that conflicts with federal patent law.”130 And the Alabama statute instructs that the act “shall be interpreted consistently with any federal law or regulations governing patents or patent infringement.”131 Under Supreme Court precedent interpreting the Supremacy Clause, however, **these new statutes likely avoid preemption. Yet the Federal Circuit has treated those Supreme Court decisions**—including decisions that deal specifically with the preemptive scope of the federal Patent Act—**as mostly irrelevant when assessing the power of the states to regulate patent enforcemen**t. **Instead, the Federal Circuit has relied on the Noerr-Pennington doctrine to hold that**, **because of the Petition Clause of the First Amendment**, **states may outlaw assertions of infringement only if the patent holder made the allegations with knowledge that they were objectively baseless.**

**2AC – FDA Regs CP**

**Links to net-benefit---FDA refers anti-competitive petitions to the FTC, so the CP necessitates antitrust actions**

**Kracov 18** (Daniel A. Kracov, co-chair of the Life Sciences and Healthcare Regulatory practice, FTC Comment on FDA's Guidance on Citizen Petition Process Underscores **Antitrust** Risk, <https://www.arnoldporter.com/en/perspectives/publications/2018/12/ftc-comment-on-fdas-guidance>, y2k)

Background

In the **pharma**ceutical context, **citizen petitions** are often submitted to request that the FDA refrain from approving a **generic drug** or biosimilar application due to various legal and/or scientific issues, such as a label carve-out or bioequivalence concern.

Among other things, the FDA's October 2, 2018 Guidance provided a nonexclusive list of factors that it will consider when **assessing** such **citizen petitions**, which are detailed in our October 16, 2018 Advisory describing the FDA's Guidance.

If the FDA determines that a petitioner submitted a citizen petition with the primary purpose of delaying the approval of a generic drug or biosimilar application, it will **deny** the petition summarily and include that determination in its petition response. **In addition**, **the FDA will refer the matter to the FTC** and publicize the determination in its annual report submitted to Congress

**FDA alone can’t do it---you need antitrust!**

**Rose 19** (Professor of Law and Associate Dean for IP: Innovation, Wake Forest University School of Law, The Biosimilar Action Plan: An Effective Mechanism for Balancing Biologic Innovation and Competition in the United States? (November 18, 2019). McGeorge Law Review, Forthcoming, Wake Forest Univ. Legal Studies Paper, Available at SSRN: https://ssrn.com/abstract=3489444 or <http://dx.doi.org/10.2139/ssrn.3489444>, y2k)

**Increasing** biosimilar informational **resources** and **streamlining the FDA** application and approval process are two of BAP’s four key strategies.30 As the regulatory agency that controls the drug approval process, the FDA possesses the **direct authority** to streamline the approval process, provide greater regulation clarity, and enhance informational resources to incentivize biosimilar product development.31 The BAP is achieving these two goals as evidenced by at least sixty ongoing biosimilar development programs and the increased rate of biosimilar drug approval.32 **The FDA’s regulatory power is insufficient, however**, to implement the BAP strategy that holds **the greatest potential** for impact on **increasing patient access** to affordable biosimilars: “getting **competitively priced** biosimilars into the market by reducing the gaming of FDA requirements and other attempts to **unfairly delay competition**.”33 While the FDA has demonstrated strength in providing adaptive regulation-enhancing regulatory schemes to facilitate innovation and competition, **anti-competitive behavior** such as rebate schemes and pay-for-delay agreements are typically within the **purview** of Congress, **the courts**, and agencies such as the **F**ederal **T**rade **C**ommission (“FTC”) and the **D**epartment **o**f **J**ustice (“DOJ”).34

**First amendment overwhelms FDA regulations**

**Chen et al. 16** (Brian, 1Department of Health Services Policy and Management, Arnold School of Public Health, the University of South Carolina, Columbia, South Carolina, United States of America; Y. Tony Yang,2 Xi Cheng,1 John Bian,3 and Charles L. Bennett3 Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis, PLoS One. 2016; 11(5): e0155259. Published online 2016 May 12. doi: 10.1371/journal.pone.0155259)

**Based on the First Amendment right of citizens to** “petition the Government for a redress of grievances,” Title 21, Section 10.30 of the Code of Federal Regulations stipulates that citizens may request the Food and Drug Administration (FDA) to “issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action.”[1] These petitions have the potential to protect the public’s health. However, the citizen petition process has primarily been used by for-profit industries, often to deter competition. Historically, one fifth of these petitions have been successful [2]. Ordinary citizens or non-profit organizations can petition the FDA regarding safety issues related to drugs, devices or other items (generally food, tobacco, cosmetics or FDA regulations).

**CP independently undermines the citizen petition process itself---it wrecks public health**

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

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

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

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

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

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

II. PHARMACEUTICAL DRUG ANTITRUST LITIGATION IN THE SECOND CIRCUIT

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

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

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

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

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

B. The Second Circuit's Reasoning in Apotex

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

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

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

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

Despite the factual similarity to its own precedent, the U.S. Court of Appeals for the Second Circuit in 2016, in Apotex Inc. v. Acorda Therapeutics, Inc., dismissed a generic drug manufacturer's claim that a brand-name drug manufacturer violated U.S. antitrust law by filing a sham citizen suit to delay the FDA's approval of the generic. 75 In so deciding, the Second Circuit effectively raised the **burden of proof** for showing a **particular** citizen suit is a sham by reducing the **presumptive weight** it had previously afforded to the **timing of the FDA's decisions**.

76 After Apotex, the significance of the timing of the FDA's review of an ANDA and its disposition of a related citizen suit has been **downgraded** from sufficient to state a claim of sham litigation to **merely relevant** in that assessment. 77 Despite the fact that the Second Circuit had held that the petitioners in 2009 in In re DDAVP Direct [\*160] Purchaser Antitrust Litigation had stated a claim for sham litigation based purely on the timing of the FDA's actions, the Second Circuit in Apotex suggested that such evidence is not enough and that plaintiffs must plead additional facts that the petition is **baseless** in order to **survive a motion to dismiss**. 78

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

Generics are not only much cheaper than brand-name drugs, but each generic that enters the market puts additional downward pressure on the price of the incumbent brand-name drug. 84 The Second Circuit's ruling that [\*161] there was insufficient evidence to infer that Acorda's citizen petition was being deployed as **an anticompetitive weapon** against Apotex risks harming not only the health and viability of generic drug manufacturers like Apotex going forward, but the American public as well. 85 The Second Circuit's ruling in Apotex will hurt generic manufacturers in the **short** and **long-run**, because brand-name manufacturers, **seeing the increased degree of difficulty** facing generic manufacturers to prove **sham suits**, may choose to **follow Acorda's** lead and **file** their own **citizen suits** whenever generic manufacturers attempt to enter the market. 86 The purpose of the brand-name manufacturer's citizen suit would be to extend its exclusivity period, which would undermine generic competition in contravention of the goals of the Hatch-Waxman Act. 87 Should that reality come to pass, the public will be harmed, as they will be forced to pay for high-priced brand-name drugs longer than the law intends. 88

CONCLUSION

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

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

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

**2AC – Taxes CP**

**Has to expand the scope of antitrust – what happens**

**Bradley 84** (Lawrence D. Bradley, Cornell Law, NOERR-PENNINGTON IMMUNITY FROM ANTITRUST LIABILITY UNDER CLIPPER EXXPRESS V. ROCKY MOUNTAIN MOTOR TARIFF BUREAU, INC.: REPLACING THE SHAM EXCEPTION WITH A CONSTITUTIONAL ANALYSIS., 69 Cornell L. Rev. 1305)

Federal antitrust laws **prohibit** activity that restrains trade or reduces competition. 1 The antitrust statutes' **prohibitions** collide **with first amendment rights** 2 when the trade restaint results from petitioning the government. In Eastern Railroad Presidents Conference v. Noerr Motor freight, Inc. 3 and United Mine Workers of America v. Pennington, 4 the Supreme Court held that activity is immune from antitrust liability if the imposition of such liability would infringe upon the actor's right to petition the government. This Noerr-Pennington doctrine does not, however, protect ostensible petitioning that is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with . . . a competitor." 5

Considerable confusion has developed regarding what one party must show to establish that another party has engaged in "sham" petitioning. 6 Some courts have **automatically** awarded alleged petitioning activity **a Noerr-Pennington exemption** from **antitrust liability** and then have had to **determine** whether that activity fit into a "**sham exception**," which would make **the activity susceptible to renewed antitrust challenges**. 7 In Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 8 the Ninth Circuit replaced this "exception-to-the-exemption" analysis with a clear first amendment analysis; under the Ninth Circuit's approach, Noerr-Pennington immunity attaches only if the activity at issue is protected by the first amendment. 9

**Using taxes as a means to create a penalty is illegal!**

**Burrus 16** (Trevor Burrus, research fellow in the Cato Institute’s Center for Constitutional Studies and managing editor of the Cato Supreme Court Review, 10/28/16, “Could It Be Unconstitutional to Raise the Obamacare “Tax” for Not Purchasing Health Insurance?,” https://www.cato.org/blog/could-it-be-unconstitutional-raise-obamacare-tax-not-purchasing-health-insurance)

As many predicted, especially us at Cato, the Affordable Care Act is beginning to make health insurance less affordable for many Americans. Part of the problem, in a nutshell, is precisely what my colleague Michael Cannon described in 2009, the young and the healthy avoiding signing up for health insurance and choosing to pay the fine, or, as Chief Justice John Roberts would call it, a tax.

MIT economist Jonathan Gruber, often described as an architect Obamacare, recently said that some of these problems can be alleviated by increasing the “tax” on those without insurance. “I think probably the most important thing experts would agree is we need a larger mandate penalty,” said Gruber.

Depending on how high the penalty goes, **there could be a constitutional problem with that**. In the opinion that converted the “penalty” into a constitutional “tax,” Chief Justice Roberts described the characteristics of the “shared responsibility payment” that made it, constitutionally speaking, **a tax rather than a penalty**. One of those characteristics **is that the penalty was not too high:** “for most Americans the amount due will be far less than the price of insurance, and, by statute, it can **never be more**. It may often be a reasonable financial decision to make the payment rather than purchase insurance, **unlike the ‘prohibitory’ financial punishment in Drexel** Furniture.” In Drexel Furniture, also known as the Child Labor Tax Case, the Court struck down a 10 percent tax on the profits of employers who used child labor in certain businesses. One reason the Court struck it down was **because its “prohibitory and regulatory effect and purpose are palpable.”**

Roberts actually went out of his way to describe paying the “tax” as a voluntary and permissible act. Even though they won, this should have irked the government a bit because the Chief was essentially giving millions of people permission to not buy insurance, which the government knew would severely undermine the law. In Roberts’s words:

Neither the Act nor any other law attaches negative legal consequences to not buying health insurance, beyond requiring a payment to the IRS. The Government agrees with that reading, confirming that if someone chooses to pay rather than obtain health insurance, they have fully complied with the law.

Indeed, it is estimated that four million people each year will choose to pay the IRS rather than buy insurance. We would expect Congress to be troubled by that prospect if such conduct were unlawful. That Congress apparently regards such extensive failure to comply with the mandate as tolerable suggests that Congress did not think it was creating four million outlaws. It suggests instead that the shared responsibility payment merely imposes a tax citizens may lawfully choose to pay in lieu of buying health insurance.

So could **raising the “tax” turn it into a “penalty” and thus make it unconstitutional**? Possibly. At some point, the tax **would take on a punitive character**, and, if people like Gruber get their way, **the tax might have to be pretty stiff**. With health insurance prices going up, it can still be cheaper to pay the “tax” rather than purchase insurance. And that tax might have to go up a lot to make some people change their minds. If the government ever tries to attach criminal penalties to noncompliance, then the argument is **even stronger that it would become an unconstitutional regulation of commerce**, given that the Court held that the individual mandate isn’t a valid use of the commerce power.

**2AC – RICO CP**

**Zero net benefit, Noerr is constitutionalized now!**

Michael **Pemstein 14.** Attorney, Quinn Emanuel Urquhart & Sullivan, LLP. “The Basis For Noerr-Pennington Immunity: An Argument That Federal Antitrust Law, Not The First Amendment, Defines The Boundaries Of Noerr-Pennington” <https://heinonline.org/HOL/LandingPage?handle=hein.journals/thurlr40&div=9&id=&page=>

The second type of error that may occur is not an error in result, but an error in reasoning. If the "proper" level of protection for petitioning activity in a non-antitrust cause of action happens to be the same level that would be required by the Noerr-Pennington doctrine, then while courts may reach the correct outcome by transposing the Noerr-Pennington doctrine outside the context of antitrust law, these courts will base this result on an improper analysis. Even though this is a mistake in reasoning and not in result, there still may be consequences. For example, courts which make this mistake may be avoiding constitutional questions concerning the proper scope and application of the First Amendment right to petition when they should be addressing them. This can occur because the Noerr-Pennington doctrine is primarily based on an interpretation of federal antitrust statutes and therefore it is imbued with **statutory interpretation principles**. These principles require courts to take a cautious approach and to be hesitant to attribute an intent to infringe or chill constitutionally protected freedoms to the legislature. For example, in Noerr, the Court avoided "difficult constitutional questions" by refusing to interpret the Sherman Act as imposing antitrust liability for political activities, noting that Congress had traditionally been hesitant to regulate such activities. 62 These statutory interpretation principles, however, are not applicable in petitioning immunity cases based on common law causes of action. The common law is the sole province of the judicial branch. By imputing these statutory interpretation principles into the realm of common law, courts, like the one in Theme Promotions,are shirking their institutional responsibility to address the "difficult constitutional questions" posed by petitioning immunity suits that are based on common law causes of action.163 As a result, the right to petition, an already underdeveloped area of law, will continue to be neglected, potentially compounding these problems in future petitioning immunity cases. Another consequence to this error in reasoning is that it attributes constitutional status to levels of protection which were primarily based on non-constitutional considerations**. As a result it entirely precludes Congress from changing the levels of protection afforded to petitioning activity in areas of law governed by statute.** **Any changes to those levels of protection would have to come by way of constitutional amendment or court decision.**

**2AC – Chilling Effect DA**

**Precedent strong, but perception low**

**Brown 17** (Citing Kimi King, professor of political science at the University of North Texas Trump's Judicial Nominees Hold Considerable Influence, Professor Argues Kimi King: Keep An Eye On Lower Court Nominations https://www.wpr.org/trumps-judicial-nominees-hold-considerable-influence-professor-argues)

That’s why Kimi King says Americans should pay more attention to the president’s lower court nominations, like that of the court of appeals and federal district courts "That’s where all of the action is," King said. "Remember that the district courts set the record. They are the triers of fact. And what they determine, their initial decision, usually winds up being predictive of how the process is going to go through the appellate stage." King is a professor of political science at the University of North Texas. She said the vast majority of the time the decision at the appeals level **is the final decision** in a case because advancement to the Supreme Court is so rare. "**It is very easy to argue that the lower courts fly under the radar** and then a president will want to stay focused on those lower courts because that’s where the real decision is made," she said.

**The Third Circuit just ruled in favor of a plaintiff bringing a sham litigation lawsuit last week by conflating the two prongs of the PRE test – that overwhelmingly thumps all DA’s by going further than the affirmative but still doesn’t resolve circuit splits**

**Gidley Et Al 4-19.** “BRIEF OF AMICI CURIAE LAW PROFESSORS IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI”<https://www.kilpatricktownsend.com/-/media/2021/Brief-of-Amici-Curiae-Law-Professors-in-Support-of-Petition-for-a-Write-of-Certiorari.ashx?la=en&hash=221AE831D5329F45CA6FA9F7C265424DB96D5063>

This Court should grant the petition for a writ of certiorari and reverse the Third Circuit’s decision because it conflicts with this Court’s sham-litigation test articulated in PRE by effectively eliminating the second step of the sham litigation test: the inquiry into whether a patent owner had a subjective belief that his patent infringement suit lacked merit or was indifferent to the outcome of the suit. The Third Circuit’s novel approach—inferring subjective bad faith from a finding of objective baselessness—is at odds with PRE itself and sham-litigation jurisprudence in the other circuit courts. The petitioners address the relevant facts of this case, as well as this Court’s applicable jurisprudence. Therefore, Amici offer additional insights concerning how the **Third Circuit’s decision threatens innovators’ property rights, as well as the Congressionally created incentives** in the HatchWaxman Act, **and poses a real and serious threat to pharmaceutical innovation, a key pillar of the U.S. innovation economy**. The FTC’s urging of the Third Circuit to adopt a truncated approach to the sham-litigation test is simply another attempt by the FTC to dictate that socalled “reverse-payment” settlement agreements in the pharmaceutical industry are necessarily anticompetitive. After failing to convince this Court in Actavis to adopt a “quick-look” approach to evaluating reverse-payment settlement agreements, the FTC is now seeking to avoid having to develop actual proof of subjective bad faith on the part of a patent owner. Instead of marshalling any such evidence, the FTC seeks to rely on an inference that a finding that a patent suit was objectively baseless given a complicated patent validity issue necessarily means that the patent owner harbored a subjective belief that the suit was without merit or was indifferent to whether the suit succeeded. This truncated inquiry into subjective intent undoes the safeguard that the bad-faith inquiry serves— namely, ensuring that litigants whose suits are ultimately found to be meritless but who sincerely sought a favorable outcome are immune from antitrust liability under the Noerr-Pennington doctrine. Moreover, the Third Circuit’s novel approach to the subjective prong of the PRE test is particularly ill suited in the context of the Hatch-Waxman Act. The Third Circuit’s subjective-motivation analysis conflicts with the incentives inherent in the Hatch-Waxman regime by subjecting an innovator to antitrust liability—and accompanying treble damages—when an innovator files a patent infringement suit against an alleged infringer and automatically activates the thirty-monthstay provision designed by Congress to encourage quick resolution of patent challenges. If this Court allows the Third Circuit’s new interpretation of the subjective-motivation prong of the sham-litigation test to stand, **it will have detrimental chilling effects** on Hatch-Waxman lawsuits and settlements, both of which are encouraged by Hatch-Waxman. **In turn, the Third Circuit’s truncated version of the sham-litigation test will discourage pharmaceutical innovation and harm our innovation economy**—an acutely undesirable result in an era where the need for rapid pharmaceutical innovation is paramount. This Court should reverse the Third Circuit’s erroneous decision.

**Not even clear if it exists**

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>

5. Other Limitations of Noerr: Exceptions for Fraud Another potential limitation on Noerr immunity is a fraud or misrepresentation exception.80 Although the Court in both California Motor Transport and Allied Tube indicated in dicta that “fraud and misrepresentations made in an adjudicatory context exceeded Noerr’s reach [but] were immune in a legislative setting,” the Court reopened the issue in PRE without giving an answer as to whether an exception exists.81 Additionally, although the Court substantially narrowed the sham exception in Allied Tube, it also limited the scope of the Noerr doctrine generally by declining to extend immunity to all genuine efforts to influence government action.82 The Court held that whether Noerr immunity applies in a particular case depends on the nature, context, and impact of the activity.83 Although certain limitations on Noerr immunity exist, the Court has continued to broaden the reach of the doctrine, as seen with the narrowing of the sham exception.84 **While it is unclear whether a fraud** or misrepresentation **exception exists**, the Court has conclusively stated that there is no conspiracy exception to Noerr immunity.85 The Court has also held that the incidental effects of petitioning will be protected by Noerr immunity.86 Thus, in Allied Tube, although petitioning a private standard-setting organization was not itself covered by Noerr, the Court held that immunity might still apply if petitioning the organization was incidental to a valid effort to influence the government.87

**There is no one singular test – the aff is a both a clarification and reduction**

**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.

**Effective IP is necessary for innovation and growth**

Stuart **Graham 12**, Chief Economist at the United States Patent and Trademark Office, “Economic Espionage: A Foreign Intelligence Threat to American Jobs and Homeland Security”, 6/28/2012, http://www.commerce.gov/sites/default/files/documents/2012/july/graham062812\_0.pdf

The report recognizes that innovation—the process through which new ideas are generated and successfully introduced in the marketplace—is a **primary driver** of U.S. economic growth and national 2 competitiveness.1 U.S. companies’ use of patents, copyright, and trade secrecy to protect their creations, and trademarks to distinguish their goods and services from those of competitors represent important supports for innovation, enabling firms to capture market share, which contributes to growth in our economy. The granting and protection of intellectual property rights is vital to promoting innovation and creativity and is an essential element of our free enterprise, market-based system. Patents, trademarks, and copyrights are the principal means used to establish ownership of inventions and creative ideas in their various forms, providing a legal foundation to generate tangible benefits from innovation for companies, workers, and consumers. Without this framework, the creators of intellectual property would tend to lose the economic fruits of their own work, thereby undermining the incentives to undertake the investments necessary to develop the IP in the first place.2 Moreover, without IP protection, the inventor who had invested time and money in developing the new product or service (sunk costs) would always be at a disadvantage to the new firm that could just copy and market the product without having to recoup any sunk costs or pay the higher salaries required by those with the creative talents and skills. As a result, the benefits associated with American ingenuity would tend to more easily flow outside the **U**nited **S**tates. The report finds that IP is used everywhere in the economy, and IP rights support innovation and creativity in virtually every U.S. industry. While IP rights play a large role in generating economic growth, too little attention has been given to identifying which industries produce or use significant amounts of IP and rely most intensively on these rights. The report was written to give policy makers and the public more information about the impacts of IP protection in the U.S. economy on which to base sound policy.

**2AC – FTC DA**

**Crushing antitrust now.**

**Saigol ’1-19** [Lina; updated January 19; Head of Corporate News, B.A. from McGill University; Barrons, “Mergers Are Booming. U.S. Regulators Are Gearing Up to Crack Down on Them,” https://www.barrons.com/articles/mergers-booming-us-regulators-crackdown-51642534456?tesla=y]

**Aggressive antitrust enforcement is back**.

That is the **stark message** that President Joe Biden has **sent the business community**, and regulators have already **kicked into action**, threatening to rein in a record-setting merger boom.

Those charged with delivering Biden’s message are two Big Tech critics: Lina Khan, chair of the Federal Trade Commission, and Jonathan Kanter, head of the Justice Department’s antitrust division. On Tuesday, they outlined a plan to revise how the agencies will review mergers. They want public comment on how to update federal guidelines “to better detect and prevent illegal, anticompetitive deals,” they said in a statement.

“Our country depends on comp etition to drive progress, innovation, and prosperity,” Kanter said. “We need to understand why so many industries have too few competitors, and to think carefully about how to ensure our merger enforcement tools are fit for purpose in the modern economy.”

That is due in part because the FTC is constrained by limited manpower and budget. Also, regulators don’t have authority on their own to block a merger—federal judges can issue orders blocking it.

“Of course there has been an increased level of scrutiny and managements and boards have raised the bar on what they will consider, but we will continue to see large deals with compelling strategic imperative,” Bruce Evans, global co-head of M&A at Deutsche Bank , told Barron’s.

In **December**, the FTC sued to block computer-chip powerhouse **Nvidia** (ticker: NVDA) from spending $40 billion for British technology provider Arm, saying the blockbuster deal would unfairly stifle competition.

Just weeks earlier, the Justice Department sued to halt a proposed $2.2 billion tie-up between publishers Penguin **Random House** and **Simon & Schuster**, which would create a mega-publisher in the books market. The agency argues that consolidation would hurt authors and readers.

The **lawsuits** come after Biden signed a sweeping **executive order** in July aimed at curbing the power of **big business** by cracking down on anticompetitive practices in sectors ranging from agriculture to pharmaceuticals to labor.

Consolidation in industries over the past several decades has denied Americans the benefits of an open economy and widened racial, income, and wealth inequality, the executive order stated. The administration sees less corporate competition as one of the causes of inflation. “Higher prices and lower wages caused by lack of competition are now estimated to cost the median American household $5,000 a year,” according to the order.

Rising equity markets and widespread stimulus measures helped spur companies worldwide to clinch more than 62,000 deals worth $5.8 trillion last year, up 64% from the previous year, according to data provider Refinitiv.

Big pharmaceutical companies could be one of the biggest sectors at risk of regulatory scrutiny. The FTC put the industry on alert in July when it said it would review more deals amid skyrocketing drug prices and ongoing concerns about anticompetitive conduct.

The industry still has record levels of cash to spend and needs to merge to innovate. By the end of this year, 18 large-cap U.S. and European biopharmas will have more than $500 billion in cash on hand, according to estimates by SVB Leerink analyst Geoffrey Porges.

Deal makers will be closely watching Pfizer ‘s (PFE) $6.7 billion takeover of Arena Pharmaceuticals , announced in December, which could become a test case for the FTC’s view of pharma M&A.

Citi analyst Andrew Baum said the deal was “highly attractive” for Pfizer, but the key issue would be whether the “newly muscular” FTC would fight it and allow it to proceed given the significant overlap between important drugs. The two companies might need to sell parts of the business to push the deal through.

Some **companies** are **calling off** their **planned mergers** as soon as they receive feedback. In December, outdoor sporting goods retailer Sportsman’s Warehouse Holdings (SPWH) and Great Outdoors Group, owner of the Bass Pro Shops chain, canned their deal in **the belief** that it **wouldn’t be approved**, according to a regulatory filing.

Months earlier, insurance brokers Aon (AON) and Willis Towers Watson (WTW) pulled their merger after the DOJ sued to stop the $30 billion tie-up. The brokers said regulators’ objections created “unacceptable **delay** and **uncertainty**.”

“While inevitably some parties may not be willing to accept increased risk and opt not to pursue a transaction, the vast majority of transactions will move forward and all but a select few will ultimately close,” Frank Aquila, global head of M&A at international law firm Sullivan & Cromwell said.

Others are fighting back. Penguin Random House and Simon & Schuster last month filed a joint response opposing the DOJ’s suit, arguing that the lawsuit “is wrong on the facts, the law, and public policy.”

The U.S. Chamber of Commerce has also sharpened its attack on the FTC, accusing the regulator of “waging a war” against American businesses, failing to strictly follow rules and caving to political interference.

“The FTC is **going rogue** and engaging in **regulatory overreach** that is **accelerating uncertainty** and **threatening our fragile economic recovery**,” the chamber said.

**Current AND future changes to law are inevitable.**

**Cooley ’1/21** [Cooley Alert; 1/21/22; Cooley LLP, American international law firm; "Antitrust Trends to Look Out for in 2022," https://www.cooley.com/news/insight/2022/2022-01-21-antitrust-trends-2022]

One year into his administration, President Joe Biden has made clear that **aggressive competition policy** is on the **agenda**. With a team of progressives filling **leadership roles** at the **F**ederal **T**rade **C**ommission and in the Antitrust Division of the US **D**epartment **o**f **J**ustice, companies are able to predict what the next several years may look like.

Lina **Khan**, a former Columbia Law professor, has headed the FTC since June 15, 2021, and has filled top spots in the Bureau of Competition and Consumer Protection with former staffers of Rohit Chopra, who left the FTC in October. Chopra’s proposed replacement, Alvaro Bedoya, was renominated on January 4, 2022, after his nomination deadlocked on a 14–14 party line vote in December. Meanwhile, Jonathan Kanter was sworn in to lead the Antitrust Division on November 18, 2021.

Procedural upheavals have swept the **merger review** process, erecting **new hurdles** that merging parties must leap over, from the “temporary” suspension of early termination to the FTC’s issuance of pre-consummation “warning letters.” Substantively, merging companies are facing **greater scrutiny** and **novel antitrust theories** of harm.

Legislators have introduced a **variety of bills** that could lead to **restrictions** on conduct in the technology and life science sectors.

As 2022 kicks off, the Cooley antitrust team has highlighted below developments and trends that corporate counsel should be aware of – and that are likely to impact businesses in 2022 and beyond.

Increasing procedural hurdles to merger review

New obstacles to the merger review process are **significant**. As the increase in reportable transactions continues to strain agency resources, this **trend may continue** into **2022**.

In February 2021, the FTC and the DOJ announced that they were temporarily suspending the granting of early termination. It has yet to be fully reinstated, though the FTC clarified in March 2021 that early termination will be granted when the agencies conclude that a transaction is unlikely to substantially lessen competition or agree to a consent agreement resolving competitive concerns before the parties fully comply with outstanding second requests.

The FTC also introduced **additional obstacles** when it rescinded a 1995 Policy Statement on Prior Approval and Prior Notice Provisions by a 3-2 vote in July 2021. The 1995 statement required prior approval and prior notice provisions only for parties who had previously consummated an unlawful merger when there was a “credible risk” of a future unlawful merger. The **recission** of the 1995 statement means that **parties** to FTC consent decrees must agree to **obtain prior approval** and give **prior notice** for future mergers in the same product and geographic market, which may put those firms at a disadvantage when competing to acquire future businesses. Whether the FTC will continue administrative litigation to impose a prior approval order when parties abandon proposed transactions during litigation, as it did before 1995, remains to be seen.

In August 2021, the FTC announced it would begin sending **letter**s notifying parties to certain transactions that its **investigation** is continuing, even **past** the 30-day statutory **waiting period**. The letters warn that the agency’s failing to challenge a transaction during the statutory 30-day waiting period does not indicate that the transaction has been approved, and that parties consummating transactions that have not been fully investigated do so “at their own risk.” We are now seeing such letters issued on a **regular basis**, even when parties are not contacted during the initial Hart-Scott-Rodino Act waiting period, and are not in fact seeing an ongoing investigation, so the letters appear to be aimed simply at **deterring transactions** or in some cases, even years later, the agency learns new information and decides to **investigate** and **challenge** a transaction.

Withdrawal of 2020 Vertical Merger Guidelines

In addition to the aforementioned procedural hurdles, the FTC introduced **ambiguity** to the **merger review** process when it withdrew its approval of the DOJ/FTC 2020 Vertical Merger Guidelines in September 2021. In its press release, the FTC stated that the guidelines “include unsound economic theories that are unsupported by the law or market realities” and that it was withdrawing its approval “to prevent industry or judicial reliance on a flawed approach.” The FTC’s **shift** signals that vertical mergers will be more **closely scrutinized**, as the FTC explores new theories of vertical harm.

Notably, the DOJ did not withdraw its approval of the 2020 Vertical Merger Guidelines, which continue to provide transparency and guidance for deals pending before that agency. By withdrawing its approval, the FTC has **increased the risk** for divergence in outcomes between the two federal antitrust enforcement agencies.

The FTC has indicated that new guidance is in the works, with a focus on the characteristics of transactions that are likely to be challenged, expansion of harms identified in the 2020 guidelines, and guidance on remedies to address vertical concerns.

Companies may expect to see **new guidance**, likely issued jointly by the DOJ and FTC, in 2022. In the meantime, parties must navigate vertical merger analysis with a **lack of transparency**.

Antitrust reform movement of 2021

During 2021, major pieces of legislation aimed at **antitrust enforcement** in key industries, including Big Tech and life sciences, were introduced.

The Competition and Antitrust Law Enforcement Reform Act (**CALERA**), introduced by Democratic Sen. Amy Klobuchar of Minnesota in February, seeks to give the FTC **more power** to block mergers and acquisitions. Provisions aimed at doing so include lowering the threshold for assessing whether a merger or acquisition is prohibited under the Clayton Act from the current standard of “may substantially lessen competition” to “creat[ing] an appreciable risk of materially lessening competition.”1 CALERA would also **shift the burden** to companies to **affirmatively prove** that their merger or acquisition would not harm competition. These provisions, together with an increase in the FTC’s budget and the establishment of an FTC division to study the effects of past mergers, would make it easier for the government to **challenge transactions**.

Another notable bill, the Platform Competition and Opportunity Act, introduced by Klobuchar and Arkansas Republican Sen. Tom Cotton as a bipartisan effort in November, shares significant elements with CALERA. The bill is focused on blocking acquisitions in the “dominant online platform” industry, by similarly shifting the burden to force tech companies to prove that proposed mergers and acquisitions are not anticompetitive.2

FTC updates to **rulemaking processes** also seek to **enhance enforcement**, empowered by Biden’s July executive order on “Promoting Competition in the American Economy” which, in part, encouraged agencies to “vigorously” enforce the antitrust laws, including through **rulemaking**. That same month, the FTC approved changes to its rulemaking process to facilitate issuance of new FTC unfair and deceptive acts and practices (UDAP) rules. Changes include **shifting oversight** from an administrative law judge to the FTC chair, eliminating a **staff report** on proceedings and **cutting public comment** periods. A recent FTC solicitation for public comments on contract terms that may harm competition, which may **lead to limits** on use of exclusive **contracts**, and FTC/DOJ workshop on **noncompete agreements** may **foreshadow future rules** limiting common **business practices**.

**Abbvie thumps**

**Isaacson and Rothschild 21** “Balancing Hatch Waxman and the Sham Litigation Exception” April Abele Isaacson and Cynthia Rothschild Ph.D. - Kilpatrick Townsend & Stockton LLP, April 29, 2021, https://www.jdsupra.com/legalnews/balancing-hatch-waxman-and-the-sham-4098835/

As previously reported on March 31, 2021, AbbVie Inc. has petitioned the U.S. Supreme Court for a writ of certiorari to review the Third Circuit’s ruling1 determining the biopharma company’s patent infringement suit was a sham litigation**. Petitioners argue the Third Circuit’s decision effectively nullifies the subjective prong of the Noerr-Pennington doctrine’s sham litigation exception**. The Noerr-Pennington doctrine allows litigants to petition the government for redress of grievances, including by litigating against a competitor without fear of antitrust liability and attendant treble damages. This immunity does not, however, extend to suits filed simply to harass a competitor, i.e., as a sham litigation. The test for identifying sham suits requires a plaintiff prove: (1) the challenged lawsuit was objectively baseless; and (2) the antitrust defendant was subjectively motivated by an improper purpose in bringing the challenged suit.2

**FTC overload now.**

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

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

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

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

## 1AR

**1AR – Regulations CP**

**Options are restricted**

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

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

**Smaller companies still choose to settle**

**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)

**Other reforms**, most notably the **SHIELD Act**, aim to counteract the incentives for PAEs to litigate by imposing **fee**- [\*2212] **shifting** mechanisms. 287 However, these reforms cannot **fully** offset the **competitive advantages** of patent privateering when unleashed against **small businesses** because most small rivals will **choose to settle** before **even defending themselves.** 288 If the analysis in Part II is sound, **small businesses should choose not to settle**; antitrust law already provides for **treble damages**, **fee-shifting**, and **criminal liability**. 289 But the evidence shows the opposite. Therefore, a proposal like the SHIELD Act would likely have no practical effect on the incidence of patent privateering. **Even if** it provided **another avenue** of recovering costs, small businesses are **unlikely** to be willing to **front the bill** for potentially several years of litigation.

**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**

\*\*MARKED 1AC\*\*

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.

**Only a direct regulation of patent troll solves---actions that tinker with the patent system can’t deter because of the high profit margins of trolliing**

**Fusco 14** (Stefania Fusco, Visiting Assistant Professor of Law, DePaul University College of Law; Senior Lecturer in Law, Notre Dame Law School; Transatlantic Technology Law Forum Research Fellow, Stanford Law School, MARKETS AND PATENT ENFORCEMENT: A COMPARATIVE INVESTIGATION OF NON-PRACTICING ENTITIES IN THE UNITED STATES AND EUROPE, 20 Mich. Telecomm. Tech. L. Rev. 439, y2k)

As for the second question, as previously mentioned, **many** have recently called for **a number of patent reforms** in the **U**nited **S**tates to solve **the patent trolling** issue. 109 The proposed reforms include, among others, **shifting litigation costs** to losing parties, **eliminating software patents**, and **reducing damage awards**. 110 The information about NPE activity gathered through this research can shed some light on which of these proposals might be successful. While a full analysis of these proposed reforms is beyond the scope of this Article, a few considerations can be made. In particular, this research suggests that **changes** modeled after the **European legal systems** might only produce **marginal** effects in the **U**nited **S**tates. This is because **fee-shifting**, **lower levels of damages**, and a reduced availability of cross border **injunctions** are all already present in European countries, and **yet NPEs operate there regardless**. More importantly, as discussed above, these features of European legal systems do not fully explain the presence of NPEs in certain markets, but not others. One possible explanation is that trolling activity is characterized by **very high profit margins**. If so, certain characteristics of European patent systems may render patent trolling riskier in Europe than in the United States, but the returns must be adequate. Consequently, it appears that, to **effectively** address patent trolling in the United States, **more direct regulation of NPE activity** is necessary. Merely adopting certain characteristics of European legal systems is insufficient.

### 1AR – Intrastate 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.

**Courts broadly defer on AT – Aff not key**

**Schmidt 20** (Derek Schmidt, Attorney General for the State of Kansas, Kansas Antitrust Developments in the 21st Century: A Perspective from the Attorney General's Office, 68 U. Kan. L. Rev. 875, y2k)

VI. A CONTINUED ROLE FOR **STATE ANTITRUST** IN THE 21ST CENTURY

Some might question the need for state antitrust laws when there are federal laws, or the need for Attorney General enforcement when there are private actions, but there are many reasons Kansas antitrust law and actions by the Kansas Attorney General are important. For example, Kansas antitrust law specifically protects Kansans. While many antitrust issues in today's global society have a national or international effect, some anticompetitive actions are still limited to a small geographic area. Or, even if it has a broad effect, the action may have a particularly detrimental effect on a small localized area. That is where Kansas antitrust law, as well as the enforcement authority of the Kansas Attorney General, are particularly important. Even in multistate cases brought in federal court, Kansas legal authority and the involvement of the Kansas Attorney General ensure that the interests of Kansas citizens and the State of Kansas are protected.

[\*919] A. **Not** Preempted by Federal Law

The Supremacy Clause of the Constitution provides that federal law is the "supreme Law of the Land," And the Tenth Amendment designates that "powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." State antitrust laws are **not** preempted by federal antitrust laws. Rather "Congress intended the federal antitrust laws to **supplement**, not displace, state antitrust remedies." State antitrust laws have also been **upheld** in the face of **other federal enforcement.** One example is the U.S. Supreme Court case Oneok v. Learjet discussed previously. One of the arguments made by the State in its amicus filing was that the harmonization requirement in the KRTA and other states' antitrust laws is evidence that state antitrust laws are consistent with the goals and purposes of federal antitrust laws. In *Oneok*, the Court affirmed that "[s]tates have a long history of providing **common-law** and **statutory remedies** against **monopolies** and **unfair business practices"** and have **a "long-recognized** power to **regulate combinations** in **restraint of trade."**

**1AR – Chilling Effect**

**The status quo is uncertainty – plan solves**

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>

B. The Noerr Court’s Failure to Recognize a Conflict Between Antitrust Law and the First Amendment in Has Resulted in an Excessively Broad Immunity Although it was a simple solution for the Court to construe the Sherman Act to avoid any conflict with the First Amendment, the goals of antitrust law and the goals of the First Amendment do frequently conflict.171 The First Amendment protects the citizens’ request for governmental action,172 but when those requests or the result of the requests create anticompetitive effects, they naturally conflict with antitrust laws.173 Although, under the Supremacy Clause, the Constitution must prevail when a conflict arises, the Supreme Court made Noerr immunity unnecessarily complicated by not recognizing that a conflict exists when it created the doctrine. 174 Instead of creating an exception to antitrust law, where immunity is carved out in deference to the First Amendment, the Court said that antitrust law did not apply at all.175 Although it seems that the result would be the same, **by taking the First Amendment issue out of the equation** altogether, **the Court failed to create any boundaries to the doctrine**.176 If there is no conflict and the Sherman Act simply does not apply, it is much harder for the courts to know when to apply Noerr than it would be if they could use the First Amendment as a guideline. **The Supreme Court’s failure has resulted in the development of an unclear doctrine, which is too broad and which the lower courts are still applying inconsistently fifty years after it was created.177**

**They don’t understand the aff – we only modify the sham exemption**

**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)

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 **P**rofessional **R**eal **E**state 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,

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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

**Objectively basis is bad**

**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

The third objective test archetype, the “objectively unreasonable” archetype, defines the “sham” exception in the broadest terms. Here, **a claim is deemed a sham if it lacks any reasonable chance of success** in producing a reasonably favorable outcome, based on the nature of the claim, from the vantage point of the reasonable prudent claimant. This test is broader than the “objectively baseless” test and that is by design. The principal evil of the “objectively baseless” test is that it allows the claimant to pursue claims **that have some non-zero chance of securing a technical win** on the subject of liability, **even though no reasonable prudent claimant would file such a claim** if he / she were genuinely seeking redress and evaluating the decision to sue on an objective cost-benefit basis. For example, under the “objectively baseless” formulation, even if the claimant is a patent holder, bearing monopoly power, who has been advised by counsel that his patent is ninety percent (90%) likely to be found invalid, and also ninety percent (90%) likely to be found not infringed by the Defendant’s product, so that the overall likelihood of success on the subject of liability is a mere one percent (1%),42 **the claimant may file suit, fully expecting to lose**, **knowing that the costs of the litigation will serve as a significant “street tax”** on the profits of its less-financially-capable startup competitor.

**The bar for retaliation post-aff is still high**

Saami **Zain** **14**. J.D., LLM (Antitrust); Assistant Attorney General, New York State Attorney General’s Office, Antitrust Bureau. 8-21-14. “Antitrust Liability for Maintaining Baseless Litigation” <https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=2783&context=lawreview>

Antitrust claims for maintaining baseless litigation are not likely to become common—even in pharmaceutical cases. **The difficulty of meeting various, formidable substantive and procedural requirements for antitrust liability will likely limit the viability of pleading and proving such claims.** **Nevertheless, even if not-often used, it could be a “big stick” to assist in combating anticompetitive conduct and deterring frivolous litigation.**

**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