# 1AC – NDT Round 4

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**Advantage 1: Innovation**

**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**

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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**

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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**.

**Independently, trolls tank medical equipment innovation**

**Tisack 21** “Protecting innovation from trolls” Gael Tisack - Global Head of Intellectual Property at Olympus Corporation, March 29, 2021, https://www.todaysmedicaldevelopments.com/article/protecting-innovation-from-trolls-olympus-medical/

Patent assertion entities (PAEs), more colloquially referred to as patent trolls, focus their attention primarily on high-tech and software companies. By one estimate, PAEs have been responsible for more than 84% of U.S. high-tech patent litigation.[1]

As medical technology and imaging companies become more reliant on technology, they increase their risk of being sued by PAEs. Throughout the last 10 years, several PAEs have aggressively attacked Olympus with threats of patent infringement cases. These lawsuits are a distraction and divert time and money away from innovation-driving activities such as **r**esearch and product **d**evelopment. Unfortunately, **we are seeing an upswing in such activity**. Unified Patents reported that in 2019 alone, patent litigation was up 4% across all industries.[2]

Patent assertion entities problem

PAEs are companies that acquire patents to monetize them by suing other companies. In 2013, RPX Corp. reported that only about 2% of medical-based companies were targets of PAEs.[3] By the end of last year, IAM found there was “a big jump in healthcare and pharma transactions with evidence of growing patent activity in the medtech space in particular.”[4] Our industry will likely see more patent transactions that could ultimately lead to more infringement litigation – **especially during an economic downturn** when distressed companies are looking to offload assets or up their patent monetization plans.

Trolls’ costs

In 2014, Massachusetts Institute of Technology (MIT) management science and marketing professor Catherine Tucker conducted a study showing that a patent troll’s litigation led to a decline of nearly one-third of medical imaging technology sales. Her research showed how product innovation also declined during the period of litigation.

In her study, she found that:

“An explanation for this lack of innovation is that the vendors didn’t want to run the risk of being found guilty of willful infringement in the patent suit and being held liable for treble damages. Therefore, one explanation of the slow-down in sales is that the product release and attendant sales cycle was halted because of litigation. This emphasizes that even if **p**atent **a**ssertion **e**ntitie**s** don’t prevail in the courtroom, their actions can have significantly negative consequences for incremental innovation while litigation is ongoing.”[5]

It’s clear that companies defending against PAEs spend less on innovation and other business strategies, and as Tucker’s study found, product sales can decline rapidly or halt.

Some estimates suggest that patent trolls are associated with more than $80 billion a year in lost wealth for defendants[6] and on average, firms forced to pay patent trolls spend $211 million less on research and development (R&D).[7]

As a company that has been the target of several patent trolls, Olympus is well aware of the high costs associated with litigating, defending, and paying licensing fees – all of which have affected our own efforts to further our **life-saving innovations** and safeguard the overall health of the company.

These costs can **derail** most R&D efforts and often can only be recouped by increasing prices, which is unfair to medical customers working hard to stretch resources to best serve their patients.

**That crushes 3D bioprinting---it’s coming online**

**Shah 17 –** Raj Shah, Coherent Market Insights, “3D Printing for Medical Sector Market by Technology and Geography - Trends and Forecast till 2024”, 1-29, http://www.mynewsdesk.com/us/pressreleases/3d-printing-for-medical-sector-market-by-technology-and-geography-trends-and-forecast-till-2024-1770704

3D printing is a **rapidly emerging** cost-effective technology with significant potential to transform healthcare delivery and clinical activities. This technology can be used in a range of devices such as prostheses, hearing aids, custom-made knee and hip implants, dental implants, and surgical instruments. The global 3D printing for medical sector market was valued at US$ 412.2 million in 2015 and is expected to expand at a CAGR of 11.7% during the forecast period (2016 – 2024).

Reasonable price of 3D printed medical products leading to increasing popularity

Regional governments of various countries are focusing on burden of expensive medicines on patients through effective **price control** measures. However, reducing **profit margins** negatively impact investments in research and development (R&D) phase. 3D printed medical products can effectively address the concerns of governments and the industry. Spritam (Levetiracetam) from Aprecia Pharmaceuticals, is the first 3D printed tablet that received U.S. FDA approval in March 2016. Low cost of production would in turn reduce cost of product and make it more affordable to patients. Researchers are the University of Toronto, Autodesk Research, and CBM Canada used 3D printing to produce low cost customizable prosthetic sockets for patients especially in low-income countries especially Uganda. This would further boost investment in 3D printing by healthcare providers to reduce product cost and increase profit margins.

**Bioprinting key to space colonization—extinction**

**Ghidini 18** (Tomasso, European Space Agency, ESA-ESTEC, Noordwijk, The Netherlands, “Regenerative medicine and 3D bioprinting for human space exploration and planet colonization” J Thorac Dis. 2018 Jul; 10(Suppl 20): S2363–S2375. doi: 10.21037/jtd.2018.03.19 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6081368/)

3D printing also known as additive manufacturing (AM) is seen as one of the key enabling technologies for a large number of high-end industrial sectors including the automotive, aerospace and medical industry. Recent advances and breakthroughs in the last years have enabled 3D printing of biocompatible materials, cells and supporting components into complex 3D functional living tissues. 3D bioprinting is being applied to regenerative medicine, addressing the need for tissues and organs suitable for transplantation. Bioprinting implies additional complexities related to the sensitivities of living cells such as printing parameters and conditions, material selection, cell types etc. Despite these challenges, beating artificial heart cells, cartilage implants, skin repairs, functional kidney tissues have been printed successfully on Earth. The present paper addresses the possibility of performing regenerative medicine in space, which may guarantee **sustainable life support** on long term/long distance planetary exploration missions, **opening to stable planet colonisation.**

Human spaceflight has undergone significant changes since its beginnings almost 50 years ago. With the establishment of the International Space Station (ISS) in low-Earth orbit (LEO), circling the earth at an altitude of around 400 km, crews sent into orbit have become larger and more heterogeneous and the duration of spaceflight has increased. To date, almost ninety crews have visited the ISS with a standard duration of each mission of around 6 months. Human missions beyond LEO refer to the Apollo Lunar programme, which was terminated in 1972, after a total of twelve astronauts had set foot on the surface of the Moon for a maximum of few days.

Today, human exploratory missions to the Moon or Mars, are widely considered as the next logical steps in human space exploration and, lately, colonisation. Almost all major national and international space agencies in the world as well as private investors and commercial initiatives are currently developing roadmaps and associated technologies to bring safely human beings to other planets in the solar system. Progressively, humanity shall get used to the concept of interplanetary travels among planets of our solar system, which shall become as natural as the concept of intercontinental flights on Earth. Human space flight will also see in the medium term a significantly increased number of travellers, longer durations of the flights, and longer distances up to stable permanence of human colonies on other planets. This will open to a number of challenges to be overcome, starting with ideological, but also political, technical, scientific, and even legal, philosophical, ethical and certainly medical.

The majority of the medical challenges faced during the human missions and associated durations performed so far, were mainly referring to radiations and micro- or reduced-gravity effects as well as psychological associated issues (1). Future exploratory missions to the Moon and Mars, including the establishment of permanently crewed base on the planet’s surface, will extend the distances travelled, the intensity of the radiation, the micro- and reduced-gravity levels, the duration of the mission, and the levels of confinement and isolation to which the crews will be exposed. This will raise several health issues which may be limiting factors during these missions, in particular radiation health, gravity related effects and psychological issues. Crew health and performance have to be ensured during transfer flights and planetary surface exploration, including Extra Vehicular Activities (EVAs), and upon return to Earth. Particularly a mission to Mars poses even further challenges: the distance of the planet, the duration of the trip (at least 500 days) and the impossibility to abort the mission lead to the necessity for the mission to be completely self-sustainable, since no support from Earth can be received in case of a health or major technical contingency.

In this scenario, 3D bioprinting for regenerative medicine and ultimately organs reproduction and transplantation is considered by the European Space Agency (ESA) **a long term enabling technology for distant planet exploration and colonisation**.

3D printing, or additive manufacturing (AM) includes a large family of processes and technologies and can be applied to a very wide range of materials, ranging from metals, polymers and ceramics but also living cells and organs (2-9). 3D bioprinting has already been used for the generation and transplantation of several tissues, including multilayered skin, bone, vascular grafts, tracheal splints, heart tissue and cartilaginous structures. Other applications include developing high-throughput 3D-bioprinted tissue models for research, drug discovery and toxicology.

ESA has pioneered in the exploration of the currently available Earth based 3D bioprinting technologies with the aim of defining a strategic roadmap for the safe, reliable and sustainable utilisation of these technologies on planet, aiming at exploration and colonisation missions support. ESA’s long-term vision is presented in the present work.

3D bioprinting—state of the art on Earth

Regenerative medicine and tissue engineering aim at the development of functional biological tissue substitutes enhancing tissue reconstruction and regeneration. Alternatively, transplantation of stem cells is a promising approach with the potential of self-renewal and differentiation. The so called stem cells niche, is the complex 3D environment which influences the cells fates. Within this system cell-cell contacts, cell-matrix adhesion, and the exchange of growth factors and oxygen are required for stem cells regulation (10). Therefore the proper fabrication of niche-like environment is a key issue in stem cell biology and regenerative medicine (10-12). The production of stem cell niches and tissue constructs is very challenging from a technical point of view with respect to their complexity. A technology is needed that allows the generation of defined 3D microstructures copying original tissues templates. By this means there is a demand to develop natural substitutes instead of traditional 3D scaffolds (13,14), which often proved to be challenging since they limit oxygen exchange within the tissue. Moreover, the structure has to be formed out of a material that is not only compatible with the cells but also enables the exchange of nutrient and soluble factors. Further, material elasticity and forces have to be taken into account since these parameters are known to influence stem cells differentiation. Also, the cells have to be arranged in 3D, enabling the formation of close cell-cell as well as cell-matrix contacts and interactions. Lastly, cell differentiation has to be guided and controlled within this complex 3D system. As differentiation is dependent on the initial cells density, the cells constructs have to be formed out of a defined, variable, and high cells amount (15,16).

3D bioprinting is an AM technology, where cells and biomaterials such cytocompatible hydrogel precursors, often referred as bioink, are simultaneously deposited in a layer by layer manner to generate biologically active 3D tissues of predesigned shape and size. Different cells types can be placed at desired locations of the bioprinted element and high cells densities can be achieved (17-19). The bioink properties before, during and after gelation are essential to its printability, and are impacting the achievable structural resolution, the shape fidelity and the cell survival. However, it is the final properties of the matured bioprinted tissue construct or niche that are crucial for the end application. During tissue formation these properties are influenced by the amount of cells present in the construct, their proliferation, migration and interaction with the material.

During the last decades, computer-aided deposition of biological materials has been investigated as a potential technique for engineering of tissue regeneration or replacement. A number of very comprehensive reviews have been published and summarise all relevant technologies, possible materials and associated benefits and limitations (11,19-37). In general, all existing bioprinting approaches can be separated into three groups, as sketched in Figure 1, including inkjet bioprinting (piezoelectric and thermal), orifice-free bioprinting (laser-induced forward transfer, LIFT, and printing by surface acoustic waves) and extrusion bioprinting (pneumatic or mechanical).

Inkjet bioprinting

An inkjet bioprinter delivers small droplets of bioink (1–100 picoliters; 10–50 µm diameter) on predefined locations of a substrate. The two most common methods used for inkjet printing of cells are piezoelectric and thermal inkjet bioprinting (23,38). The piezoelectric inkjet printer uses piezoelectric crystals to produce acoustic waves forcing small amounts of liquid through the nozzle. The thermal inkjet system produces pulses of pressure by vaporising the bioink around the heating element and expelling the droplets out of the printing head. Inkjet bioprinters are successfully applied with a micrometer resolution (10–50 µm) for the deposition of cells and are compatible with a number of bioinks (38-40). However, the major drawback of this technology is the achievable low viscosity and low cells density (41,42), since high cells density and associated high viscosity of the bioinks could result in clogging of the printing head. On the other hand, high scanning speeds can be achieved.

Orifice-free bioprinting

Orifice free bioprinting can be further divided into laser-induced forward transfer (LIFT) and surface acoustic waves printing. In LIFT, a pulsed laser beam is focused and scanned over a donor substrate coated with an absorbing layer (e.g., titanium or gold) and a bioink layer (11,37,43-46). Focused laser pulses cause local evaporation of the absorbing layer thereby creating a high-pressure bubble propelling small portions of the bioink towards the collector platform. Since this bioprinting technique is orifice free, it is not affected by clogging problems. Very high precision can be achieved combined with high cells survivability, since shear stress and extrusion are avoided. The resolution is in the range of 10–100 µm and bioinks with a viscosity ranging from 1 to 300 mPa and medium cells densities of ~108 cells mL-1 can be printed (31,47,48). The reduced scanning speed is the limiting factor of this technology.

Surface acoustic waves is the other orifice-free bioprinting method (49,50). Acoustic waves are produced by an acoustic ejector which uses a surface acoustic wave piezoelectric substrate (e.g., quartz, lithium niobate, etc.) with interdigitated gold rings placed on top of the substrate.

The waves have a circular geometry, hence an acoustic focal plane is generated at the air-liquid interface in the microfluidic channel and bioink droplets are ejected from it. The diameter of the droplets is uniform and ranges from 3 to 200 µm by tuning the wavelength of the acoustic ejector. High cells viability is achieved and bioinks with various surface tensions and viscosities can be ejected and processed.

Extrusion bioprinting

Extrusion bioprinting is probably the most common method for the fabrication of 3D cell-laden constructs (51-53). The bioink is normally inserted in disposable plastic syringes and dispensed either mechanically or pneumatically (piston or screw based) on the receiving substrate. This technology releases rather large amount of hydrogel filaments in the order of 150–300 µm in diameter. High viscosity and cells densities can be achieved with this method, though with an increased risk of cells damage due to the mechanical interaction with the orifice and the associated shear stress. Nozzle clogging and a reduced resolution (in the order of 200–1,000 µm) are the recognised drawbacks of the process. A new bioprinting approach is now proposed to improve the achievable environment for cells migration and spreading, currently suboptimal (54,55). In particular, a gel-in-gel bioprinting method bioink is extruded into a volume of self-healing hydrogel acting as a support material. The support hydrogel deforms after the injection of the bioink and heals immediately repairing and enclosing the printed structure inside. This method opens to multi-material printing, improves the mechanical properties of the construct and results in high cells viability.

Bioprinting has emerged in recent years as an attractive method for engineering of 3D tissues and organs in the laboratory, which can subsequently be implemented in a number of regenerative medicine applications. Currently, the primary goals of bioprinting are to (I) create complete replacements for damaged tissues in patients and (II) rapidly fabricate small-sized human-based tissue models or organoids for high-throughput diagnostics, pathology modelling, and drug development, examples of which are reported in Figure 2.

3D bioprinting has already been used for the generation and transplantation of several tissues, including multilayered skin, bone, vascular grafts, tracheal splints, heart tissue and cartilaginous structures. However, the capability of bioprinting fully functional complex tissues and organs still imply the resolution of a number of technical challenges (including e.g., the vascularisation, cells stability, production time and associated costs, capabilities of printing multi-materials, resolution vs. size of the print, cells viscosity and number, etc.), and addressing them requires the integration of technologies from the fields of engineering, biomaterials science, cell biology, physics and medicine.

ESA is considering this technology as a key enabler for long term/long distance missions, including planetary exploration and colonisation. This is particularly the case for the missions where the link with Earth will not be possible anymore and full mission self-sustainability shall be guaranteed.

Why other planets?

After the realisation of the ISS, human exploratory missions to the Moon or Mars, are widely considered as the next logical steps in human space exploration and, lately, colonisation. The ISS is the first example of an international cooperation for the joint development, operation and utilisation of a permanent space habitat in LEO. Hence, with the ISS a new era of peaceful cooperation in space on a global scale has started. Major partners are the USA, Russia, Japan, Europe and Canada. The experience matured with the ISS has shown that human beings can live, operate and perform science in space and that this can be done peacefully. The next logical step is to build on the technological, human, scientific and political lessons learnt matured in this endeavour and start bringing humanity to live, operate and perform science in other planets and in a permanent manner. The benefits and opportunities of exploring and eventually establishing permanent outposts on other planets (e.g., the Moon and Mars) **are tremendous** as described in (56) and reported here. They include:

❖ Determine if life is or was present outside of Earth and understand the environments that supported or could support it;

❖ Extend the human presence, exploring a variety of destinations beyond LEO with a focus on continuously increasing the number of individuals than can be supported at these destinations, the duration of time that individuals can remain at these destinations, and the level of self-sufficiently;

❖ Develop the necessary level of exploration technologies and capabilities: this shall include the knowledge, the capabilities, and the infrastructure required to live and work at destination beyond LEO through development and testing of advanced technologies, reliable systems, and efficient operations scenarios in an off-Earth environment;

❖ Perform science to support human exploration. Reduce the risk and increase the productivity of future missions in our solar system by characterising the effect of the space environment on human health and exploration systems;

❖ Provide other survivability options and resources to humankind **beyond Earth**;

❖ Stimulate economic expansion. Support and encourage the provision of technology, systems, hardware and services for commercial entities and create new markets based on space activities that will return economic, technological, and quality-of-life benefits for the whole humankind;

❖ Perform space, Earth and applied science. Engage in science investigations of, and from, solar system destinations and conduct applied science in the unique environment of solar system destinations;

❖ Provide opportunities for the public to engage interactively in space exploration;

❖ **Enhance Earth safety**. Enhance the safety of Earth by understanding the degradation processes of other (similar) planets, by following collaborative pursuit of planetary defence and orbital debris management mechanisms.

In support of the vision described above, a number of activities are ongoing and are currently paving the way for human planetary exploration and colonisation. In the following a number of the most relevant developments presently supporting the realisation of long term stable mission on the Mars surface are briefly described.

**Existential**

**Bostrum 03** (Nick, Professor of Philosophy at Yale, 2003, Is Cosmology Relevant to Transhumanism?)

Suns are illuminating and heating empty rooms; unused energy is being flushed down black holes; our great common endowment of negentropy is being irreversibly degraded into entropy on a cosmic scale, as I write these words. These are resources that an advanced civilization could have used to create value-structures, such as sentient beings living worthwhile lives. The rate of this loss boggles the mind. One recent paper speculates, using loose theoretical considerations based on the rate of increase of entropy, that the loss of potential human lives in our own galactic supercluster is at least ~10^46 per century of delayed colonization (Cirkovic 2002) . This estimate assumes that all the lost entropy could have been used for productive purposes, although no currently known technological mechanisms are even remotely capable of doing that. Since the estimate is meant to be a lower bound, this radically unconservative assumption is undesirable. We can, however, get a lower bound more straightforwardly by simply counting the number or stars in our galactic supercluster and multiplying this number with the amount of computing power that the resources of each star could be used to generate using technologies for whose feasibility a strong case has already been made. We can then divide this total with the estimated amount of computing power needed to simulate one human life. As a rough approximation, letÕs say the Virgo Supercluster contains 10^13 stars. One estimate of the computing power extractable from a star and with an associated planet-sized computational structure, using advanced molecular nanotechnology (Drexler 1992) , is 10^42 operations per second (Bradbury 2000) . A typical estimate of the human brainÕs processing power is roughly 10^17 operations per second (Bostrom 1998; Kurzweil 1999) or less (Moravec 1999). Not much more seems to be needed to simulate the relevant parts of the environment in sufficient detail to enable the simulated minds to have experiences indistinguishable from typical current human experiences (Bostrom 2001) . Given these estimates, it follows that the potential for approximately 10^38 human lives is lost every century that colonization of our local supercluster is delayed; or equivalently, about 10^31 potential human lives per second.

**Patent Thickets---1AC**

**Contention 2: Patent Thickets**

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

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

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

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

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

**Widely available generics prevent millions of deaths**

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

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

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

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

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

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

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

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

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

**Disease causes extinction**

**Diamandis 21** (EP, Lunenfeld-Tanenbaum Research Institute, Mount Sinai Hospital, Toronto, Canada 2. Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Canada 3. Department of Pathology and Laboratory Medicine, Mount Sinai Hospital, Toronto, Canada 4. Department of Clinical Biochemistry, University Health Network, Toronto, Canada, “The mother of all battles: Viruses vs. humans. Can humans avoid extinction in 50-100 Years”, PrePrint)

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

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

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

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

1. Introduction

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

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

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

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

Introduction

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

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

Infectious Diseases, Security and Ethics

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

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

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

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

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

Tuberculosis and Drug Resistance

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

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

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

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

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

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

**Circuit Split---1AC**

**Contention 3: Circuit Split**

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

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Filing lawsuits to **injure rivals**—especially **nascent competitors**—is as old as the hills and as American as apple pie.1 As **competition law** developed in the 20th century, so did the **risk** of antitrust liability for **dominant firms** that attempted to protect their **market position** by burdening **rivals** with litigation.2 For example, in 1938, a group of radio speaker manufacturers were subjected to Section 1 scrutiny for filing at least 54 patent infringement lawsuits, along with additional letters threatening infringement suits. As the Ninth Circuit stated, “We may assume that each of those acts would be lawful, and still a conspiracy might be shown. If the agreement has an unlawful purpose, it is a conspiracy, notwithstanding that the means used to carry it out were lawful.”3 **Litigation**, it has been said, “can be **an integral part** of a scheme **prohibited by the Sherman Act**.”4 In the 1960s, **however**, the **Supreme Court** conferred antitrust **immunity** on lawsuits filed against **rivals** with the creation of the **Noerr-Pennington doctrine**. That doctrine immunizes formal requests–– such as **litigation** and **regulatory protests**––to secure government action intended to harm competitors, **except** when that petitioning is a “**sham**.”5 A sham, as the term implies, is not a legitimate effort to exercise the constitutionally protected right to petition the government to redress a grievance; rather, it is a cover for the “true” purpose of employing the courts or regulatory machinery of government in bad faith to inflict economic pain upon a competitor. That pain can take many forms, including raising rival’s costs, erecting costly entry barriers, delaying or deterring entry, or using a combination of obstacles to drive a rival out of business.6 **Although** the **Supreme Court** expressly carved out a **sham exception** to Noerr-Pennington immunity, **lower courts** disagree over **the applicable standard** when multiple lawsuits are challenged as sham petitioning. In 2020, two cases solidified a 5-2 **circuit split** on this issue, but **no cert** petition was filed in either case. The majority of circuits—the Second, Third, Fourth, Ninth, and Tenth—have held that **a different analysis** applies when the legality of a pattern of lawsuits or petitions is challenged than when just a single petition is at issue. When multiple lawsuits are implicated, these courts have held antitrust immunity may be lost under the sham exception if the series of petitions demonstrates a pattern of filings made solely to inflict harm through burdensome process, without consideration of the merits or interest in the requested relief. As a result, the majority of circuits have held that the overall pattern of filings can qualify as a sham––therefore subject to antitrust scrutiny and damages––even if a small percentage of the petitions were objectively reasonable or ultimately proved successful. In contrast, two circuits—the First and Seventh––have held that a separate standard for immunity does not apply when scrutinizing a pattern of sham petitioning. In those circuits, every petition is subject to the same two-step test: (1) whether it was objectively baseless (i.e., had no reasonable chance of success) and if so, (2) whether the subjective intent of the petitioning was to harm a rival. Under this standard, only objectively baseless petitions can give rise to potential antitrust liability, and Noerr-Pennington shields a pattern of petitions which had merit, were successful, or at least were objectively reasonable. As a result, an antitrust defendant who succeeds in barring entry of a competitor or raising its rival’s costs through a long series of unsuccessful lawsuits or administrative petitions may be immunized from liability so long as each unsuccessful petition had a reasonable chance of success (even if achieving that success was not the purpose of the petitioning) With the **split** now covering more **than half of the federal circuits**, the issue of **when** the Noerr Pennington doctrine **shields** litigants who file a series of **lawsuits** or **regulatory petitions** is **ripe for Supreme Court resolution**. In 2018, the Supreme Court declined to grant certiorari to review the First Circuit’s decision on the issue, and in 2020, the unsuccessful plaintiff declined to appeal the Seventh Circuit’s decision on the issue. Until **Supreme Court review** occurs, antitrust practitioners tussling with **potential** sham litigation claims—which **frequently** arise in **pharmaceuticals**, **health care**, **telecom**munications, and other **patent**-intensive sectors—lack the **certainty** needed to advise historically **litigious clients** of the **antitrust risk** associated with filing additional lawsuits **against** rivals. From the perspective of antitrust practitioners (and their **clients**) with a vested interest in the **predictability of outcomes**, this is **unfortunate** since “**federal** [antitrust] law, in its area of competence, is assumed to be **nationally uniform**, whether or not it is in fact.”7

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

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**FTC v AbbVie**, Inc

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

Background

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

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

**Third Circuit decision**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Effective business planning solves extinction**

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

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

**Solvency---1AC**

**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.

**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.

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

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

IV. Analysis

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

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

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

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

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

**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.

# 2AC – NDT Round 4

**Case – 2ac —patent thickets**

**Patent thickets eviscerate competition and innovation**

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

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

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

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

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

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

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

**T Per Se**

**2AC**

* **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.

**Adv CP**

**Circuit splits – returning to the old standard is JUST as incoherent - ALSO means they link to the net benefit**

**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.

**b) Patent Regime and innovation – they can give companies all the money they want, but no one will develop drugs or space col tech if they think they’ll be sued**

**Duan 21** Ran Duan - University of Rochester, Simon Business School Thesis. “Patent Trolls and Capital Structure Decisions in High-Tech Firms” <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3730425>

In this paper, I provide novel evidence that **the threat of patent litigation** **leads to overly conservative capital structures and an inefficient level of innovation in high-tech firms**. I show that decreased cash flow volatility, especially in treated firms closer to financial distress, provides a key channel for my results. In addition, I show that TC Heartland directly impacts NPE litigation and the value of newly granted patents. I also show a dark side of the anti-patent troll protection: The value of newly granted patents decreases after TC Heartland, potentially because anti-troll laws could increase the cost for firms to enforce patent rights in court. This dark side points to the endogeneity in the passage of state anti-troll laws: Large high-tech firms who are patent enforcers lobbied against these laws. To the states which declined to pass anti-troll laws, the harm of the laws to big high-tech firms overweighs the benefit of protecting small innovating firms. Thus, the endogeneity problem suggests that caution should be exercised when inferring from my results the effects of curbing patent trolls on the control firms. **The legal system that defends patent rights is critical to economic growth.** However, the patent litigation system provides an opportunity for patent trolls to exploit high-tech firms. **The threat of patent trolls is an under-explored economic friction that hinders growth in high-tech firms.** My paper contributes to the growing literature on the economic consequences of NPEs by showing that TC Heartland directly impacts the way that patent rights are enforced. Together with the anti-patent troll state laws, the TC Heartland decision changes the dynamics of patent litigation in the U.S. These findings should be taken into consideration in debates over anti-patent troll laws and the optimal strength of intellectual property rights.

**c)Subsidies fail – incoherent policy**

**Boskin 12** Michael J. Boskin, is Professor of Economics at Stanford University and Senior Fellow at the Hoover Institution, and a former chairman of the US President's Council of Economic Advisers. "PICKING LOSERS, KILLING WINNERS" [www.stanford.edu/~boskin/Publications/boskin%20wsj%2002%2015%202012%20industrial%20policy%20-%20long.pdf](http://www.stanford.edu/~boskin/Publications/boskin%20wsj%2002%2015%202012%20industrial%20policy%20-%20long.pdf)

Firms make mistakes and markets are not perfect, but it's a **deeply dangerous conceit** for anyone to conclude they can **pick technology**, firm, **and industry winners and losers** more successfully than the market. And a possible market failure **won't necessarily be improved by government intervention**. We must compare the imperfect government policies likely to be implemented with imperfect market outcomes; will they improve the situation AND merit the cost? Government failure, including crony capitalism, rent-seeking and dispensing, pork, and regulatory capture, **is as pervasive as market failure** due to monopoly, externalities, or information problems.¶ America certainly has energy security and potential environmental needs to diversify sources by type and by geography. The shale gas hydraulic fracturing revolution -credit due to Halliburton and Mitchell Energy; the government's role was minor is rapidly providing a piece of the intermediate-term solution.¶ Government should set sensible goals and enact even-handed policies to achieve them, then let entrepreneurs, investors, and consumers decide how best to do so. It should fund applicable, pre-competitive generic scientific and technological research, eliminate specific subsidies and lower tax rates for all with the proceeds.¶ The arguments mustered to promote industrial policy - infant industries; benefits of clustering and learning; and jobs, do not stand up to serious research and historical evidence. Echoing 1980s Japan-fear and envy, some claim we must enact industrial policies because other countries, e.g. China, do. Presidents Johnson and Nixon wanted the U.S. to build a supersonic transport (SST) plane because the British and French were doing so. The troubled Concorde was shut down after a brief run of subsidized travel for wealthy tourists and Wall Street types.¶ Our response instead should be 1) remove our own major competitive obstacles, e.g. more competitive corporate tax rates; more sensible regulation, improved K-12 education, and better job training for commercially demanded skills; (Mr. Obama's green jobs training program - added on top of four dozen federal training programs -- spent hundreds of millions; 3% of enrollees had the targeted jobs six months later). 2) Base policies on sound economics. If another country has a comparative cost advantage, we gain from exchanging such products for those we produce relatively more efficiently. If we tried to produce everything in America, our standard of living would plummet. 3) Pursue rapid redress for illegal subsidization and protectionism in appropriate venues, e.g. the WTO, and strengthen those processes.¶ Fortunately, there is some promising news. Ethanol subsidies and tariffs (but not the increasing use mandate) expired in the New Year and there is a growing consensus to kill California's high-speed rail boondoggle. The state-appointed High Speed Rail Authority recommended against the program, as cost projections tripled to almost $100 billion, ridership projections plummeted and potential startup delayed a decade or more. Yet Mr. Obama offers subsidies to induce Governor Brown to add funds the state doesn't have for a first stage between Fresno and Bakersfield that Californians don't want enough to pay for.¶ So pervasive is this new government intervention in so many sectors that a vast array of unsubsidized firms are competing for capital and customers with government-subsidized firms forced to make non-commercial decisions. **The end result cannot be good**; **witness the damage wrought by Fannie and Freddie.**¶ **Industrial policy failed miserably in the 1970's and 1980's.** Letting governments rather than marketplace competition pick specific winners and losers is just as bad an idea today.

**CIL**

**AT: CIL CP**

**Zero risk of the net-benefit and solvency take out---CP can’t solve CIL because they can’t apply to constitution issues within a country**

Jack **Goldsmith 9** Henry L. Shattuck Professor of Law, Harvard Law School, LAW FOR STATES: INTERNATIONAL LAW, CONSTITUTIONAL LAW, PUBLIC LAW, <https://web.law.columbia.edu/sites/default/files/microsites/law-theory-workshop/files/IL&CLColumbiawkshp.pdf>

Finally, in case it does not go without saying, our argument is not that international and constitutional law are the same **in all respects**. Some formal differences between the two kinds of legal regime are **obvious** (if not entirely clear-cut). International law predominantly addresses **relations between and among states**, whereas **constitutional law** predominantly addresses **the political structure of a single state**; rules of international law are created primarily through **treaties** entered into by states or by customary state practice, whereas rules of constitutional law are created primarily by popular **ratification of an authoritative text** or conventions of political life that have achieved normative status as higher law; and so on. And while our analysis of the two legal regimes along the functional dimensions of uncertainty and enforcement and the normative dimension of sovereignty emphasizes important similarities, we also pause to notice differences. From a functional perspective, the size and heterogeneity of the international community may make it more difficult for the international legal system to develop institutional mechanisms for specifying and enforcing legal rules than for constitutional systems of smaller and more homogenous states to do the same.24 **The fact that American constitutional law is made, interpreted, and implemented exclusively by Americans** may make a normative difference to those who believe that sharing governance authority with a broader political community will invariably threaten American sovereignty, or that a politico-legal community can only be sustained at the level of the nation-state. We recognize these and other differences, but the ambition of this project is to reveal an important set of similarities that such differences may have masked.

**Ilaw is toothless and cant solve any of their impacts**

**Hiken 12** "The Impotence of International Law" Luke Hiken, Associate Director Institute for Public Accuracy, 7-17-'12 <http://www.fpif.org/blog/the_impotence_of_international_law>

Whenever a lawyer or historian describes how a particular action “violates international law” many people stop listening or reading further. It is a bit alienating to hear the words “this action constitutes a violation of international law” time and time again – and especially at the end of a debate when a speaker has no other arguments available. The statement is inevitably followed by: “…and it is a war crime and it denies people their human rights.” A plethora of international law violations are **perpetrated by every major power** in the world **each day,** and thus, **the empty invocation of international law does nothing** but reinforce our own sense of impotence and helplessness in the face of international lawlessness. The **U**nited **S**tates, alone, and on a daily basis **violates every principle** of international law ever envisioned: unprovoked wars of aggression; unmanned drone attacks; tortures and renditions; assassinations of our alleged “enemies”; sales of nuclear weapons; destabilization of unfriendly governments; creating the largest prison population in the world – the list is **virtually endless**. Obviously one would wish that there existed a body of international law that could put an end to these abuses, but such laws **exist in theory, not in practice.** Each time a legal scholar points out the particular treaties being ignored by the superpowers (and everyone else) **the only appropriate response is “so what!”** or “they always say that.” If there is **no enforcement mechanism** to prevent the violations, and no military force with the power to intervene on behalf of those victimized by the violations, what possible good does it do to invoke principles of “truth and justice” that border on fantasy? The assumption is that by invoking human rights principles, legal scholars hope to reinforce the importance of, and need for, such a body of law. Yet, in reality, the invocation means nothing at the present time, and goes nowhere. In the real world, it would be nice to focus on suggestions that are enforceable, and have some potential to prevent the atrocities taking place around the globe.

**Legitimacy DA----2AC**

**Conditioning the court ruling undermines judicial impartiality and independence**

**Dinh 8** (Viet Dinh, Viet D. Dinh is professor of law and codirector of the Asian Law and Policy Studies Program at Georgetown University Law Center, Threats to judicial independence, real & imagined, <https://www.amacad.org/publication/threats-judicial-independence-real-imagined>)

Up to this point, I have voiced some doubts that public criticism of judges poses a severe threat to judicial independence. But there is one way in which pervasive criticism of judges’ decisions can compromise the independence of the courts, without offsetting benefits in the form of democratic participation or judicial restraint. **A real danger exists** that the **publicly stated views** of political elites – activists, the news media, and officeholders – will **condition** the environment in which **judges operate**, leading career-minded members of the federal judiciary to **tailor** their **rulings** to **conform** to the views of the politically influential.

The **process** by which career judges – those who seek promotion to higher or more prestigious courts – can **internalize** elite opinion is fairly straightforward. It is only natural that many state-court judges and judges on lower federal courts would seek to advance through the ranks. They know that presidents and senators historically have preferred to appoint judges who have previous judicial experience.38 They also know that judges whose prior rulings have proved unpalatable to presidents or senators have had a harder time being nominated and confirmed to new judicial posts. Such career judges thus will have an incentive to placate the officeholders who they anticipate would play a role in their future elevation (as well as the private opinion-makers who would hold forth on their nominations). Career judges will have reason to decide cases based **not** just on their **honest estimation** of what the law **actually** requires, but also, at the margins, on their sense of what **outcomes** the political elites may favor.

My sense is that the threat here largely comes from members of the elite: the presidents who nominate judges, the senators who decide whether to confirm them, the journalists and editorialists who cover the process, and the activists who bring pressure to bear on their allies in office. The threat to judicial independence does not come from criticisms leveled by ordinary members of the public (except insofar as those citizens have the power, either individually or collectively, to move elites). Judicial independence has more to fear from an editorial in The Washington Post than from a posting by an anonymous blogger.

A few qualifications are in order. This analysis is not meant to malign the integrity of American judges, who in my experience strive mightily to resolve legal disputes in good faith and seek to minimize the influence of external considerations when they decide cases. It is only to recognize that judges are human beings and that, as humans, they are susceptible to self-interest as everyone else. Note also that elite criticism sometimes can have the opposite effect. It can cause judges to dig in their heels and refuse to buckle in the face of public sentiment. The need to maintain judicial independence notwithstanding the views of powerful elements of the public was one of the reasons the Supreme Court in Planned Parenthood v. Casey cited as a basis for retaining Roe v. Wade.

How, then, do we counter (or at least minimize) the natural incentive to curry favor with elites that is experienced by judges who hope for elevation to a higher court? A good starting point would be to lower the temperature of the judicial-appointments process. Judges who have no reason to fear that the president or Senate will scrutinize their rulings, line by line, in a hunt for evidence of ideological orthodoxy (or heresy), will be less prone to craft those rulings to be amenable to elite opinion. This is not a call for the Senate to abdicate its historically robust and important role in the confirmation process. It is only a call to focus on nominees’ general judicial philosophies and interpretive methodologies in lieu of their preferred outcomes in particular cases.

Few would dispute that judges must be “free to make decisions according to the law, without regard to political or public pressure.”39 But **judicial independence is not a one-way street**. We **insulate** our judges from day-to-day public pressures not because we want them to function as platonic guardians of the public interest, but precisely because in our constitutional system their role is so **carefully circumscribed**. In other words, **the principal beneficiaries** of judicial **independence** are not the judges themselves, but the litigants who appear before them in the hopes of getting a fair shake, and, ultimately, the American people who **look to** their **courts** for **impartiality**. Seen in this light, public criticism of the courts does not invariably present a threat to judicial independence, but actually can play a key role in ensuring that the judiciary remains independent. Such critiques are a way of calling on judges to remain faithful to their role as detached expounders of the law, and to eschew irrelevancies such as their own predilections and public opinion when deciding cases. As Chief Justice William Howard Taft cautioned, “Nothing tends more to render judges careful in their decisions and anxiously solicitous to do exact justice than the consciousness that every act of theirs is to be subject to the intelligent scrutiny of their fellow men, and to their candid criticism.”40

**That’s death-knell for rule of law and democracy**

**Levi 20** (David F. Levi, Family Professor of Law and Judicial Studies and Director of the Bolch Judicial Institute, Protecting Fair and Impartial Courts: Reflections on Judicial Independence, Summer 2020, Volume 104 Number 2, https://judicature.duke.edu/articles/protecting-fair-and-impartial-courts-reflections-on-judicial-independence/)

Why are fair and **impartial courts** important? And how does judicial independence preserve fairness and impartiality in our courts?” Perhaps the questions are too obvious. If you are an originalist, the answers are easy. The Framers and the ratifiers considered that **a fair** and **impartial judiciary** — one that followed the law and was not biased, partisan, intimidated, or seeking preferment — was **central** to a republican form of **government**. They believed that judicial independence was critical to fairness and impartiality. They thought of judicial independence in its two facets: **the decisional independence** of the judge from outside **pressures** or **inducements** when deciding a case, and the independence of the judicial branch as a whole, as a separate branch of three.

The Declaration of Independence prominently featured King George III’s attacks on both the judicial branch and the individual judge in its bill of particulars: “He has obstructed the Administration of Justice by refusing his Assent to Laws for establishing Judiciary Powers.” And: “He has made Judges dependent on his Will alone for the tenure of their offices, and the amount and payment of their salaries.” The founders were steeped in Montesquieu and other thinkers of the late 17th and early 18th century, and they came to believe that a “fair and impartial” judiciary was only possible were it embodied in a separate judicial branch and were the judges protected in their tenure and compensation.

Article III of the Constitution reflects this view: It provides for a separate branch of judges who themselves are insulated from pressure by lifetime tenure during good behavior and by a guaranteed livelihood. The Framers did not provide that the judges would be entirely divorced from the ebb and flow of political life. Their initial appointment was through the political branches, and they could be impeached. Nor were they autonomous. They were confined by law and by the assent of the other branches. Moreover, for much of their activity, they would be sharing the judicial power with citizens through the jury trial, which has such a prominent place in the Bill of Rights and our traditions.

Federalist 78 celebrated the separation of powers and the independent judiciary in often quoted language. Alexander Hamilton famously said: “The judiciary . . . has no influence over either the sword or the purse; no direction either of the strength or of the wealth of the society; and can take no active resolution whatever. It may truly be said to have neither FORCE nor WILL, but merely judgment; and must ultimately depend upon the aid of the executive arm even for the efficacy of its judgments.” And, he said: “[A]s liberty can have nothing to fear from the judiciary alone, [it] would have everything to fear from its union with either of the other departments” — which is why separation and independence were so important.

Hamilton’s comments speak to us even now. Judges should not by party or for any other reason be united to the other branches. Nor should they be involved on their own initiative and authority in the redirection of the wealth of the society. Hamilton understood that the judicial spirit of independence, the judicial culture, would be essential to the arduous task of resisting encroachments by the other branches. He also understood that judges would exercise discretion, but that there was a distinction between the exercise of judgment and the guided exercise of discretion on the one hand and the imposition of personal will and preference on the other. He saw the importance of courageous judges to the preservation of individual liberty and to the amelioration of oppressive legislation. Judges in this Republic, protected by life tenure, would unite integrity and fortitude to wisdom and knowledge of the law. And this knowledge of and fealty to the law, gained through practice and study, would be the bulwark against judicial overreaching.

Even if the authority of the founding generation were not enough, it seems that, in fact and over time, their beliefs have proven themselves: Indeed, it is **not** possible to have a **successful democracy** without a **fair** and **impartial judiciary**, and it is not possible to have a fair and impartial judiciary that lacks independence in both of its aspects. Are there examples of **successful democracies** where the judicial function is **dependent** or subsumed in the **other branches** such that the **judicial branch** lacks institutional independence? Are there successful democracies where the judges lack **decisional independence** but are routinely subject to pressure or external command or inducement? The answer is **“no.”**

Americans need to have faith in the independence, fairness, and impartiality of our judges because they **look to** our **courts** as the place where they can get **a fair shake** whether their complaint is with the government or a business or a neighbor. That is a huge entrustment. I draw the following principles or assertions from what I have covered so far:

First, **fair** and **impartial** courts are essential to **a successful democracy;**

Second, judicial independence is not for the personal benefit of the judicial officer but so that the judiciary may be fair and impartial;

Third, there are two primary aspects to judicial independence: decisional and institutional;

Fourth, the selection, compensation and tenure of judicial officers is important to their independence;

Fifth, the judicial culture, the independent spirit of the judiciary, is critical. Judges must be careful to guard the culture and be true to it;

Sixth, the judiciary must not be in league with either of the other branches and must not supplant the role of those branches or be supplanted by them;

Seventh, while there must be separation, there must also be collaboration. The judiciary depends heavily on the other branches for its support, the execution of its orders, and the substance and procedures of the law itself. We consider that **judicial independence** serves the **rule of law**, but this is **only** the case if the judiciaries’ **rulings** command **assent** and **respect** and if the **substance of the law** and the prescribed **procedures** are **consistent** with our common sense of **justice** and **fair play**. In other words, the ecology of judging is important and depends mostly on the other branches;

And finally, we acknowledge that the **appearance of fairness and impartiality is** almost as **important** as the reality, and the two are not easily separated.

When we depart from these principles, **we put ourselves at risk**.

**Taxes**

**Links to N/B---Declare Unlawful---2AC**

**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

**CP expands the scope of antitrust laws because it defines anticompetitive sham petitioning**

**Ünal 13** (LERZAN KAYIHAN ÜNAL, Ph.D., Turkish Competition Authority, INTERNATIONALIZATION OF COMPETITION: IS CONVERGENCE OF COMPETITION LEGISLATION ENOUGH TO DEAL WITH INTERNATIONAL ANTICOMPETITIVE PRACTICES?

LERZAN KAYIHAN ÜNAL, <https://www.rekabet.gov.tr/Dosya/akademik-calismalar/24-pdf>)

**The US Antitrust Laws** and Their Global Reach

The overriding policy of the federal antitrust laws is to protect competition in the US markets. In an increasingly internationalized and intertwined global economy, both domestic and foreign activities potentially threaten competition in the US markets. The US realized the importance and the necessity of extending the scope of application of its antitrust rules beyond a narrowly interpreted principle of territoriality at a very early stage of enforcement in order to cover anticompetitive practices that take place across border but have a restrictive effect within its domestic markets. The Sherman Act87, the landmark federal statute, for instance applies to conduct that restrains trade or commerce “among the several States, or with foreign nations”. The US Congress, however, did not speak out the extent to which the federal antitrust laws were to reach anticompetitive activities occurring outside the US. Moreover, neither the statutory language nor the legislative history of the antitrust laws provided any guidance as to the meaning of “commerce…with foreign nations”. This **ambiguity** has left the task of **determining** the extraterritorial **scope of the antitrust laws to federal courts**. Within this context, **the effects doctrine** was developed in time by the US Courts as an extension of territoriality principle. Antitrust laws generally **define anticompetitive practices** by referring to their **effects** since the **effect** is a **constituent** part of the law. By granting jurisdiction to the national competition agencies where the effects are felt, the effects doctrine can be considered to be in conformity with the territoriality principle. The EU was also among the first and prominent actors that realized the significance of effects doctrine as a fundamental instrument to address international restrictive practices (Zanettin 2002, 8). The innovation of US antitrust laws and policy has been followed extensively by most of the competition agencies worldwide. In other words, the US antitrust enforcement in all respects has been benchmarked by many jurisdictions worldwide.

**PDCP**

**That establishes a prohibition because market participants had violated antitrust laws**

**Melamed 9** (A. Douglas Melamed, law professor @ Stanford, THE PURPOSES OF ANTITRUST REMEDIES, Antitrust Law Journal , 2009, Vol. 76, No. 1 (2009), pp. 359-368)

The remedy inquiry is **different**. The remedy inquiry takes **the liability** standards **as given** and addresses the **consequences** of a violation of those standards. Remedies can deal with the harm caused by a violation (the compensation, termination, and restoration purposes discussed above), and they can use the violation as an occasion to take steps to prevent future violations (the deterrence and prevention purposes). But remedies are hard to get right and, when suboptimal, can undermine antitrust objectives by interfering with markets and prohibiting or deter- ring procompetitive conduct. As the contributions to this symposium demonstrate, optimizing antitrust remedies requires, among other things, clear thinking about the purpose of the remedies.

**Establishing liability requires a violation of the Sherman Act---that’s a prohibition**

**Flatt 9** (Ethan Flatt, J.D. Candidate, Vanderbilt University Law School, 2010; M.B.A., University of Mississippi, 2007; B.B.A., University of Mississippi, 2006. Solidifying the Defensive Line: The NFL Network's Current Position Under Antitrust Law and How it Can Be Improved, 11 Vand. J. Ent. & Tech. L. 637

I. Background

A. The **Legal Foundations** of Antitrust **Liability**

1. The Sherman Antitrust Act of 1890

The Sherman Antitrust Act of 1890 (the Sherman Act) was a major legislative effort by the Fifty-first Congress to codify common law prohibitions of anticompetitive conduct. 14 Enacted to protect consumers, the Sherman Act targets market restraints that increase price and decrease output, which are inherently "unresponsive to consumer preference." 15 Under the Sherman Act, antitrust claims come within federal jurisdiction, 16 and the consequences of a violation can include criminal sanctions. 17 Virtually all contracts restrain trade to some degree, so a workable standard was needed to target only the agreements deserving of antitrust liability. 18 The courts have adopted a reasonableness standard so that the statute only **prohibits** unreasonable restraints of trade. 19

**AT: Taxes Thing**

**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—Progressive Taxes Bad**

#### Doesn’t solve anything – Republican midterms coming up, historically disproven under Biden, no political will. No terminal – not reverse causal

**Progressive causes tax revolt**

**Lind 10** Michael, co-founder of the New America Foundation, 8/10/10, “The liberal case for regressive taxation,” <https://www.salon.com/2010/08/10/liberal_case_regressive_taxation/>

The ironies are rich on both sides. Many of the conservatives who denounce the very idea of an American VAT support less efficient flat national consumption taxes, like the proposed Fair Tax. Meanwhile, many American progressives want a European-style welfare state, but don’t want to pay for it the way the Europeans do: with payroll and consumption taxes that **fall on everybody, not just the rich**. Instead, they dream of funding more generous Social Security benefits and a reformed Medicare program out of higher progressive taxes on the wealthy few -- something that not even the social democratic Swedes have done.

A little background. American cities and states employ sales taxes, but unlike other countries the U.S. has no major consumption tax like a VAT at the national level. Whereas other central governments rely on a triad of consumption, payroll and income taxes, the U.S. federal government relies chiefly on payroll and income taxes alone. While income tax rates have been lowered since the Reagan revolution, exemptions and deductions have removed the lower half of U.S. taxpayers from effectively paying any income taxes at all, although they still pay payroll taxes. This means that on the revenue collection side the U.S. federal tax system is **much more progressive** than those of Western Europe, which rely more on flat payroll and flat VAT taxes that fall more heavily on the middle and working classes than on the rich.

Fine, some American progressives say. Let the people who have received a disproportionate share of the gains from economic growth pay even more in progressive income taxes. There are three arguments, however, against basing social insurance benefits for the majority like Social Security, Medicare and unemployment insurance on progressive taxes that fall chiefly on the rich: a moral argument, a political argument and a macroeconomic argument.

The moral argument is this: Social insurance is not charity. Social insurance programs like Social Security and Medicare are based on horizontal solidarity among the members of a majority middle class. In an imaginary classless society, where all workers made the same incomes, social insurance would consist solely of transfers from employed members of the universal middle class to members of the middle class who cannot or should not work -- retirees, the sick, and the parents of newborns.

Social insurance is not intended to be a transfer of resources from the rich to the poor. That is Victorian-style philanthropy, even if it happens to be mediated by government. Conservatives and libertarians want to roll back the clock to the 19th century by means-testing Social Security and Medicare, thus saving money by eliminating middle-class social insurance. Liberals should oppose the replacement of social insurance by means-tested charity, even if the deal is sweetened by paying for means-tested benefits for the poor only by progressive taxes on the rich.

The progressive ideal is benefits for everybody, including the rich, **paid for by taxes on everybody, including low-income workers**. Deficit hawks who claim that it is possible to save significant amounts of money by means-testing Social Security and Medicare to exclude the rich are either lying or ignorant. There are so few rich, as a percentage of the U.S. population, that eliminating their Social Security and Medicare benefits would hardly save any money. Only by reducing benefits for huge numbers of middle-class Americans would it be possible to reduce the costs of these entitlements by means-testing. So don’t believe deficit hawks who pretend to want to means-test Social Security in order to spend more money on the poor. It’s a cynical trick.

In his new book, "The Narcissism of Minor Differences: How America and Europe Are Alike," Peter Baldwin notes that "the U.S. tax system is at once less demanding and more progressive than the Continental European, while at the same time social benefits are stingier." He concludes: "Robin Hood may have helped the poor of Sherwood Forest by taking from the rich ... [But] [m]ost redistribution takes place via social spending, largely **paid for by taxing the same groups that receive the bulk of benefits**."

If the moral argument is that social insurance should consist chiefly of transfers within the middle class, **rather than redistribution** from rich to poor, the political argument is that invisible taxes like payroll taxes (taken out of biweekly paychecks) and consumption taxes like sales taxes and a VAT are **more sustainable**. The two **tax revolts** in the U.S. since the 1970s -- the property tax revolt that began in California and the income tax reductions under Reagan and George W. Bush -- both involved taxes that cause sticker shock on April 15, when many Americans are startled by the amount of money they owe. In contrast, few people have any idea of how much they have paid in sales taxes or how much has been withheld from their paychecks. This quirk of human psychology means that relying less on direct, progressive taxation might **free the U.S. from the destructive cycle of voter tax revolts** and the **deficits** that result when the same voters reject spending cuts.

Finally, there is the macroeconomic argument for basing national taxation chiefly on taxes paid by the majority of the population, rather than by a small rich minority. In a section of his new book, "Capitalism 4.0," titled "Progressives Will Fight for Less Progressive Taxes," Anatole Kaletsky points out:

The U.S. and British governments [with more progressive tax systems] both suffered **big drops in revenues**: 2.2 percent of GDP in Britain and 3.2 percent in the United States. In Germany [with a more regressive tax system], meanwhile, the revenue-to-GDP ratio increased by 0.9 percent of GDP. Translating these percentages into dollar figures, if the United States had a tax structure similar to Germany’s, the Federal deficit would have been $600 billion smaller each year.

Similarly, states like New York and California, with highly progressive state tax systems, are in much worse fiscal condition than states like Texas, which has no income tax at all and relies chiefly on property and sales taxes. Because the incomes of the few are much more closely tied to the stock market and other asset markets than the wages of the many, relying on a small number of financiers or tech billionaires rather than the moderately paid majority results in **wild fluctuations in government tax revenues**.

Kaletsky argues that over-reliance on progressives taxes creates “a **perverse incentive** for governments to **promote income inequality**. If the solvency of the state and the ability to fund basic services for the poorest people in society depends on the rich getting even richer, it is tempting for **even the most progressive politicians** to **support widening inequalities**.” Bill Clinton in the U.S. and Tony Blair and Gordon Brown in the U.K. succumbed to the temptation, **deregulating Wall Street** and the City of London at least in part out of hope that **higher revenues from financial industry tycoons** could **fund progressive social spending**.

**New, sudden financial deregulation causes a quick global crisis**

**Savard 17** Keith, fellow at the Milken Institute, an independent economic think tank, held positions at Zurich Investments, The Institute of International Finance, the U.S. Department of State and the Board of Governors of the Federal Reserve System, 4/24/17, “Rapid deregulation, complacency and the next financial crisis,” <http://thehill.com/blogs/pundits-blog/finance/330225-rapid-deregulation-investor-complacency-and-the-next-financial>

Despite the usual, ever-present economic, political and geopolitical concerns, is there anything else to suggest that **the world could spiral into another financial meltdown?**

In the aftermath of the 2007-2008 crisis, authorities in many countries took regulatory steps to reduce the risk that the system could again unravel and bring the global economy to its knees. In addition to regulatory safeguards, coordinated action was taken through the G-20, the Bank for International Settlements and other institutions to reduce regulatory arbitrage.

Measures also were taken to stimulate economic activity and restore confidence. Financial markets recently have hit record highs as consumer confidence and business survey indicators registered solid gains. Economic activity in most countries picked up, although, on balance, it continues to lag previous recoveries.

With the world economy — and the U.S. economy in particular — seemingly on the mend, the question is, **what might derail the recovery and trigger another collapse?** Here is one scenario worth exploring: a combination of investor complacency plus a **major sudden rollback of U.S. financial regulations**, carried out in an environment of rising interest rates and fears of protectionism, could send a shockwave through the markets and trigger a sharp economic contraction.

You could add to this one more cause for unease — the market volatility prompted by rising tensions over North Korea and Syria.

The Trump administration includes a number of senior officials who believe that tighter regulations enacted during the Obama administration are holding the economy back. However, there is little research to support this view. An argument can be made that a sudden, deep rollback in regulations could **destabilize markets** because banks and investors are still interpreting and adapting to the Dodd-Frank Act.

The risk of turmoil is even greater given that markets already are trying to absorb a technological revolution that includes enhanced algorithmic trading, the proliferation of electronic bond trading platforms and increased reliance on exchange-traded funds (ETFs).

Market participants’ complacency only adds to concern that **few are keeping an eye out for the reappearance of systemic risk** or, at a minimum, a significant price correction in one or more asset classes. “Priced to perfection” is often heard these days in discussions of financial markets with value metrics in a number of asset classes hovering several standard deviations above the norm.

Conventional wisdom is that economic growth will improve and rising inflation will be well managed and contained by central banks. This has led many equity investors to believe that company earnings will improve this year following two years of disappointment.

However, this interpretation could become frustrated quickly, particularly if the Trump administration’s promise of tax reform and infrastructure spending collapse as healthcare reform did. Already much of the positive news on the economy comes more from survey data than hard economic data.

The most recent estimate of annual first-quarter real GDP growth by the Atlanta Federal Reserve is 0.6 percent. Such anemic activity could trigger a reassessment of earnings growth for the year.

With economic forecasts showing little upward momentum, the monetary tightening by the Federal Reserve could create problems both for the real economy and financial markets.

If market participants get nervous about rising rates, coming as they are on the heels of a prolonged period of exceptional monetary stimulus and unprecedented low yields, it is not hard to imagine the possibility of a sharp reassessment that could send asset prices tumbling. The risk of rising market tensions and volatility, notably in exchanges rates, could lead to wider instability.

At this juncture, the Federal Reserve should be extremely cautious about raising policy interest rates. While the desire to normalize rates is understandable after years of outsized monetary accommodation, the likelihood of success is doubtful given the central banks’ track record.

Similarly, for those who believe that the regulatory pendulum has swung too far toward oversight, a **gradual and prudent adjustment** first requires a thorough consideration of the effectiveness of regulations. Substantial changes in Dodd-Frank could prompt market participants to reassess the likelihood of future systemic risk, putting downward pressure on asset prices.

In addition, any effort to turn back the clock by re-imposing old regulations, like Glass-Stegall, could quickly turn into a disaster. Financial markets have changed significantly since the repeal of Glass-Stegall. Even since the global financial crisis, the operation of markets has evolved to the point where regulators are wrestling with how to deal with liquidity risk, contagion and a host of ancillary issues.

All the effort that has gone into reducing the risk of another financial meltdown could be jeopardized if the administration **rushes to deregulate** in order to fulfill campaign promises despite not enough time spent on rigorous analysis, open discussion and simple patience.

Failure to recognize the disconnect between financial markets and economic fundamentals in an environment of low asset price volatility and policy uncertainty could be an accident in the making.

## States

**Even with durable fiat, courts side with defendants**

**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

**Pharma DA**

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**Turn – the plan is gidley’s solution**

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

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

**Turn the Plan is exactly what Gidley wants**

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

SUMMARY OF THE ARGUMENT **This Court should grant the petition for a writ of cert**iorari **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 so called “reverse-payment” settlement agreements in the pharmaceutical industry are necessarily anticompetitive. After failing to convince this Court in Actavis to adopt a “quick-look” approach to evaluating reverse-payment settlement agreements, the FTCis **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 pharma**ceutical **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.

**Innovation low---rising costs and conservative R&D**

**Rea and Raveendran 21** “Drug R&D is broken; how to put the tech in biotech” MIKE REA AND TARA RAVEENDRAN, Mike Rea is the founder of Protodigm, a next generation CRO that innovates, invents, develops, and prototypes possibilities for drugs to be brought to market, as well as the CEO and founder of IDEA Pharma, a specialist in pharmaceutical product positioning and path-to-market strategies. bachelor’s degree in genetics from the University of Newcastle-upon-Tyne. Tara is the Principal at Protodigm where she oversees research and finance strategy. She earned her B.Sc. in Biochemistry and Ph.D. in Structural Biology, from the Imperial College London. Jul 1, 2021, https://medcitynews.com/2021/07/drug-r-how-to-put-the-tech-in-biotech/

**Despite headlines** indicating recent growth, R&D productivity in the biotech and pharma industries has been in steady decline. So, why is an industry that was built on bold, visionary leaps of faith through much of the 20th century – think insulin, antibiotics, the Salk polio vaccine, the rise of biotechnology and monoclonal antibodies – struggling to reclaim the innovative and entrepreneurial spirit from which it sprung?

Rising costs of developing an asset and longer development timelines are partly to blame. However, it is also reflective of a more surreptitious culprit – increasingly conservative R&D management practices which focus on the predictability of drug development, but which have led the industry to a decade of incremental innovation (with a few notable exceptions such as antivirals / Hepatitis C, Immuno-oncology).

Embracing risk in drug development

Drug development is riddled with failure and, thus, a risky business. Only 5% of compounds that enter clinical development become commercial products and many products that make it to market then fail to return their own development costs. Most of the R&D budget is spent on these failures, a fact not lost on those in the industry. This explains why **many companies invest primarily in already-approved drugs**. In an attempt to smooth new drug output, minimize financial risk, and introduce more predictability into the process, there has been an industry-wide trend towards portfolio management techniques where detailed forecast and risk prediction numbers provide a false impression of confidence in progression through the pipeline.

Ironically, this attempt to reduce the perceived riskiness of the development process has driven pharma to the pursuit of more narrow development strategies, referring to the idea that a drug enters development with a pre-determined purpose, narrowing its development. While these strategies (validated targets, proven mechanisms of action, and more targeted patient groups) may seem less “risky” on one hand, innovation remains incremental from a commercial perspective due to a high clinical data standard, pricing, and adoption barriers, such as market access, pricing constraints and prescribing guidelines. These narrow development strategies increase the risks associated with premature specialization or choosing a development path too quickly.

Pharma continues to overlook the role of **obliquity**, the ability to pivot during development in the presence of new data, or **serendipity**, seeing opportunity in what actually happened, in drug development. To ignore the roles of obliquity and serendipity would be to ignore famous examples such as Avastin, which notoriously ‘failed’ many times before entering development, Herceptin, which pivoted 180 degrees upon seeing its phase II data, and the whole statin class which saw many ‘false fails’ before becoming one of the industry’s biggest blockbuster classes. In most of these cases, the ability to ‘know’ in advance was at odds with the appetite to explore.

**Small companies do the best innovation, big pharma doesn’t invest in R&D, and the link is industry lies**

**Orucevic 22** “A Machete for the Patent Thicket: Using Noerr-Pennington Doctrine’s Sham Exception to Challenge Abusive Patent Tactics by Pharmaceutical Companies” Lisa Orucevic | 75 Vand. L. Rev. 277 2022, https://vanderbiltlawreview.org/lawreview/wp-content/uploads/sites/278/2022/01/A-Machete-for-the-Patent-Thicket.pdf

Additionally, despite the various research and development support that large pharmaceutical companies receive and their astronomical drug prices, **it is small pharmaceutical companies that are mostly responsible for new drug development.**304 Small drug companies developed **over 70%** of the nearly three thousand drugs in phase III clinical trials.305 Perhaps more shocking, “[s]ince 2009, about one-third of the new drugs approved by the [FDA] have been developed by pharmaceutical firms with annual revenues of less than $100 million.”306 Meanwhile, large pharmaceutical companies like AbbVie only spend a fraction of their revenues from blockbuster drugs like Humira on **r**esearch and **d**evelopment. Case in point: in 2018, AbbVie spent only $5.1 billion on research and development, but earned $19.9 billion in worldwide net revenues from Humira alone in the same year.307 Studies have also indicated that “[i]ncreases in pharmaceutical industry competition have been found to increase firms’ R&D spending.”308 This implies that pharmaceutical companies’ dire warnings about the necessity of patent thickets to fund research may be overblown.

**Thickets kill innovation**

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

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

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

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

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

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

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

**Profits don’t go to R&D, most R&D isn’t actually innovative, most innovation occurs in non-profit centers, and innovation is useless if it’s ultra-expensive**

**Kesselheim 16** – Aaron S. Kesselheim, Associate Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women’s Hospital, M.D. and J.D. from University of Pennsylvania School of Medicine and Law School, MPH from Harvard School of Public Health, primary care physician at the Phyllis Jen Center for Primary Care at Brigham & Women’s Hospital, Jerry Avorn, Professor of Medicine at Harvard Medical School and Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women’s Hospital, M.D. from Harvard Medical School in 1974, and completed a residency in internal medicine at the Beth Israel Hospital in Boston, Ameet Sarpatwari, PhD in epidemiology at the University of Cambridge, Instructor in Medicine at Harvard Medical School, an Associate Epidemiologist at Brigham and Women’s Hospital, and Assistant Director of the Program On Regulation, Therapeutics, And Law (PORTAL) within the Division of Pharmacoepidemiology and Pharmacoeconomics, JD at the University of Maryland as a John L. Thomas Leadership Scholar, Principal Investigator on a Greenwall Foundation Making a Difference in Real-World Bioethics Dilemmas grant and a Faculty Affiliate with the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Behavioral Insights Group at the Harvard Kennedy School (“The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,” *Journal of the American Medical Association*, Vol. 316, No. 8, pgs. 858–871, August 23rd, Available to Subscribing Institutions)

Justifications for High Drug Prices

The pharmaceutical industry has maintained that high drug prices reflect the **research and development costs** a company incurred to develop the drug, are necessary to pay for future research costs to develop new drugs, or both. It is true that industry often makes expensive investments in drug development and commercialization, particularly through late-stage clinical trials, which can be costly.84 These assertions have been used to justify high prices on the grounds that if drug prices are constrained, the pipeline of new medications will be adversely affected. Some economic analyses favored by the pharmaceutical industry contend that it costs $2.6 billion to develop a new drug that makes it to market.85 However, the rigor of this widely cited number has been disputed.86,87

**A number of factors weigh against these rationales** for high drug prices. First, important innovation that leads to new drug products is often **performed in academic institutions** and supported by **investment from public sources** such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that **more than half** of the 26 products or product classes identified had their origins in publicly funded research in such **nonprofit centers**.88 Other analyses have highlighted the importance of small companies, many **funded by venture capital**.89,90 These biotech startups frequently take early-stage drug development research that may have its origins in academic laboratories and continue it until the product and the company can be acquired by a large manufacturer, as occurred with sofosbuvir.

Arguments in defense of maintaining high drug prices to protect the strength of the drug industry **misstate its vulnerability**. The biotechnology and pharmaceutical sectors have for years been among the very best-performing sectors in the US economy. The proportion of revenue of large pharmaceutical companies that is invested in **research and development** is just **10%** to 20% (Table 4); if only **innovative product development** is considered, that proportion is **considerably lower**.91 The contention that high prescription drug spending in the United States is required to spur domestic innovation has not been borne out in **several analyses**.92 A more relevant policy opportunity would be to address the stringency of congressional funding for the National Institutes of Health, such that its budget has barely kept up with inflation for most of the last decade. Given the evidence of the central role played by publicly funded research in generating discoveries that lead to new therapeutic approaches, this is one obvious area of potential intervention to address concerns about threats to innovation in drug discovery.

Thus, **there is little evidence of an association** between research and development costs and drug prices93; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear. This explanation also helps to account for several high-profile case studies, including high-priced new branded products94 and exorbitantly priced generic drugs described above.95 In preparation for recent hearings on this topic, the US House Committee on Oversight and Government Reform subpoenaed internal correspondence from Turing and Valeant Pharmaceuticals, which had sharply increased the prices of older drugs the companies had acquired. The investigation revealed, for example, that Turing received “no pushback from payors” when it increased “Chenodal price 5x... [Thiola] price 21x... [and Daraprim] price 43x.”96 Similarly, Gilead spent $11 billion to purchase sofosbuvir from Pharmasset, a small biotechnology firm that developed the drug, based in part on federally funded research led by an investigator at Emory University.97 Gilead recouped almost all of this cost in the first year that sofosbuvir was on the market, recording sales of $10.3 billion in 2014.98 In December 2015, the US Senate Committee on Finance released a **detailed report** based on its access to internal company documents on Gilead’s strategies to maximize the prices it could charge for both that drug and its planned successor, which the company also owned.99 In the current system for drug payment in the United States, few options exist to counter this approach.

Companies should of course be rewarded fairly for the research innovations they make that help generate new drug products and for their costly trial work that facilitates the assessment and availability of new medications. But providing them with large incentives to do the opposite is counterproductive.

Clinical Consequences of High Drug Prices

The high cost of prescription drugs in the United States has **clinical as well as economic consequences**.100,101 Even though more Americans have drug coverage as a result of the Medicare drug benefit plan and the Patient Protection and Affordable Care Act, cost-containment strategies in recent years have **shifted** an increasing share of drug expenses **to patients**.102 Private insurers have increased deductibles103 and most co-payments, and added a new payment tier for certain specialty drugs in which patients must pay coinsurance—often between 20% and 33% of the total drug price—rather than a simple co-payment.104 Although such cost-shifting measures have helped “bend the cost curve” for employers and payers, **they can reduce use of effective medications**.105,106 Almost **a quarter of** 648 **respondents** to a 2015 poll reported that they or another family member did not fill a prescription in the last year because of cost.107 In other studies, patients who were prescribed a costly branded product rather than a more affordable generic alternative were found to adhere to their regimen less well than those receiving a similar generic drug12 and to have worse health outcomes.108 Nonadherence due to all causes has been estimated to contribute to $105 billion in avoidable health care costs annually.109

In some cases, manufacturers have attempted to circumvent higher co-payments by providing patients with coupons that reimburse their out-of-pocket expenses.110 Coupons can be useful for patients with no other option, but they leave the insurer obliged to pay the much larger amount of each prescription’s costs, thereby increasing health care spending. This approach has become common for branded drugs that have comparable but much less expensive alternatives.111

Faced with fixed health care budgets, states with higher drug costs for their Medicaid programs have had to **reduce other services** or increase health care eligibility requirements.112 Several state Medicaid programs, for example, have imposed nonevidence-based policies to restrict sofosbuvir, including **denying coverage** to users of alcohol or other drugs.113,114

**Excessive revenue causes large share buybacks**

**Roy 16** – Victor Roy, MPhil, Department of Sociology, University of Cambridge, Luke Hawksbee, MPhil, Department of Sociology, University of Cambridge, Lawrence King, PhD, Department of Sociology, University of Cambridge (“Factors Influencing Prescription Drug Costs in the United States,” *Journal of the American Medical Association*, December 13th, Available Online)

To the Editor In their Special Communication, Dr Kesselheim and colleagues1 challenged an industry claim by finding that “**there is little evidence of an association between research and development costs and drug prices**,” with drugs instead priced in the United States based on what health systems and society can bear. **Several interrelated trends in corporate governance and the financial sector** can further explain this phenomenon of high and often escalating prices despite large companies investing only 10% to 20% of their revenue on research and development.

First, large, publicly traded companies are valued by shareholders and investment analysts based on expectations of growth of approximately 10% on a year-to-year basis. This near-term growth expectation partially explains why **companies are averse to risky long-term in-house research** and instead rely on acquisitions of compounds often developed with public and venture capital. Gilead’s approach to hepatitis C drugs has demonstrated the possibilities of financial success by specializing in late-stage acquisition and regulatory approval.2

Second, **these acquisitions are typically financed with debt** as well as stockpiled cash accrued via high prices on prior sales. Price increases on medicines, which in turn can raise a company’s share price based on the promise of future growth, are also a form of leverage used to borrow from investors for acquisitions. The EpiPen case demonstrates this strategy. Mylan’s successive price increases facilitated the raising of more than $6 billion via stock issuances and debt between 2015 and 2016.3 These moves positioned Mylan for their $7.2 billion acquisition of Swedish biotech company Meda.4

Third, large companies have directed inordinate flows of revenue toward a financial maneuver known as **share buybacks**, in which companies buy their own shares to increase the value of the remaining ones. From 2005 to 2014, the 19 pharmaceutical companies in the S&P 500 Index spent $226 billion repurchasing their own shares, equivalent to 51% of their combined research and development expenditures over this period. Composing 4.14% of the sample, these companies contributed 7.38% of returns to shareholders.5 Thus, companies could increase access and affordability of medicines in the form of **lower prices** or reinvest more of their revenue into research for areas of unmet medical needs and still amply reward shareholders.

**Makes collapse inevitable**

**Morgenson 17** (Gretchen, assistant business and financial editor and a columnist at The New York Times and Pulitzer Prize winner, "Big Pharma Spends on Share Buybacks, but R&D? Not So Much," https://www.nytimes.com/2017/07/14/business/big-pharma-spends-on-share-buybacks-but-rd-not-so-much.html?\_r=0)

(The other authors are: Matt Hopkins, Ken Jacobson, Mustafa Erdem Sakinç and Öner Tulum, all researchers at the Academic-Industry Research Network, a nonprofit organization.) While stock buybacks appear to be particularly troublesome among drugmakers, big companies in other industries — in sectors like banking, retail, technology and consumer goods, among others — are also buying back boatloads of their shares. Through May, some $390 billion in buybacks have been announced this year, $13 billion more than at this time in 2016, according to figures compiled by Jeffrey Yale Rubin at Birinyi Associates, a stock market research firm. June 28 was the biggest single buyback announcement day in history. That was when 26 banks disclosed buybacks worth $92.8 billion, largely a response to having 8/12/2017 Big Pharma Spends on Share Buybacks, but R&D? Not So Much - The New York Times https://www.nytimes.com/2017/07/14/business/big-pharma-spends-on-share-buybacks-but-rd-not-so-much.html?\_r=0 3/4 just passed the stress tests administered by the Federal Reserve Board. That figure blew past the previous record of $56.4 billion announced on July 20, 2006. Many companies contend that stock buybacks are a great way to return value to their shareholders. Investors often agree. By reducing the equity outstanding at a company, the repurchases increase its per-share earnings, often giving a boost to its stock. Buybacks made at low cost can be a fine use of a company’s capital. But when **share repurchases replace** a company’s **r**esearch-**and**-**d**evelopment **spending**, that indicates its management is unable or unwilling to spend on innovation that could generate future earnings to shareholders. As the **buyback binge** continues, another new academic study shows, a heavy reliance on them actually **hurts corporate performance** over the long haul. These researchers found that the more capital a business invests in stock repurchases based on its current market capitalization, “the less likely that company is to experience long-term growth in overall market value.” “Secular Stagnation” is by Robert U. Ayres, emeritus professor of economics, political science and technology management at the global business school Insead, and Michael Olenick, a research fellow there. It compares the performance of companies that lean heavily on buybacks with those that do not. Spending money on buybacks and dividends has increased among United States companies from negligible levels in the 1980s, the researchers said, to 38 percent of earnings in 2000. By 2011, buybacks had grown to 79 percent of earnings, rocketing to 110 percent in 2015. The research looked at 1,839 large company buybacks from January 1990 through last month, examining 6,516 inflation-adjusted transactions. The academics then examined the amounts these companies had spent on repurchases compared with their current market capitalizations. Mr. Ayres and Mr. Olenick found that 199 companies repurchased shares equal to at least half their current value. Some 64 companies spent over 100 percent of 8/12/2017 Big Pharma Spends on Share Buybacks, but R&D? Not So Much - The New York Times https://www.nytimes.com/2017/07/14/business/big-pharma-spends-on-share-buybacks-but-rd-not-so-much.html?\_r=0 4/4 their current market capitalization on buybacks. When the academics combined these companies’ current market values with the amounts they had spent on buybacks, the sum showed what the companies should have been worth if they had invested the money in a money-market account instead. Fifty companies have spent more inflation-adjusted capital buying back stock than their businesses are currently worth in market value, the study found. Companies on this list include HP Inc., J. C. Penney and Sears Holdings. By contrast, the research identified 269 strong performers that have repurchased stock worth just 2 percent or less of their current market values. They include Facebook, Xcel Energy, Berkshire Hathaway and Amazon. Company executives who buy back large numbers of shares instead of investing in their businesses are committing corporate suicide, Mr. Olenick said. “When managers can’t create value in the business other than buying their own stock,” he said in an interview, “it seems like it’s time for a management change.” His co-author, Mr. Ayres, said he suspected the buyback craze was rooted in executives’ laser focus on short-term results. “They have short-term expectations,” he said in an interview. “They’re in their jobs for a few years at most; they’re not really interested in the long-term future of the company.” Share buybacks provide immediate gratification, the stock market equivalent of a sugar high. That makes them alluring in the short term. Until the **crash** that **usually follows.**

**BizCon**

**Enforcement High---2AC**

**FTC is massively ratcheting up enforcement actions---creates business minefields**

Colin **Kass 1-4** is a partner and co-chair of the antitrust group at Proskauer Rose LLP, How To Navigate The Coming Antitrust Policy Tests, Law360 Expert Analysis – Corporate, L/N

2021 will be remembered in antitrust law. Not since **the 1970s** has there been **so much chatter** over the fundamental purposes of antitrust policy, or such potential for **actual sea change**. Half a century ago, Robert Bork and the Chicago School argued that antitrust law had lost its way and should focus on consumer welfare. Bork's view was that antitrust enforcement was getting in the way of legitimate competition, and the U.S. Supreme Court was quick to embrace the consumer welfare standard. Now, Federal Trade Commission Chair Lina Khan and the new Brandeisians argue that antitrust law has again lost its way and must shed the constraints of the consumer welfare standard. Khan's view is that consolidation has gone unchecked in the American economy, resulting in structural harms to competition that the consumer welfare standard is unable to address. She believes the agency has historically defined markets too narrowly to effectively police broader economic impacts of sustained consolidation, and favored gerrymandered remedies over outright challenges. Khan has imposed **sweeping changes** aimed at **chilling merger activity** and shaping the future of **merger** enforcement. Against **dissents from** Republican Commissioners Christine Wilson and Noah Phillips, and **charges of going rogue** from the U.S. Chamber of Commerce, the FTC **stripped** away **long-standing exemptions** and interpretations that streamlined merger review. The action came in response to an unprecedented merger wave - 3,845 acquisitions filed with the agencies in the first 11 months of 2021, substantially more than most full years. The changes are **having an impact**, making investigations more **intrusive**, **lengthy** and **less predictable**. Still, policy precedes practice, and while the FTC has been heavy on policy, it has yet to test those policies in the courts. The tests may come in the next year. Meanwhile, we can also expect the FTC and the U.S. Department of Justice under Assistant Attorney General Jonathan Kanter's leadership, to not only continue the trajectory of policy changes but also begin the task of entrenching them in agency practice. Here, **we review the year in FTC policy moves**, what they mean and how to navigate **the newly laid minefields. Warning Letters After the Close of HSR Waiting Periods** In an **unprecedented** move, the FTC recently began issuing letters to parties in transactions the agency may intend to investigate after expiration of the **H**art-**S**cott-**R**odino **A**ct waiting period. According to the agency in an Aug. 3, 2021, blog, this is the result of "a tidal wave of merger filings that is straining the agency's capacity to rigorously investigate deals ahead of the statutory deadlines." Wilson, however, said on Twitter on Aug. 12, 2021, that she was "gravely concerned that the carefully crafted HSR framework is suffering a death by a thousand cuts," following her Aug. 9 statement that said "For the HSR Act to retain meaning, it cannot be that the FTC will keep merger investigations open indefinitely, as a matter of routine, every time there is a surge in filings." The FTC's jurisdiction to review transactions is independent of the HSR reporting requirements, with the power to investigate any transaction before or after closing, whether subject to reporting or not, and whether the HSR waiting period has expired or not. There are examples of the agencies reviewing nonreportable transactions, and even investigating reportable transactions after expiration of the HSR waiting period, though they are rare. The warning letters do not assert new authority not already existing under law, but notifying parties that an investigation may remain open post-HSR clearance implicates finality and certainty of investigations, but not every transaction gets a warning letter. Those with no issues go through unscathed. Those with clear issues are investigated. The deals that might pose some issues, but not enough to draw an investigation, might trigger the newly minted warning letter. To show the letters have teeth, the FTC will sooner or later have to challenge a deal post-HSR waiting period, putting it to the test before courts, where it is likely to face hurdles to the extent the deal did not warrant a full investigation in the first instance. Still, the practice is ushering a change in how provisions are drafted in deal documents. A buyer asserting that it is not required to close over the - arguably - still-pending investigation may face an uphill battle depending on how the closing conditions are drafted, for they typically point to the expiration of applicable waiting periods and not the absence of potential ongoing investigations or issuance of warning letters. So careful buyers seek closing requirements that no investigations are threatened and that no warning letters have been issued. Recent examples include the 3D Systems Corp.'s agreement to acquire Oqton Inc. and Universal Corp.'s agreement to buy Shank's Extracts Inc. The parties' agreements provided that if a warning letter is issued, the investigation would be treated as closed 30 days after receipt of such letter. Buyers may want to consider similar provisions until more emerges on how the FTC will proceed with warning letter transactions. **More Intensive Merger Investigations** The FTC announced plans on Aug. 3, 2021, to make the second request process both "more streamlined and more rigorous." The changes include the following: Merger investigations will address additional potentially impacted competition, such as labor markets, cross-market effects, and the impact on incentives of investment firms. Modifications to second requests will be more limited. The agency will require parties to provide more information relating to their use of e-discovery in responding to the investigation. Additional information will be required with respect to privilege claims. The FTC said these changes are in recognition that "an unduly narrow approach to merger review may have created blind spots and enabled unlawful consolidation." Possibly in response to such steeped up investigative techniques and resistance to find common ground with merger parties, Sportsman's Warehouse Holdings Inc. and Great Outdoors Group LLC abandoned their proposed merger at the end of 2021, citing indications that the FTC would be unlikely to approve the outdoor sporting goods transaction. The changes, though, do little to streamline the second request process. They make it more complex, burdensome and time-consuming. Perhaps most **notable** is the use of the process to delve into **labor markets**. Republicans Wilson and Phillips argued that FTC leadership may have themselves to blame for the merger review crunch, saying in a Nov. 8, 2021 statement: If the agency is lowering thresholds of concern and broadening theories of harm, this certainly would explain why the FTC is unable to conduct merger reviews in a timely manner while our sister agency remains capable of addressing the same increased filing volumes within statutory timeframes. More Onerous Consent Decree Provisions Where merger parties settle a challenge rather than litigate, the consent decree process sets out the parties' obligations. Historically, such consent decrees, among other things, required parties to notify the agency prior to certain future acquisitions. The FTC **rescinded** this long-standing policy, noting that it: Returns now to its prior practice of routinely requiring merging parties subject to a Commission order to obtain prior approval from the FTC before closing any future transaction affecting each relevant market for which a violation was alleged. The agency will also require divestiture buyers to agree to prior approval for any future sale of the assets they acquire. Khan explained the move was to avoid "drain[ing] the already strapped resources of the Commission" on "repeat offenders." The FTC included the new provision in its Oct. 25, 2021, consent decree settling a proposed transaction by DaVita Inc., a dialysis service provider. DaVita is now required to receive prior approval from the FTC of 10 years before any new acquisitions, a dialysis clinic business in Utah being in question. This is a **significant change** and will **chill** not only settlements with the FTC, but **also M&A transactions** at the outset where such provisions are commercially untenable. Wilson and Phillips noted in dissent that "a prior approval requirement imposes significant obligations on merging parties and innocent divestiture buyers." The FTC clearly aims to **chill** M&A activity, and merger agreements that provide more optionality to abandon deals will become more common, though parties intent on pushing their deal through may see a consent decree with 10-year approval provisions as less palatable than litigating, and force the FTC to cave or go to court. **Withdrawal of the Vertical Merger Guidelines** In another party-line vote, the FTC withdrew the **vertical merger guidelines**, which were issued just last year. Democratic commissioners criticized the guidelines as based on "unsound economic theories that are unsupported by the law or market realities," and reflecting a "flawed discussion of the purported procompetitive benefits (i.e., efficiencies) of vertical mergers." Vertical transactions are between firms at different levels in the supply chain. Historically, antitrust enforcement of exceptional vertical mergers were rare and difficult given the previously presumed efficiencies. Vertical mergers can eliminate double marginalization, in which firms at each level mark up prices above marginal cost. Elimination of one markup results in lower prices and can be pro-competitive. Khan, however, argues the guidelines' "reliance on [elimination of double marginalization] is theoretically and factually misplaced." Going forward, "the FTC will analyze mergers in accordance with its statutory mandate, which does not presume efficiencies for any category of mergers." This too drew a strong rebuke from the Republican commissioners, who said "The FTC leadership continues the disturbing trend of pulling the rug out under from honest businesses and the lawyers who advise them." The commission's challenges to chipmaker Nvidia Corp.'s $40 billion acquisition of U.K. chip design provider Arm Ltd. alleged the transaction would combine one of the largest chip producers with a firm that has essential design technology - critical inputs. In a Dec. 2, 2021, statement, the FTC said the acquisition "would distort Arm's incentives in chip markets and allow the combined firm to unfairly undermine Nvidia's rivals." The FTC's lawsuit should "send a strong signal that we will act aggressively to protect our critical infrastructure markets from illegal vertical mergers that have far-reaching and damaging effects on future innovations," FTC Bureau of Competition Director Holly Vedova said in the statement. Given that vertical mergers will be closely scrutinized as a matter of course, parties need to consider concerns the FTC may identify and prepare strong counters - other than elimination of double marginalization. For example, parties could argue that the transaction expands access to products and expands consumer choice. Parties willing to go the distance with a vertical merger should also remain mindful that the guidelines have never been cited or relied on by a court, and it is the established jurisprudence on vertical transactions that will carry the day. **Rescinding the Consumer Welfare Standard** In July 2021, the FTC rescinded its policy interpreting its statutory mandate to root out "unfair methods of competition" as coterminous with **promoting consumer welfare** under the Sherman and Clayton Acts. In a July 19, 2021, statement, the FTC called the rescinded policy was "bind[ing] the FTC to liability standards created by generalist judges in private treble-damages actions under the Sherman Act." Still, the consumer welfare standard has been entrenched in antitrust jurisprudence for decades, and the FTC cannot change that. The immediate impact is thus more likely to be seen in administrative actions in the FTC's own court. In a dissenting statement, Republican commissioners countered that FTC leadership does not propose a replacement standard and "that efforts to distance Section 5 from the consumer welfare standard are a recipe for bad policy and adverse court decisions," adding that, "unlike those in academia, the FTC will have to defend its interpretation of Section 5 in court, where it should expect a hostile reception if it cannot offer clear limiting principles." **Labor Market Scrutiny** Government investigations and private litigation relating to **no-poach** and **wage-fixing agreements** are **ballooning**, and criminal indictments are now a reality. Encouraged by President Joe Biden's executive order on competition, the FTC and the DOJ have doubled down on investigating labor markets. **Merger investigations** now routinely include requests for employee compensation data, inquiries regarding noncompete and nonsolicit agreements, and are more likely to delve into both the merger's effects on labor, and the parties' prior labor practices. The DOJ's challenge to Penguin Random House LLC's proposed acquisition of Simon & Schuster Inc. focuses on harm to the labor market - for authors. In his first public comments, the DOJ's Kanter said: We will fight for American workers including in connection with illegal mergers that substantially lessen competition for laborers. Going forward, you can expect efforts like these not only to continue but to increase. Khan echoed the sentiment, saying: Competition and conduct can hurt us not just as consumers who buy products from a shrinking number of large firms, but also as workers who are especially vulnerable and subject to the whims of a boss we can't equally or practically escape. Antitrust compliance policies now must extend to addressing practices with respect to employee recruiting and compensation. Antitrust compliance training must extend beyond the sales team, and include HR. Businesses are reviewing and revising their compliance policies, and beginning new antitrust training programs to ensure that they are not subjected to claims of depressed wages and barriers to worker mobility. Looking Ahead to the Year to Come The year 2021 has been like no other for antitrust enforcement. While the FTC's various policy pronouncements are clearly intended to chill merger activity, it does not appear to have had the intended outcome. HSR filings continue at off-the-charts levels. Amid this strong showing of M&A activity, the advice is to keep moving transactions forward, stay ahead of the new tacks the agencies might take, and account for newly injected risk and uncertainty. Looking ahead, **expect another energetic year**. So far, the FTC's policy changes have not seemed to slow the pace of merger activity, but the frenzy cannot last forever. Nonetheless, merging parties are now going into the merger review process with **eyes open**, knowing **it is likely to be more intense and uncertain**. Parties to vertical transactions will no longer ride easy on double marginalization theories, and parties will be handing over their HR and payroll files. At the same time, the heavy resistance to these changes will continue, if not strengthen, and will play out not just in courts and the halls of Congress, but will also spill into the political mainstream. The U.S. Chamber of Commerce is planning to spend hundreds of thousands of dollars on an ad campaign across 10 states denouncing what it calls the FTC's overstepping of regulatory authority. And the Americans for Prosperity Foundation, an advocacy group backed by the Koch family, is starting to lay the groundwork of a challenge to the FTC's merger policy changes. It recently filed a Freedom of Information Act suit seeking communications and directors related to the decisions. Yes, 2021 will be remembered in antitrust law. But **the real show may be 2022.**

**Thumpers---2AC**

**1---Maritime antitrust**

Eric **Kulisch 1-10**, Air Cargo Editor, **Mission creep**: Why the FTC is investigating retail supply chain distortions, https://www.freightwaves.com/news/mission-creep-why-the-ftc-is-investigating-retail-supply-chain-distortions

The **F**ederal **T**rade **C**ommission’s mission is to protect consumers and businesses against anticompetitive, deceptive and unfair business practices, but **historically** it hasn’t **touched** ocean **shipping**. Overseeing competition in sea freight is the primary jurisdiction of the Federal Maritime Commission. The Department of Justice gets involved if international container lines engage in anticompetitive behavior outside antitrust immunity that allows discussion about rate guidelines for individual service contracts and vessel sharing. **Yet** **the FTC**, in late November, launched a study into the **supply chain operations** of nine major retailers, wholesalers and packaged goods suppliers. The companies were asked to turn over detailed information to help the agency determine whether steps they took to ensure adequate inventories exacerbated widespread transportation bottlenecks, supply shortages and inflationary pressures in ways that harmed smaller companies and consumers. The responses are due Wednesday. The **probe** is part of **a Biden administration** effort to show that it is, at least symbolically, focused on issues driving up prices for food, gas and merchandise, which are hitting people in their pocketbooks and contributing to lower confidence in the economy and the president. And torrid inflation — consumer prices jumped 6.8% in November, the biggest increase in 39 years — is giving the Biden team an opportunity to initiate a competition agenda aimed at reducing market consolidation based on a narrative, advanced by progressives, that inflation is caused by greedy big business. Today’s inflation is the result of a bullwhip recovery from the pandemic, government stimulus programs that allowed people to order more goods, supply chain bottlenecks and labor shortages, according to economists. Supply chain impediments are the result of port congestion and tight ocean capacity in the face of record U.S. import demand, which has resulted in a tenfold increase in shipping rates from Asia compared to pre-pandemic levels. The White House recently claimed its Port Action Plan was responsible for reducing shipping rates and backlogs at the ports of Los Angeles and Long Beach, although short-term container rates are rising again and logistics experts say there hasn’t been any material improvement in cargo processing. Critics say **the FTC’s scope expansion** is **misguided**. Retailers are “the wrong target,” said Steve Lamar, president of the American Apparel & Footwear Association. “That’s not where the bad behavior is being exhibited. It’s at the carrier level. And if you are really looking at trying to reduce inflationary pressures, the administration has a handy tool they can use” — removing and refunding tariffs on imports from China to offset harmful freight costs. Lawrence Summers, the head of the National Economic Council under President Barack Obama and Treasury secretary for President Bill Clinton, said on Twitter, “The emerging claim that antitrust can combat inflation reflects ‘science denial.’ … Increases in prices and profit margins are what happens when competitive industries experience increases in demand. That is what calls forth increased supply. This is how a market system operates.” Other financial experts argue concentrations of power allow companies to arbitrarily price goods much higher than they would in a free market. In their view, inflation is the rate of change in prices and oligopolies more easily pass through higher costs, so antitrust action can lower prices. **In the crosshairs** The FTC supply chain review came after the White House, and port envoy John Porcari in particular, pushed federal agencies to find tools they could leverage to alleviate chokepoints, said a Washington trade attorney who asked not to be named to protect access to the executive branch. Without a jurisdictional hook to investigate the ocean freight industry, Chair Lina Khan — an advocate for curbing the dominance of big companies — told the White House the FTC could look at the trickle-down impact on the economy from how big companies are dealing with port congestion and downstream distribution bottlenecks, according to the source. The commission eventually invoked a provision of **the FTC Act**, which authorizes it to conduct wide-ranging studies that don’t have a specific law enforcement purpose. The order, which gives the companies 45 days to respond, was fine-tuned after the two Republican members of the commission expressed concern about jurisdictional overreach. The National Retail Federation expressed concern that the FTC inquiry is a distraction from investigating the behavior of ocean carriers and is an administrative headache for the companies involved. “The current supply chain crisis is affecting companies large and small who are being impacted by disruptions at every stage of the supply chain. Focusing on the practices of a few U.S. retailers who have been trying to address the shipping crisis will not help to solve the issues that persist today,” Jonathan Gold, the NRF’s vice president for supply chain and customs policy, said at an open FTC meeting on Dec. 16. Importers face a multitude of challenges, including shortages of materials; COVID outbreaks that threaten foreign factories and ports; shortages of empty containers and chassis to carry them over the road; and marine terminals restricting returns of empty containers, according to trade experts. Cargo owners complain ocean carriers regularly renege on container contracts so they can charge other shippers higher rates on the spot market; don’t guarantee space on their vessels even when premiums are paid; refuse to negotiate service contracts; limit the amount of capacity they provide shippers; and unfairly charge rent for port storage and late return fees when full terminals are not accepting truck appointments. Many retailers placed orders earlier, used alternate vendors and ports, and moved more cargo by air to get goods to stores in time for the holidays, but are still experiencing delays. Gold said the NRF supports White House efforts to collaborate with supply chain stakeholders on congestion solutions, FMC investigations into ocean carrier and terminal practices and new legislation to regulate the maritime industry. “These are the kind of solutions we need to see — not a study focused on a few retailers who are working to address these challenges,” he told the FTC. Agency watchers say it usually takes a year or two for it to issue a report resulting from a Section 6B order, but Kahn made clear in announcing the study that it needed to move quickly and gather as much information as possible. “Focusing on the practices of a few U.S. retailers who have been trying to address the shipping crisis will not help to solve the issues that persist today.” “The FTC has a long history of pursuing market studies to deepen our understanding of economic conditions and business conduct, and we should continue to make nimble and timely use of these information-gathering tools and authorities,” she said. After the FTC receives the requested documents, it will probably take another 45 to 60 days for staff to review them and make requests for any additional information. The agency will be under pressure to issue a preliminary report by March, the government affairs source predicted. Busting up corporate trusts The FTC’s probe also **fits** within the Biden administration’s worldview that **antitrust rules** need redefining to **contain corporate power**, especially tech giants like Amazon, Apple, Facebook and Google. In recent weeks, officials have blamed food producers, retailers and energy companies for anticompetitive behaviors and pushed for antitrust investigations. Officials say dominant corporations in uncompetitive markets are taking advantage of their market power to raise prices and increase profit margins.

**2---CHIRA repealed the antitrust exemption for insurers**

**MBB 21** Mondaq Business Briefing, United States: New Law Eliminates 75-Year-Old Antitrust Exemption For Business Of Health Insurance, 2-10, l/n

United States: New Law Eliminates 75-Year-Old Antitrust Exemption For Business Of Health Insurance

The Development: Congress unanimously passed and before leaving office, President Trump signed into law, the **C**ompetitive **H**ealth **I**nsurance **R**eform **A**ct ("CHIRA"). CHIRA **limits** application of the McCarran-Ferguson Act, an **exemption** from the federal antitrust laws, as it relates to the business of health insurance. The Context: Since 1945, the McCarran-Ferguson Act has exempted certain conduct of insurers from challenge under the federal antitrust laws. State insurance regulators and the health insurance industry's trade group have long maintained that repealing the McCarran-Ferguson Act is unnecessary, in part, because state antitrust and insurance laws already prohibit conduct such as price fixing that CHIRA proponents claim that McCarran-Ferguson insulates. United States: New Law Eliminates 75-Year-Old Antitrust Exemption For Business Of Health Insuranc Looking Ahead: In addition to the reasons above, CHIRA is not likely to bring significant changes to the operations of health insurers because (i) it leaves the exemption in place for certain critical activities; (ii) other federal antitrust exemptions may nonetheless apply; and (iii) health insurers' procompetitive activities should be found lawful under the federal antitrust laws. However, **antitrust** claims **abhor** a **vacuum**. In the past, **expansion** of antitrust liability in **an industry**, including **health care**, has spawned **waves of litigation**, attracted by automatic treble damages in successful challenges. Health insurers should expect **increased** antitrust **litigation**, and possibly **government investigations**, and therefore should review their **business practices** to ensure compliance with the federal antitrust laws.

**3---NCAA decision---signaled hostility to immunities**

Michael A. **Carrier 21**, Distinguished Professor, Rutgers Law School, The Alston Case: Why the NCAA Did Not Deserve Antitrust Immunity and Did Not Succeed Under a Rule-of-Reason Analysis, 28 Geo. Mason L. Rev. 1461

Conclusion The NCAA did not deserve an antitrust immunity enjoyed by no other entity in American law. The courts' **hostility** to **limits on the scope of antitrust** and social-value defenses made clear that the **NCAA** could not decide that values other than price, quality, and output justify trade restraints. The NCAA's arguments in Alston also did not gain support from Board of Regents. Although the NCAA cited the case 145 times in its briefing, the Supreme Court's ruling in Board of Regents did not rely on amateurism. Rather, the discussion of amateurism was limited to dicta in a setting in which the Court was actively replacing rigid rules with more nuanced economic analysis. 178 Finally, the application of hornbook Rule-of-Reason analysis favored the student-athlete plaintiffs. First, the plaintiffs showed "**severe**" anticompetitive effects. 179Second, the NCAA's purported procompetitive justifications largely rested on its definition of "amateurism" with no showing of any benefit to price, quality, or output. 180And the NCAA succeeded at all at this step only because the courts worked to help it, looking for evidence within its presentation on "amateurism" that could be understood in legally cognizable terms of consumer demand. The NCAA's claims that the lower courts should have considered its justifications as a whole rather than as individual justifications, and that the failure to do so led to a "least restrictive alternative" requirement, did not bear support in the caselaw. 181In fact, the "less restrictive alternative" formulation used was the most demanding standard employed in the caselaw. 182And even if the plaintiffs had not shown a competitively preferred alternative, the case would have proceeded to Step Four - balancing - and under the lopsided evidence of net competitive injury, the plaintiffs most likely would have won. In short, the NCAA was not entitled to the radical restructuring of antitrust law it sought. **The Supreme Court agreed**, finding that the district court's "judgment does not float on a sea of doubt but stands on firm ground - an exhaustive factual record, a thoughtful legal analysis consistent with established antitrust principles, and a healthy dose of judicial humility." 183 In *Alston*, the NCAA sought the knockout punch of antitrust immunity. To put it mildly, **it was not successful**. Student-athletes will be the beneficiaries.

**4---Federal court is limiting farm coop immunities**

Lauren **Berg 1-26**, No Antitrust Immunity For Mushroom Co-Op In Winn-Dixie Suit, https://www.law360.com/articles/1459033/no-antitrust-immunity-for-mushroom-co-op-in-winn-dixie-suit

A Pennsylvania federal judge handed Winn-Dixie Stores a win on Wednesday, finding that even though a mushroom **farm cooperative** changed its name, the group hasn't done enough to **qualify** for antitrust **immunity** in the supermarket company's price-fixing suit. U.S. District Judge Berle M. Schiller granted Winn-Dixie's motion for summary judgment on the issue of whether Eastern Mushroom Marketing Cooperative, now called American Mushroom Cooperative, can claim **antitrust immunity** under the **C**apper-**V**olstead **A**ct, finding that EMMC hasn't satisfied the statute's requirements, according to the 13-page order. The **C**apper-**V**olstead **A**ct gives **ag**ricultural **coop**eratives a limited exemption from antitrust laws if the cooperative and its members produce agricultural products, each member receives an equal vote, the cooperative doesn't pay dividends over 8% per year and it doesn't deal in nonmember products "to an amount greater in value" than those handled by it for members, the order states. In the related case In Re: Mushroom Direct Purchaser Antitrust Litigation, the late U.S. District Judge Thomas N. O'Neill ruled in 2009 that EMMC and its members didn't qualify for immunity because one of the members was actually not a grower and that the cooperative was conspiring with nonmember distributors. In that case, the plaintiffs were only seeking to recover damages sustained through August 2005, while Winn-Dixie seeks damages through at least 2008, the order states. Judge Schiller asked the parties whether Judge O'Neill's ruling applied to EMMC's conduct after August 2005. In its motion, Winn-Dixie contended that after the cooperative changed its name, EMMC still didn't meet the law's requirements because it continued to conspire with nonmember distributors. In its own motion for summary judgment, EMMC argued that it cured the issues Judge O'Neill identified in his 2009 ruling. In his order on Wednesday, Judge Schiller said he can't conclude that EMMC has shown that cooperative member Bella Mushroom Farms and its distributor Buona Foods - which share some overlap in ownership from the same family - should be treated as a single entity incapable of conspiring with one another. Because of that, EMMC can't invoke the protection of the Capper-Volstead Act, the order states, granting Winn-Dixie's motion and denying EMMC's motion. Counsel for the parties did not immediately respond to requests for comment on Wednesday. In 2015, Winn-Dixie and its parent company Bi-Lo Holdings LLC accused **a number of farms** and a **mushroom** marketing **coop**erative of plotting to fix the **price** of fresh Agaricus mushrooms, a genus that includes portobello mushrooms, according to court documents. Others participated in the alleged scheme, but the co-op itself was formed as a "front and a pretext" for "naked price-fixing." Mushroom sellers met to set minimum prices and restrict the supply, court documents state. Almost two dozen farms were released from the suit in January 2019, after the court found that being a member of the co-op was not reason enough for the supermarkets to go after them individually. Winn-Dixie and Bi-Lo renewed their complaint, laying more specific claims that the individual farms participated in the alleged price-fixing scheme. The farms moved for a partial win in August 2020, arguing that Winn-Dixie cannot sustain its antitrust argument for a part of the alleged conspiracy period since it did not buy the mushrooms directly from a purported conspirator. But in May, Judge Schiller denied that bid. Winn-Dixie is represented by Patrick J. Ahern and Theodore B. Bell of Ahern & Associates PC. EMMC is represented by William A. DeStefano, Terri A. Pawelski and Matthew C. Brunelli of Stevens & Lee and Francis X. Taney Jr. of Taney Legal LLC. The case is Winn-Dixie Stores Inc. et al. v. Eastern Mushroom Marketing Cooperative et al., case number 5:15-cv-06480, in the U.S. District Court for the Eastern District of Pennsylvania.

**Trolls**

**Trolls thump R&D---plan is prerequisite**

**Heinecke 15** (Grace Heinecke, J.D. Candidate, 2016, Fordham University School of Law, 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, y2k)

a. Recent **Studies** Provide **Concrete Evidence** of a **Negative Impact on Innovation**

Several recent studies indicate the damage that patent trolls have on innovation. One study, conducted by Harvard University and the University of Texas, aimed to discover how trolls affect innovation at publicly traded companies. 261 As an initial matter, the researchers concluded that "NPEs on average behave as patent trolls," 262 so the study generally uses the terms synonymously. The study found that "as NPEs become **effective** at bringing **opportunistic lawsuits**, they can inefficiently **crowd out** some firms that would otherwise produce welfare-enhancing innovations without engaging in infringement." 263 The study also determined that certain types of firms, including "firms with **large cash balances** and firms with **positive shocks to** their **cash holdings**," are more likely to be **targeted** by NPEs. 264 The study found that "losing to an NPE has a **large** and **negative** impact on future **R&D activities**," with the study's results showing that "firms that lose to a large aggregator NPE … invest **significantly less in R&D** in the years following the loss … relative to firms that were also targeted by NPEs but won." 265 Additionally, patent **trolls** are more likely to sue companies that have a **small legal department** or are tied up in **other litigation**, which may encourage companies to spend [\*1181] money on hiring **lawyers** that could instead be spent on developing **new technology**. 266 Companies may thus invest less in new technologies. 267 They may also make settlement payments to patent trolls to avoid the time and expense of litigation. 268

**Link**

**Turn – sham litigation harms legitimate suits**

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

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

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

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

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

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

**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.

**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.

**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

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**FTC**

**UQ**

**Antitrust is surging and overloading FTC**

Lina **Saigol 22**—reporter for Barron's in London, writes about corporate and financial news. ("M&A Is Booming. Gear Up for an Antitrust Crackdown.," 1/19/2022, from Barron’s, https://www-barrons-com.ezp-prod1.hul.harvard.edu/articles/mergers-booming-us-regulators-crackdown-51642534456?tesla=y)

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.

The FTC may not be able to **cope with the increased workload**. The agency is facing a “**tidal wave**” of merger filings, Holly Vedova, director of the agency’s Bureau of Competition said in a blog post last summer. Its publicly reported numbers bear this out: regulators received **607** Hart-Scott-Rodino premerger notices in November 2021 alone, up from 443 in October.

Because of this **surge**, the FTC said it would be **unable to complete all** reviews within the standard 30-day window and warned companies not to proceed with transactions that have not been fully investigated. The Biden administration, though, has been trying to boost the budget for the FTC.

“Given the significant increase in merger filings, it may be difficult for the FTC and DOJ to fully investigate all mergers that they may feel raise competitive concerns,” James Fishkin, a partner at Dechert’s global antitrust group and a former FTC attorney, said in an interview with Barron’s. “Even the best fisherman can’t catch all the fish and there were many more fish than last year.”

**Thumpers---2AC**

**Antitrust enforcement is rising because Noerr**

**Koenig 1-3** (Bryan Koenig, Senior Competition Reporter @ Law360, The Antitrust Conduct Cases To Watch In 2022, <https://media2.mofo.com/documents/220103-antitrust-conduct-cases-to-watch.pdf>)

U.S. **antitrust enforcers** carried out **dramatic efforts** to combat anticompetitive conduct last year, and all signs show that the **aggressive efforts** will continue in **2022**. Among the **areas** to watch will be criminal and civil cases accusing companies of anticompetitive **collusion** to restrict their workers' **wages** and mobility. Important developments in the cases against **Big Tech** and a key decision on the **i**ntellectual **p**roperty strategies of **pharma**ceutical giants are also expected. Here, Law360 looks at the major antitrust conduct cases to watch in 2022. A Labor Of Enforcement Like 2021 before it, 2022 is expected to see major developments in labor-side antitrust enforcement. After years of promising that it was no longer satisfied with purely civil enforcement and would be pursuing labor-side criminal enforcement as well, the Department of Justice declared the first such indictment in late 2020. The department has also brought charges against alleged wage-fixing, with most charges so far brought in the healthcare space. In December, the DOJ also crucially announced a major expansion of its prosecutions in the form of criminal charges beyond the healthcare space, accusing an apparent former Pratt & Whitney global engineering services director of participating in a conspiracy to restrict the hiring of engineers and other skilled laborers working for engineering services suppliers. Some of the DOJ's new criminal prosecutions will go to trial in 2022. UnitedHealth Group unit Surgical Care Affiliates, for instance, is scheduled to go to trial in May in the DOJ's first criminal case targeting "no-poach" deals between direct competitors restricting the recruitment and hiring of each other's workers. Of particular interest there is whether the Texas federal judge will deem alleged nonsolicitation agreements a per se, or automatic, antitrust violation, which would allow the DOJ to continue pursuing the case criminally. As a matter of policy, the department only pursues harder-to-prove rule of reason cases, which balance allegedly anticompetitive conduct against outcomes and consumer prices, through civil litigation. So far, the DOJ has managed to get per se treatment in at least one wage-fixing case — scheduled for trial in April — but nonsolicitation agreements may be trickier. "DOJ's authority to bring no-poach cases under its criminal authority I think will be tested in the next year," said Megan Gerking of Morrison & Foerster LLP. Beyond Criminal Cases The DOJ likely won't be alone in targeting labor-side conduct as anticompetitive in the new year. The Federal Trade Commission has similarly expressed an interest in protecting workers, including through rulemakings. Davis Wright Tremaine LLP's David Maas said **enforcers** have shown **every sign** they're **not** done with **labor-side enforcement**, which has worked its way into **major policy** statements at both **the DOJ** and **FTC**. "**They're very active** in the space," Maas said. "I would expect to see **significant enforcement** actions." The efforts to expand labor-side enforcement is driven by President Joe Biden's summer executive order aimed at bolstering competition across the economy. David Shaw of Morrison & Foerster notes that the executive order also called for initiatives by other government agencies, too, imposing mandates on and making requests of "a whole bunch of regulators and offices scattered throughout the executive branch." Nor are government agencies the only ones making a mark in labor-side enforcement. State attorneys general and private plaintiffs have been making waves for several years now against major franchisors, especially chain restaurants, accused of baking into their no-poach agreements language restricting individual franchisees from recruiting and hiring from others within the chain. Dozens of chains have sworn off the practice under pressure from state enforcers. In terms of private cases, Christopher G. Renner of Jenner & Block LLP is watching the Eleventh Circuit, where a proposed class of Burger King workers is trying to revive a suit over no-poach provisions in the chain's franchise agreements. The court heard oral arguments in September. According to Renner, the case is one of the first that could shed light on key questions, including the district judge's findings that a franchisor and franchisee are legally incapable of conspiring over the terms of their franchise agreement. Tech Cases Moving Forward The new year is certain to see **important developments** in the **array of litigation** moving forward against **online platforms**, amid a broader reckoning over the power of Big Tech and the ability of antitrust law as written to keep it in check. Practitioners will also be watching Capitol Hill closely for what if any legislation lawmakers manage to finalize as part of that reckoning. The litigation includes the various state and federal enforcement actions against Google and Facebook, as well as the D.C. Attorney General's solo suit against Amazon. Also important is the private litigation against Apple, especially the competing Ninth Circuit appeals from the iPhone-maker and Epic Games after a California federal judge said that Apple wasn't a "monopolist" but barred it from enforcing "anti-steering" provisions meant to keep purchases within the App Store and thus subject to Apple's commissions of up to 30%. The ruling against the anti-steering provisions has been put on hold pending the appeal. Michael Murray of Paul Hastings LLP said that the Ninth Circuit case is "very important for the business community in terms of understanding the relationship of state law to federal law." The reason: U.S. District Judge Yvonne Gonzalez Rogers found that, under federal law, Epic hadn't made out its case, concluding that only under California's Unfair Competition Law could the anti-steering provisions be deemed anticompetitive for their rules barring app developers from telling users about, or directing them to, alternative payment options beyond the App Store. Most of the government enforcement actions against Google will not see trial in the new year. However, one suit from state enforcers consolidated with Epic's claims and proposed classes of Android consumers and developers of apps for the Play Store is eyeing trial in the Fall of 2022 over the search giant's Play Store policies, although that timing could change. A separate group of state attorneys general led by Texas had been eying trial for March or April 2022 on allegations centered on Google's facilitation of and alleged control over the market for placing ads displayed on third-party websites, well ahead of the private lawsuits or other enforcement actions, including one by the DOJ targeting Google's search and search advertising business. But the consolidation of the Texas-led suit with private cases in New York federal court, at least for pretrial purposes, has likely upended those plans, setting back the trial clock significantly. Nevertheless, there is still likely to be a great deal of progress in the cases in 2022, including the continuously contentious discovery process in the DOJ and state attorneys general case accusing Google of monopolizing search and search advertising through a web of contracts with phone companies and others. Evidence gleaned from third parties, according to Jim Mutchnik of Kirkland & Ellis LLP, "can take these cases in a variety of directions." Kirkland's Andrea Agathoklis Murino agrees. Third-party discovery, she said, helps "shine the spotlight." Even so, according to Murino, "the most compelling evidence is from the parties themselves," evidence Mutchnik said enforcers likely already gleaned from their pre-suit investigations. Waiting On The 7th Circuit's **'Patent Thicket' Decision** Almost a year after a Seventh Circuit panel heard oral arguments, a decision could come at any time on whether to revive Humira buyers' suit accusing AbbVie of using a "patent thicket" to illegally shield the blockbuster immunosuppressant from competition. The Humira purchasers launched their first-of-its-kind suit in March 2019, alleging that AbbVie's colossal "patent thicket" had empowered it to block less-expensive versions of the biologic treatment, called biosimilars, in violation of antitrust law. According to the suit, AbbVie also convinced companies such as Amgen Inc. and Sandoz Inc. to drop patent litigation over Humira and stay out of the U.S. until 2023 by giving them access to the $4 billion European market in October 2018. U.S. District Judge Manish Shah tossed the suit in June 2020 after finding AbbVie's patent litigation was **not objectively baseless** and was largely protected by the **Noerr-Pennington doctrine**, which shields certain activity intended to influence legislation or the enforcement of existing laws. The judge also found that AbbVie's settlements with potential biosimilar competitors were lawful because they allowed immediate entry in Europe in exchange for staying out of the U.S., and that the buyers failed to prove they were injured by the alleged activity. The closely watched appeal could send important signals about the legal footing for biologics' patent practices. Buyers seemed to encounter a divided panel in February oral arguments, with Circuit Judge Frank H. Easterbrook pressing plaintiffs to explain how they can accuse AbbVie of protecting the world's bestselling drug with a thicket containing many allegedly "overlapping and non-inventive" patents even though they were granted by the U.S. Patent Office. Conversely, Circuit Judge Diane P. Wood noted that, given the limited selection of patents from the thicket asserted in a given biosimilar case, it wouldn't matter if a patent outside that group was invalid. The plaintiffs argue it's enough to show that at least one company trying to produce a substitute biosimilar version would have prevailed in a challenge to Humira's exclusivity if not for the thicket comprised of some 132 patents — which appears to be the largest of any biologic treatment. That thicket, according to the plaintiffs, forced biosimilar companies, several of which are also **being sued in the current case**, to cut deals allowing earlier entry in European markets in 2018 — access valued in the hundreds of millions of dollars — in exchange for delaying entry into U.S. markets until 2023.

**No Link---2AC**

**Other entities enforce the aff**

Alison **Jones &** William E. **Kovacic 20**, Jones is a professor at King’s College London; Kovacic is Global Competition Professor of Law and Policy, The George Washington University Law School, “Antitrust’s Implementation Blind Side: Challenges to Major Expansion of U.S. Competition Policy,” The Antitrust Bulletin, vol. 65, no. 2, SAGE Publications Inc, 06/01/2020, pp. 227–255

C. Improving Capability: Agency Cooperation and Project Selection The U.S. antitrust system is famous for its **decentralization of the power to prosecute**, giving **many entities** – **public agencies** (at both the **federal and state levels**), **consumers**, and **businesses** – competence to **enforce the federal antitrust laws**. The federal enforcement regime also coexists with state antitrust laws and with sectoral regulation, at the national and state levels, that include competition policy mandates. The **extraordinary decentralization** and **multiplicity of enforcement mechanisms** supply **valuable possibilities** for experimentation and **provide safeguards in case any single enforcement agent is ~~disabled~~** **[hamstringed](**e.g., **due to capture**, **resource austerity**, or **corruption**).75 Among public agencies, there is also the possibility that **federal** and **state** government institutions, while preserving the benefits of experimentation and redundancy, could improve performance through cooperation that allows them to perform tasks collectively that each could accomplish with great difficulty, or not at all, if they act in isolation. In the discussion below, we suggest approaches that preserve the multiplicity of actors in the existing U.S. regime but also promise to improve the performance of the entire system through better inter-agency cooperation – to integrate operations more fully “by contract” rather than a formal consolidation of functions in a smaller number of institutions.

**That’s specifically true with plan---it’s all done via private enforcement**

James D. **Hurwitz 85**, J.D., University of California (Berkeley) Law School, 1972; LL.M., University of London School of Economics and Political Science, 1973; Senior Staff Attorney, Federal Trade Commission, Abuse of Governmental Processes, the First Amendment, and the Boundaries of Noerr. \*, 74 Geo. L.J. 65

Second, even assuming **Noerr's** boundaries are **perfectly drawn**, there nonetheless remain significant policy, **resource**, and practical **constraints** on the ability of **federal antitrust agencies** to redress abusive invocations of governmental process. Antitrust enforcement agencies **do not** and cannot commence litigation **every time** they observe likely antitrust violations. The agencies should limit themselves to situations in which, ideally: there is a demonstrable violation of antitrust law; there is harm is competition, as opposed to specific competitors; less adversarial and resource-intensive forms of enforcement (such as voluntary restraints or consent agreements) appear inappropriate or unpromising; there is a remedy within the agency's jurisdiction; 262 and application of that remedy will advance competition policy. 263 In addition, considerations of comity may inhibit antitrust enforcement agencies from bringing actions against abuses of another agency's processes. Such a case, if not artfully selected, prepared, and articulated, may suggest that the agency whose processes are abused cannot protect the integrity of its own proceedings, or that the antitrust agency has a greater ability to determine what constitutes an abuse than the petitioned agency's own procedural and substantive specialists. The fact that an agency does not act against an alleged abuse of its procedures should raise an inference that there was no abuse. Conversely, if an agency penalizes an abuse, it presumably applies the remedy it deems most appropriate to redress the situation. With the resulting harm minimal in either event, arguably the federal antitrust authorities should leave further action to private enforcement efforts. There will be exceptions, of course, such as when an agency is derelict in protecting its own processes or lacks sufficiently stringent or comprehensive remedial authority, but these situations probably will arise infrequently. **Thus**, shifting the **contours** of the **Noerr** doctrine will **not** predictably **jeopardize** or enhance the contributions **antitrust enforcement agencies** can make in forestalling or correcting abuses of administrative agency processes. Of course, it may be **necessary** to **contract** or expand Noerr in order to achieve **an optimal level of private enforcement**. It is not clear, however, that the present mix of public and private competition policy enforcement is undesirable or, assuming changes are needed, what specific doctrinal alterations would accomplish those changes without creating additional problems.

**Turn---2AC**

**Harkrider**

**Existing standards waste time and resources**

**Helsel 95** (Scott D. Helsel, attorney, Preventing predatory abuses in litigation between business competitors: Focusing on a litigant's reasons for initiating the litigation to ensure a balance between the constitutional right to petition and the Sherman act's guarantee of fair competition in business, 36 Wm. & Mary L. Rev. 1135)

Proposing **a Fairer Test** To Determine When the **Decision To Litigate** Should Create **Antitrust Liability** The Supreme Court's holding in Columbia Pictures completely immunizes meritorious litigation from antitrust liability, regardless of the plaintiff's purpose in initiating the litigation. 139 In practice, Columbia Pictures has **limited** courts' inquiries as to whether litigation was "**objectively baseless**." 140 However, at least one court refused to extend the Court's test further than the facts specific to Columbia Pictures. In USSPOSCO Industries v. Contra Costa County Building and Construction Trades Council, 141 the Ninth Circuit held that Columbia Pictures "provides a strict two-step analysis to assess whether a single action constitutes sham petitioning." 142 When the complaint alleges a series of lawsuits, however, the court held that "[t]he inquiry in such cases is prospective: Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?" 143 Although there is no reason to predicate the direct purpose/incidental effect test on the number of filings made, 144 the 0000\*1162 court's holding does recognize the central focus placed on a litigant's subjective intent. 145 At least two concerns punctuate the Court's decision in Columbia Pictures. First, **a subjective test** that looks only to the litigant's **subjective** motivations in bringing the litigation may punish unjustly litigants who **legitimately** bring suits seeking **a favorable outcome** and may **chill** potential litigants from asserting untested **legal claims**. 146 Second, "**[a] subjective test** also could cause a **tremendous increase** in **time** and **judicial resources** spent to **punish** the rare litigant who lacks any concern for the judicial outcome of a meritorious lawsuit." 147

**Noerr causes FTC trolling**

**Jurata 14** (John "Jay" Jurata, Jr. and Amisha R. Patel, 17TH ANNUAL ANTITRUST SYMPOSIUM: TAMING THE TROLLS: WHY ANTITRUST IS NOT A VIABLE SOLUTION FOR STOPPING PATENT ASSERTION ENTITIES, 21 Geo. Mason L. Rev. 1251)

While no consensus exists on whether Section 5 treatment is appropriate for PAEs under an unfair competition theory of liability, 233 there is less controversy regarding the FTC's authority to pursue claims against deceptive conduct. 234 Earlier this year, well-known **patent troll** MPHJ Technology Investments, LLC ("MPHJ") filed **suit** against the **FTC** in the Western District of Texas in an attempt to **stop the FTC** from taking action against MPHJ under a Section 5 deceptive conduct theory of liability. 235 [Footnote 235] Complaint at 41, MPHJ Tech. Invs., LLC v. FTC, No. 6:14-cv-11, (W.D. Tex. Jan. 13, 2014). In its complaint, MPHJ also alleges that it is bound by Federal Rule of Civil Procedure Rule 11 to engage in presuit investigation (i.e., infringement due diligence) by sending out demand letters, which were designed to identify potential infringers. Id. at 21; see also Hoffman-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1360-61 (Fed. Cir. 2000). As with **traditional allegations** of antitrust liability, the FTC faces the same **Noerr-Pennington** hurdles that **protect** PAE enforcement activity absent proof of "**sham litigation" efforts**. See supra Part II.C.2. [End] Several state attorneys general also have filed suit to stop MPHJ from sending deceptive demand letters to unsophisticated end users. 236 Regardless of the outcome of these disputes, the message is clear: if PAEs engage in activity that is deceptive, they may be held liable under consumer protection laws.

# 1AR – NDT Round 4

## Case

### Circuit Splits

#### Chilling and uncertainty now

Economist 22—Special report: Competition Policy. ("The growing demand for more vigorous antitrust action," Jan 10th, 2022, from https://www-economist-com.ezp-prod1.hul.harvard.edu/special-report/2022/01/10/the-growing-demand-for-more-vigorous-antitrust-action)

Yet bosses, lobbyists and corporate lawyers acknowledge that a chill has descended as regulators test their powers. The dealmaking frenzy may partly reflect a desire to get in under the wire. Without clear rules, companies no longer know when to notify regulators about a deal and must think about competition from the outset. One lobbyist claims that clients with deals pending at the ftc are not getting answers. They may face an investigation halfway through a deal or even after it closes—and in a growing number of jurisdictions. Just one hold-out can put paid to a merger. In March 2021 Applied Materials, an American semiconductor company, scrapped its acquisition of a Japanese rival, which had been approved in America, Europe and Japan, but not in China. Boeing got clearance to merge parts of its business with Embraer, a Brazilian planemaker, everywhere except Europe.

The uncertainty over mergers and rules that might curtail certain practices adds hassle, risk and cost to potential deals. Some business decisions that might once have been made will now never be considered. Value not created as a result is impossible to quantify, but it is surely there.

## CIL

### 1AR -- Constitutionality

**Foreign citations of law crushes the legitimacy of the court**

**Parrish 7** (Austen L. Parrish, Associate Professor of Law, Southwestern Law School. J.D., Indiana University Maurer School of Law, Storm in a Teacup: The U.S. Supreme Court’s Use of Foreign Law, Law<https://www.repository.law.indiana.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1889&context=facpub>)

With this background, it is useful to understand how the scholarly debate has unfolded. First, what is the debate not about? **No one argues** that **foreign institutions** should control **constitutional** meaning. Jurists and scholars do not suggest-indeed would be **foolish** to suggest-that \* foreign rulings are legally binding on American courts;69 or courts may impose **foreign perspectives upon Americans** through **constitutional interpretation**.7 " Nor is this particular debate about whether international law and norms can become authoritative in U.S. constitutional adjudication.71 Rather, the debate is whether the U.S. Supreme Court must categorically ignore foreign law-the opinions of courts in foreign nations-in all constitutional cases.72 Are these authorities, as some imply, "affirmatively barred from U.S. constitutional adjudication? 73 Opponents of the use of foreign law sources answer yes, and base their opposition on two principal arguments. First, some scholars argue that citing to foreign law undermines judicial legitimacy by impermissibly expanding judicial discretion.74 Justice Scalia, for example, asserts that using foreign sources threatens the Court's legitimacy by implicating personal value judgments as to which foreign law to cite.75 His argument is an extension of originalism: the judiciary is an undemocratic institution within a political system whose legitimacy is derived from the consent of the governed. 76 To overcome a threat of illegitimacy, the argument goes, the Court must adhere closely to the text and the original intent of those upon whose authority the legitimacy of the text rests.7 7 "A court that **moves** beyond the **formalism of the text** and the boundaries of original history has exited the objective domain of law and has entered the **subjective enterprise of politics**. 78 Others have made the same point in slightly different ways. Kenneth Anderson argues that citing to **foreign law** invites "judges to 'troll deeply... in the world's corpus juris' to reach **a politically preferred outcome**, '79 a practice which "swings wide the door for the exercise of judges' purely private sensibilities as public justices... [which is] unconstrained and unconstrainable."8 In his recent confirmation hearings, Chief Justice Roberts suggested that relying on **foreign precedent** allows a judge "to incorporate his or her own **personal preferences**, [and] cloak them with the authority of **precedent**."81 He explained it this way: [RIelying on foreign precedent doesn't confine judges. It doesn't limit their discretion the way relying on domestic precedent does.... Foreign law, you can find anything you want. If you don't find it in the decisions of France or Italy, it's in the decisions of Somalia or Japan or Indonesia, or wherever. As somebody said in another context, looking at foreign law for support is like looking out over a crowd and picking out your friends. You can find them. They're there.82 Judge Richard Posner, in the 2005 Harvard Law Review Forward, summed up the concern, suggesting that using foreign law "opens up" "promiscuous opportunities."'83 Second, some argue that citing foreign law is somehow inconsistent with sovereignty. 4 Sovereigntists85 bristle at the idea that **U.S. sovereignty may be impinged upon**, and they therefore attempt to firmly locate **the U.S. Constitution** in peculiarly **American realities** and dismiss the idea that decisions from other courts in other countries may be illuminating.86 Sujit Choudhry has described this view as legal particularism in its mild form and legal hegemony in its extreme version.87 Others have called it exceptionalism, the idea that "the United States Constitution is unique and that the experience surrounding it is unique."' For example, Jed Rubenfeld has argued that Americans and Europeans have funda mentally different constitutional conceptions.89 Ernest Young, in a similar vein, has said that when comparing Western Europe to the United States, "we see divergence rather than convergence on many aspects of values and political culture." 9° In many ways, both arguments are cut from the same cloth. Roger Alford has referred to it as the "international countermajoritarian difficulty": 91 the notion that "federal judges will impose a particular elite's view of good law on a public that might disagree if it understood what was at stake."' Ken Kersch, a political scientist from Princeton, has employed harsher words, arguing that use of foreign materials "is part of an elite-driven, politically-motivated worldwide trend toward judicial governance, which is antithetical to democratic self-rule, if not to the rule of law itself."93 For others, the crux is more banal: unless judges confine themselves to **original** constitutional understandings, they act **illegitimately** and **undemocratically**. 94

#### Even with durable fiat

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

#### First amendment

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

2. First Amendment Interfaces in Non-Antitrust Contexts

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

a. Commercial Speech

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

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

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

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

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

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

#### 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

### 1AR – I/L

**Ilaw is toothless and cant solve any of their impacts**

**Hiken 12** "The Impotence of International Law" Luke Hiken, Associate Director Institute for Public Accuracy, 7-17-'12 <http://www.fpif.org/blog/the_impotence_of_international_law>

Whenever a lawyer or historian describes how a particular action “violates international law” many people stop listening or reading further. It is a bit alienating to hear the words “this action constitutes a violation of international law” time and time again – and especially at the end of a debate when a speaker has no other arguments available. The statement is inevitably followed by: “…and it is a war crime and it denies people their human rights.” A plethora of international law violations are **perpetrated by every major power** in the world **each day,** and thus, **the empty invocation of international law does nothing** but reinforce our own sense of impotence and helplessness in the face of international lawlessness. The **U**nited **S**tates, alone, and on a daily basis **violates every principle** of international law ever envisioned: unprovoked wars of aggression; unmanned drone attacks; tortures and renditions; assassinations of our alleged “enemies”; sales of nuclear weapons; destabilization of unfriendly governments; creating the largest prison population in the world – the list is **virtually endless**. Obviously one would wish that there existed a body of international law that could put an end to these abuses, but such laws **exist in theory, not in practice.** Each time a legal scholar points out the particular treaties being ignored by the superpowers (and everyone else) **the only appropriate response is “so what!”** or “they always say that.” If there is **no enforcement mechanism** to prevent the violations, and no military force with the power to intervene on behalf of those victimized by the violations, what possible good does it do to invoke principles of “truth and justice” that border on fantasy? The assumption is that by invoking human rights principles, legal scholars hope to reinforce the importance of, and need for, such a body of law. Yet, in reality, the invocation means nothing at the present time, and goes nowhere. In the real world, it would be nice to focus on suggestions that are enforceable, and have some potential to prevent the atrocities taking place around the globe.

**ILaw fails --- states will either inevitably cooperate, or ILaw can’t convince them to**

Eric A. **Posner 9**, Kirkland and Ellis Professor of Law at the University of Chicago Law School. The Perils of Global Legalism, 34-6

34 Most global legalists acknowledge that international law is created and enforced by states. They believe that states are willing to expand international law along legalistic lines because states’ long-term interests lie in solving global collective action problems. In the absence of a world govern- ment or other forms of integration, international law seems like the only way for states to solve these problems. The great difﬁculty for the global legalist is explaining why, if states create and maintain international law, **they will also** **not** **break it** when they **prefer to free ride. In the absence of an enforcement mechanism, what ensures that states** that create law and legal institutions that are supposed to solve global collective action prob- lems **will not ignore them?** For the rational choice theorist, the answer is plain: **states cannot solve** **global collective action problems** **by creating institutions that** **themselves** **depend on global collective action.** This is not to say that international law is not possible at all. Certainly, states can cooperate by threatening to retaliate against cheaters, and where international problems are matters of coordination rather than conﬂ ict, international law can go far, indeed.7 But if states (or the individuals who control states) cannot create a global government or q uasi-g overnment institutions, then it seems unlikely that they can solve, in spontaneous fashion, the types of problems that, at the national level, require the action of governments. Global legalists are not enthusiasts for rational choice theory and have 35 grappled with this problem in other ways.8 I will criticize their attempts in chapter 3. Here I want to focus on one approach, which is to insist that just as individuals can be loyal to government, so too can individuals (and their governments) be loyal to international law and be willing to defer to its requirements even when self-i nterest does not strictly demand that they do so. International law has force because (or to the extent that) it is legitimate.9 What makes governance or law legitimate? This is a complicated ques- tion best left to philosophers, but a simple and adequate point for present purposes is that no system of law will be perceived as legitimate unless those governed by that law **believe** that **the law** does good — **serves their interests** or respects and enforces their values. Perhaps more is required than this — such as political participation, for example — but we can treat the ﬁ rst condition as necessary if not sufﬁ cient. If individuals believe that a system of law does not advance their interests and respect their values, that instead it advances the interests of others or is dysfunctional and helps no one at all, they will not believe that the law is legitimate and will not **voluntarily submit to its authority**. Unfortunately, **international** **law** **does not satisfy this condition**, mainly **because of its institutional weaknesses**; but of course, **its** **institutional weaknesses stem from** **the state system —** **states** **are** **not willing to tolerate** **powerful** **international agencies.** In classic international law, states enjoy sovereign equality, which means that international law cannot be created unless all agree, and that international law binds all states equally. What this means is that if nearly everyone in the world agrees that some global legal instrument would be beneﬁ cial (a climate treaty, the UN charter), it **can be blocked by a tiny country** like Iceland (population 300,000) **or** **a** **dictatorship** like North Korea. What is the attraction of a system that puts a tiny country like Iceland on equal footing with China? When then at- torney general Robert Jackson tried to justify American aid for Britain at the onset of World War II on the grounds that the Nazi Germany was the aggressor, international lawyers complained that the United States could not claim neutrality while providing aid to a belligerent — there was no such thing as an aggressor in international law.10 Nazi Germany had not agreed to such a rule of international law; therefore, such a rule could not exist. Only through the destruction of Nazi Germany could international law be changed; East and West Germany could reenter international so- 36 ciety only on other people’s terms. How could such a system be perceived to be legitimate? There is, of course, a reason why international law works in this fash- ion. Because no world government can compel states to comply with inter- national law, states will comply with international law only when doing so is in their interest. In this way, international law always depends on state consent. So international law must take states as they are, which means that little states, big states, good states, and bad states, all exist on a plane of equality.

## Pharma

### 1AR – UQ

#### It's been declining for a decade – check the chart

Lesser and Shah 2019 “Ten years on” Neil Lesser - principal with Deloitte Consulting LLP in the Life Sciences strategy practice and a leader in the Research & Development strategy practice, Sonal Shah – senior manager with the Deloitte Center for Health Solutions within Deloitte Services LP and leads the center’s life sciences research.

https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/measuring-return-from-pharmaceutical-innovation-2019.html

Measuring the return from pharmaceutical innovation

Analysis from the first nine years of our Measuring the return from pharmaceutical innovation series concluded that a transformational change in R&D productivity is required to reverse declining trends in R&D returns across the biopharma industry. Analysis from this, our tenth report, shows that this conclusion is still true today.

Key findings for top 12 biopharma companies:

R&D returns have declined to 1.8 percent—a slight decrease of 0.1 percent from 2018. This represents an average decline of 0.83 percent per year.

The cost of bringing a drug to market decreased from $2,168 million in 2018 to $1,981 in 2019.

This year, the average forecast peak sales per pipeline asset fell below $400 million for the first time, to $376 million in 2019, down from $407 million in 2018.

R&D returns have steadily declined since 2010



**Existing innovations are not “innovative”**

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

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

#### R&D low now

Palgon 17 [Gary Palgon is vice president of healthcare and life sciences solutions at Liaison Technologies. Gary holds a Bachelor of Science degree in Computer and Information Sciences from the University of Florida. 4-7-2017 https://www.liaison.com/2017/04/07/pharmaceutical-rd-process-inherent-data-challenges/]

While pharmaceutical research and development spending is expected to grow at a compounded annual growth rate (CAGR) of 2.8% through 2022, experts and stakeholders are seeing a downward trend in its return on investment (ROI). Pharmaceutical companies are under increasing pressure to either improve the success rates of their R&D or reduce their cost of failure, which a breakthrough typically would cover.

The pharma R&D process yields an average success rate of 4.9% from first toxicity dose to market approval. However, experts are questioning whether drug approvals had already reached its peak in 2015 and will continue to decline following the lower number FDA-approved drugs in 2016. With a bleak outlook on improving success rates for pharma R&D, more and more pharmaceutical companies are reducing their costs of failures through collaboration.

#### Pharma innovation failing

Gaffney 15 [Adam, M.D. Instructor in Medicine at Harvard Medical School, Secretary of Physicians for a National Health Program, MD from New York University “Your Wallet or Your Life: A lifesaving drug’s overnight price hike shows why we must fight for a radically different health care system” 9-22-15 http://www.pnhp.org/news/2015/september/your-wallet-or-your-life]

Some notable exceptions notwithstanding, pharmaceutical development in recent years has been rather disappointing. In a 2012 article in the British Medical Journal, health policy scholars Donald Light and Joel Lexchin laid out this criticism well, arguing that the pharmaceutical industry’s flawed approach towards drug development produces “mostly minor variations on existing drugs” that are usually “not superior on clinical measures.” The pursuit of truly innovative new molecules, in other words, is discarded in favor of highly lucrative, derivative drugs — a consequence of a “hidden business model,” as they describe it, that spends an estimated $19 on marketing for every $1 on basic research.

### 1AR – Joseffer

#### The Joseffer Amicus Brief advocates for the aff

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

\*Same amicus brief as Joseffer

**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**

#### \*\*\* if they dispute, here’s the section of brief about the aff \*\*\*

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

The Third Circuit’s opinion waters down important limits on the “sham” litigation exception to the NoerrPennington doctrine. Litigants, including members of the Chamber, will be deterred from filing suit to vindicate their rights, for fear that courts may declare their lawsuits a “sham”—even where, as here, a trial produced no evidence of subjective unlawful intent. 1. **This Court Established a Two-Step Test for “Sham” Litigation that Requires Proof of Subjective Unlawful Intent** Under the Noerr-Pennington framework, “[a] party who petitions the government for redress generally is immune from antitrust liability.” A.D. Bedell Wholesale Co. v. Philip Morris Inc., 263 F.3d 239, 250 (3d Cir. 2001) (cleaned up). An exception to the doctrine exists if a party files a “sham” lawsuit, which is what the Federal Trade Commission (FTC) alleged here. PRE, 508 U.S. at 56. If the plaintiff succeeds in establishing that the lawsuit is “objectively baseless,” as required in the first step of PRE, then a court “may ... examine the litigant’s subjective motivation.” Amarel v. Connell, 102 F.3d 1494, 1518 (9th Cir. 1996) (citing PRE, 508 U.S. at 60-61); see also U.S. Futures Exch., LLC v. Bd. of Trade of the City of Chicago, Inc., 953 F.3d 955, 963 (7th Cir. 2020) (“The exception requires a two-step inquiry: (1) only if challenged litigation is objectively meritless may a court (2) examine the litigant’s subjective motivation ... In other words, an antitrust plaintiff must ‘disprove the challenged lawsuit’s legal viability’ before proceeding to the second, subjective step.”) (first emphasis in original, second emphasis added); CSMN Inv., LLC v. Cordillera Metro. Dist., 956 F.3d 1276, 1283 (10th Cir. 2020) (“Under the first step, a court considers whether the petitioning has an objectively reasonable basis … If so, immunity applies ... But if not, a court proceeds to the second step, considering the subjective motivation behind the petitioning.”) (citations omitted) **Where a court makes a threshold determination of objective baselessness, the second, subjective prong serves a critical purpose.** It requires the court to determine “whether the baseless lawsuit conceals ‘an attempt to interfere directly with the business relationships of a competitor...’ through the ‘use [of] the governmental process ... as an anticompetitive weapon.’” PRE, 508 U.S. at 60-61. Courts have described this second, subjective prong as demanding. See, e.g., Omni Res. Dev. Corp. v. Conoco, 739 F.2d 1412, 1414 (9th Cir. 1984). 2. The Third Circuit Improperly Conflated the Objective and Subjective Prongs Despite enunciating both prongs of the exception and characterizing the analysis as a “delicate task,” the Third Circuit incorrectly allowed mere satisfaction of the first prong to satisfy proof of the second: subjective intent. Pet. App. 67a. **The Court held**, based on a “syllogism,”2 that if a reasonable person pursues a lawsuit later found, in hindsight, to be **objectively baseless, subjective bad faith can be presumed from that alone**. This defective reasoning effectively collapsed the objective and subjective prongs into a single element. Id. at 69a. The Third Circuit’s erroneous legal standard was necessary to its decision because—even after a 16-day trial—there was “no direct evidence of [these individuals’] subjective intent.” Id. at 66a. This posture, wherein the case has gone through full discovery and a lengthy trial (but produced no evidence of subjective bad faith apart from an attenuated syllogism), illustrates the extent to which the court effectively eliminated the subjective prong. **Unquestionably, the Third Circuit’s decision is at odds with this Court’s decision in PRE that the “sham” litigation exception requires a discrete two-step inquiry**. PRE, 508 U.S. at 60-61. The Third Circuit’s opinion **risks infringement of the protection afforded companies** and businesses to vindicate their rights in an increasingly competitive marketplace. Were this error to stand, it would remain unclear in many circumstances how a court can determine the line between the right to freely petition the government, which Noerr-Pennington protects, and the use of litigation as an “anticompetitive weapon,” which Noerr-Pennington does not. See, e.g., Westmac, Inc. v. Smith, 797 F.2d 313, 318 (6th Cir. 1986) (“Determining whether a party who filed suit was indifferent to obtaining a favorable judgment may often be a difficult question of fact.”); see also Winterland Concessions Co. v. Trela, 735 F.2d 257, 263 (7th Cir. 1984). In light of the considerable confusion displayed by courts about the “sham” litigation exception, including the mistaken view of the Third Circuit (see Part C, infra), this Court should intervene and provide much needed clarity.

### --AT: Objecitve

#### Here are objective criteria

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>

B. Evaluating Cases for Potential Antitrust Liability While antitrust liability should be imposed against companies which maintain anticompetitive, frivolous lawsuits, determining whether a particular action is baseless and anticompetitive may be quite difficult. Indeed, there may be significant legal and practical difficulties in establishing a prima facie antitrust claim, much less proving it. **Nevertheless**, by focusing on Hatch-Waxman cases, **this section suggests several potential criteria** that may assist in identifying appropriate cases. **The first criterion** evaluated is the litigant’s efforts (or lack thereof) in ascertaining infringement prior to filing suit. If a patentee failed to take reasonable steps to evaluate infringement prior to litigation, this may be indicative that the action was filed (and maintained) for an improper purpose. For example, the court **in** In re Neurontin Antitrust Litigation denied a motion to dismiss the antitrust claim in part due to allegations that the patentee never tested or examined the allegedly infringing product prior to filing suit.149 **Second** is examining whether a patentee continuously insists upon an interpretation of its patent claims that is nonsensical, wholly unsupported, or contradicted by either the patent’s specification or its own assertions made before the P.T.O. For example, Raylon v. Complus Data150 involved Raylon’s patent for a hand-held ticketing device that contained its own internal keypad and printer and included a display that was “pivotally mounted on” the device.151 The patent included a drawing that illustrated the invention’s preferred embodiment, which was comprised of (among other things) a rectangular body with buttons for entering data, a location where tickets could be printed out, and a separate display attached to the device.152 Raylon filed patent infringement actions against various software and hardware manufacturers of hand-held ticketing devices.153 In defending the lawsuits, several defendants countered that their products could not infringe on Raylon’s patent because their devices had rigid, fixed-mounted displays that could not be pivoted.154 Raylon did not contest that defendants’ products contained fixed-mounted, non-pivoting displays, but nonetheless maintained that defendants’ devices infringed its patents because those devices could be manually pivoted, i.e., by the person holding the device.155 The District Court rejected Raylon’s arguments as one which “stretch[es] the bounds of reasonableness,” because it was unsupported by the evidence and would essentially ignore the “pivotally mounted” limitation of the patent.156 Nevertheless, the District Court denied defendant’s motion for sanctions and fees under Rule 11 and Section 285.157 On appeal, the Federal Circuit reversed, holding that Raylon’s interpretation of “pivotally mounted” was “frivolous” and “unreasonable” because the patent’s claims, specifications, and preferred embodiment all clearly “show[] a display that is mounted to pivot relative to the housing on which it is attached.”158 Moreover, the Federal Circuit concluded that Raylon’s construction was unsupported by the patent prosecution history (made before the P.T.O) and “does not conform to the standard canons of claims construction.”159 **Third** is examining whether a patentee inexorably asserts infringement, even after discovery and evaluation of the accused product(s) or method(s) substantiate non-infringement. For example, in AstraZeneca v. Dr. Reddy’s, the court was critical of AstraZeneca’s continued position that Dr. Reddy’s generic product infringed its formulation patent despite substantial evidence that Dr. Reddy’s formulation was not 70% crystalline, as required by the asserted patent.160 Similarly, the court in In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation granted fees under Section 285 in part because patentee maintained its lawsuit despite failing to provide any evidence of infringement as to certain claims—even as late as trial.161 **Fourth,** litigation misconduct may evince that the action was initiated and maintained for an improper purpose. For example, in AstraZeneca v. Dr. Reddy’s, one factor in the court’s awarding of fees was patentee’s discovery abuses, i.e., its “wide-ranging” discovery requests which were a mere “fishing-expedition” done for the purpose of deterring competition.162 Similarly, engaging in a pattern of dubious litigation may suggest an improper purpose, particularly when the allegations made in the various actionsappear weak and/or unreasonable. 163 **Finally**, evaluating anticompetitive effects of litigation is also an important consideration in identifying suitable antitrust cases. In the Hatch-Waxman context, filing and maintaining baseless litigation is likely to impede competition in cases where it delays generic entry. In other contexts, it may be far more difficult to demonstrate that sham litigation, either by itself or along with other conduct, is **anticompetitive. Applying these criteria will assist in identifying appropriate cases for potential antitrust liability**. And while the criteria discussed focuses on patent litigation in the Hatch-Waxman context, several may be applied in other contexts. For example, a lack of due diligence in evaluating the strength of one’s claim prior to filing suit may be indicative of improper motive in nearly any action. Similarly, continuing to take an unreasonable and unsupportable position throughout litigation concerning the language of a relevant document (such as a contract)—particularly if inconsistent or even contradicted by other evidence—is likely to suggest an improper motive for the litigation. Finally, misconduct during the course of litigation surely happens in all types of cases, and in certain situations may evidence that the litigation is being maintained for an improper purpose.

### 1AR – L/T – Good Faith Good

**Turn the Plan is exactly what Gidley wants**

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

SUMMARY OF THE ARGUMENT **This Court should grant the petition for a writ of cert**iorari **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 so called “reverse-payment” settlement agreements in the pharmaceutical industry are necessarily anticompetitive. After failing to convince this Court in Actavis to adopt a “quick-look” approach to evaluating reverse-payment settlement agreements, the FTCis **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 pharma**ceutical **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.

### 1AR – L/T – Small Companies O/W

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

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

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

**Turn – sham litigation harms legitimate suits**

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

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

### 1AR -- Patent Thickets Bad

#### Models demonstrate patent thickets substantially deck innovation

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

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

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

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

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

Figure 2. The effect of thickets on technology entry

Chart

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

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

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

#### Specifically, in pharma

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

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

#### Broad consensus agrees

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

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

#### Thickets blunt competition even without entry

James Bessen 4—Research on Innovation, Boston University School of Law. ("Patent Thickets: Strategic Patenting of Complex Technologies, http://www.researchoninnovation.org/thicket.pdf)

The model presented here suggests that patents may be an inefficient or defective property right if technologies are complex and patent standards are low. This is because patents do not, in fact, convey exclusive ownership over the relevant productive assets when a single technology involves large numbers of patents. The patent race model and the prospect model of patents depend on the crucial assumption that a productive innovation uniquely corresponds to just a single patent.

But when technologies are complex and standards are low, ownership is shared and the rents earned on an innovation are shared as well. This means that innovation incentives are too low even with efficient contracting and ignoring entry deterrence. Moreover, patents do not merely fail to provide sufficiently strong incentives in this case; they may also destroy the market-based incentives of lead time advantages. In effect, with low standards and complex technologies, patents serve to subsidize the losers of innovation races (paid by the winners), especially if those losers are large patent holders in mature industries. Schumpeterian competition is blunted.

Schumpeterian competition and more optimal R&D levels can be sustained in industries with lead time advantages if patenting standards are sufficiently high (or if few patents are granted, as in the software industry historically). But competition is not enhanced by reducing patenting standards, even if such changes “strengthen” patents in the sense of making patents less costly to obtain or otherwise favoring patent holders.

Much of the literature discussing patent thickets has focused on potential problems of transaction costs, holdup and vertical monopoly. This paper demonstrates that patent thicket strategies can discourage innovation even without these problems. This means that although cross-licensing and patent pools may resolve some problems of transaction cost and vertical monopoly, these institutions do not correct all problems associated with patent thickets.