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#### The 1AC’s construct of the firm as the locus of competitive innovation reproduces neoclassical economic orthodoxy. Antitrust is justified as an intervention to correct “market failures.” Market failure relies on the ideal of perfect competition.

Nathan **TANKUS** Research Director Modern Monetary Network **AND** Luke **HERRINE** PhD Candidate @ Yale Law, JD NYU & Former Clerk Second Circuit of Appeals **’21** “Competition Law as Collective Bargaining Law” <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3847377> p. 1-3

­ “[T]oo often discourse about ‘the market’ conveys the sense of something definite—a space or constitution of exchange...when in fact, sometimes unknown to the term’s user, it is being employed as a metaphor of economic process, or an idealisation or abstraction from that process.” – E.P. Thompson2 Introduction To those who study governance of the labor relationship, it is obvious that the relationship between business and labor must be governed, and that stability in this social relation is something valued by labor, business, and society writ large.3 Strangely, the idea that governance is necessary and price stability is good are both obscure interlopers to the study of competition law. To bridge the gap between these two areas of law--and incidentally give labor a greater role and stature in theorizing competition law--we aim to provide a general “market governance” framework for understanding how markets are governed in the context of the legal rules that allow and disallow certain forms of coordination. This framework draws from multiple heterodox traditions in political economy, but is particularly oriented toward building out the emerging framework of Neochartalist microeconomics.4

[Insert Footnote 4 – Turner]

Neochartalism, or Modern Monetary Theory (MMT), began as a macroeconomic framework for understanding how legal institutions produce and reproduce money and monetary value, particularly the acceptance of monetary objects in payments of taxes and court-ordered obligations. In developing over the last twenty-five years, Neochartalism has become an interdisciplinary perspective for understanding and reinterpreting a variety of social phenomena. Some scholarship, particularly the path-breaking work of the late economist Fred Lee (who we rely on in conceptualizing issues in this chapter) builds up a microeconomic framework that is uniquely consistent with--and reliant on--MMT insights. We hope others choose to follow Lee and ourselves in making contributions to Neochartalist Microeconomics and expanding the reach of Neochartalism in a variety of subfields that remain dominated by mainstream microeconomics.

While it is beyond the scope of the current chapter to identify all the ways in which our current perspective accords with unique insights of Neochartalism, our focus on potential financial and market instability, money prices and money income as a focus of analysis rather than relative prices and “real variables'' reflect our Neochartalist lens. Our focus on the legal construction of markets also adds to Neochartalism’s emphasis on the legal construction of a monetary production economy in general. Our focus on inherent and irreducible mediated social interdependence also accords with the scholarly perspective that Neochartalist humanities scholars bring to Neochartalism e.g. SCOTT FERGUSON, DECLARATIONS OF DEPENDENCE: MONEY, AESTHETICS, AND THE POLITICS OF CARE (2018).

[End footnote 4]

Arriving at a theory of market governance requires rejecting economic common sense. Far too much economics scholarship--both among orthodox scholars and their critics--treats “perfect competition” as the analytical (and often normative) baseline for all markets, including labor markets. Under perfect competition, prices (including wages) are arrived at entirely via the uncoordinated matching of bids and asks, assumed to result in settled equilibriums represented by intersecting supply and demand curves. If all markets are perfectly competitive (and certain other conditions obtain), then each input and output has its proper price which sends “signals” throughout the economy and results in a perfectly “efficient” allocation of resources. From this perspective, coordination, especially coordination over prices (again, including wages), appears as an unnatural intervention, a way for those acting collectively to collect “rents” above the “real” value of their contribution to society. If coordination is to be justified, it is usually to correct for some other deviation from perfect competition: workers might bargain collectively to capture some of a monopsonist's rents, for example. And, indeed, many of those trained in economics who advocate for collective bargaining or other worker-empowerment measures appeal to one or more “market failures”.5 In doing so, they reproduce the idea— intentionally or not—that if competition were finally left to do its work it would reveal the prices that reflect the allocation of goods and services that perfectly matches relative scarcity, that markets would work “better” if they were moved “closer” to (or to “resemble” or “approximate”) the “competitive” ideal.6 Collective bargaining is a distortion, but it is the best we can do in our distorted world.

But here's the rub: collective bargaining is not a distortion of a preexisting “labor market”. More generally, coordination between market participants (over price or other matters) is not in itself a distortion of any market. There is not and has never been a market without coordination, including over prices.

#### Neoclassical paradigm will destroy humanity and the biosphere.

Anne **FREMAUX** PhD Political Ecology & Philosophy @ Grenoble ‘**19** *After the Anthropocene: Green Republicanism in a Post-Capitalist World* p. 1-3

If the main starting point of this book is the severe environmental crisis we are facing and the natural planet-wide collapse toward which we are heading, today’s ecological reality is powerfully connected to other issues such as growing socioeconomic inequalities, the erosion of democratic institutions, the organized apathy of citizens, the loss of power of nation-states in favor of corporations, the progressive disappearance of the notion of common good, and the economic colonization of the social, cultural, and political life by economic objectives. The global ecological crisis reveals these interlinked disasters caused by the core components of capitalism that include: an excessive exploitation of nature, the rise of industrialism, the self-destructive over- confidence in human-technical power, the arrogant anthropocentric mind- set, and denial of ecological limits, as well as the narrow rationalism and materialism that develop within a reductionist predominant form of science.

Neoliberalism as a ‘global system’ threatens societies as a whole and more especially the core values of social communities and democracy, such as justice, ‘common decency,’ civic virtue, or citizenship. In neoliberal patterns, economic efficiency, market values, employability, consumer freedom, and instrumental rationality are favored over democratic participation, civic values, personal autonomy, active citizenship, intellectual development (‘enlightenment’1), and moral rationality (reasonability2). Institutions dedicated to the common good are systematically turned into competitive structures to satisfy the interests of markets and greedy elites. Pluralism is disappearing under the assault of a one-dimensional consumer pattern which treats humans and non-humans as commodities under the hegemony of private interests. Civil society, an essential element of the agonistic and critical democracy defended in this book, is losing out to ‘spectator democracy.’ Indeed, citizens are more and more passive and self-centered in part because existing political and democratic structures leave them with few opportunities to participate and make collective decisions. As a consequence, the link between democratic politics and citizens is being critically weakened. Neoliberal individuals end up being overtaken by lassitude and resignation, indifference, and loss of interest for the shared common world. What defines neoliberal society is, indeed, a widespread disaffection for democracy and social bonds entailed by the loss of political agency and self-determination. In such a system, propaganda is necessary to manufacture consent3 and to shape the fundamental values to ensure that individuals see themselves as consumers, workers, or owners of capital, rather than citizens, spiritual or relational individuals, friends, or members of social and ecological communities. In order to be fully operational, such a system must also rely on high doses of cynicism and the value of relativism cultivated by deconstructive postmodern views.

Neoliberal competitive market-state systems have colonized all aspects of life, but mainly, they have subjugated nature and used it as an ‘unlimited’ spring of profit and resources intended to feed the logic of growth. The globalized neoliberal framework behaves as if nature were only a neutral background for profit-seeking and economic development. In order to push back the ecological limits that are more and more visible, neoliberals argue that those limits can be transcended through decoupling and technological innovations (Chapter 5). Indeed, constructivist neoliberal governments act as if the biosphere were a mere component of the socioeconomic sphere. As an anti-ecological ideology, neoliberalism denies the existence of natural limits and promotes unlimited material wants vs. limited resources, a cult of endless consumption (consumerism), and techno-fixes (techno-optimism) as the solution to social and ecological problems. The appropriation and commodification of nature undertaken by this form of economic ideology and the freedom it enshrines—understood mainly as the legitimate exercise of extractive power—entail that the environment is viewed only as an instrumental source of raw material and sinks of fossil fuels rather than as an ethically valuable physical, biological, and chemical context of life. Inevitably, this type of economy has supported an insatiable extraction that is today overwhelming ecosystemic capacities. Neoclassical economics is certainly the instrumental form of rationality ‘that most actively opposes the ethical valuation of the environment’ (Smith, 2001: 26).

The neoliberal capitalist agenda, associated with an arrogant anthropocentrism and the technological optimism of many political leaders, experts, techno-scientists, academics, and citizens, has transformed nature and people into raw materials (‘natural’ and ‘human resources’). It has replaced democratic and republican institutions—defined by their concern for the common good—by structures aiming at facilitating the activities and profits of corporations and markets. It has deprived Western political structures of substantial democratic energy by turning citizens of wealthy liberal nations into demoralized and nihilist homo oeconomicus (‘neoliberal citizens’), that is, passive consumers as opposed to active citizens. More than that, neoliberalism, through mass media, entertainment, information, and educational systems, has incrementally converted all the spheres, activities, and dimen- sions of life into economic ones (‘economization’ or ‘marketization’ of life). Private and public institutions are used as ways to transmit the values of capitalism.4 As an unethical and unsustainable model of commercialization, ultraliberal capitalism supports crass commodification, intensifies ine-ualities and transforms everything in its way—from non-human nature to human beings—into replaceable, dispensable and disposable products. As a global threat, neoliberalism leads to ‘environmental stresses (water shortages, deforestation, soil erosion or climate change), food and energy insecurity, peak oil, rising poverty and inequalities within and between societies, increasing passivity of citizens within democracies and the inexorable rise of corporate power within and over the democratic state’ (Barry, 2008: 3).

The price we, humans, are socially, politically and ecologically paying and will continue to pay in the future for the triumph of the neoliberal ideology is disproportionate with anything humankind has experienced so far (see Fig. 1.2). However, human relatively recent history already shows that the popular passivity and political apathy (mentioned above) fostered by cynical and disempowering systems of ideas have the potential to favour the rise of dictatorial regimes in which a father figure or ‘strong man’ could take upon the conduct of public affairs. At a time when chauvinistic, racist, anti-elitist, and macho-ist parties are dangerously rising in all Western countries, this fear is taking a serious turn, which includes the risk of an authoritarian ecology.

#### We should use the framework of challenge-driven political economy instead of a competitiveness framework. Using the power of the state to make and shape markets is key to direct policy to solve inequality and climate change.

Mariana **MAZZUCATO** Inst. for Innovation & Public Purpose @ University College (London) **AND** Rainer **KATTEL** Inst. for Innovation & Public Purpose @ University College (London) **’20** “Grand Challenges, Industrial Policy, and Public Value” Non-paginated

Twenty-first-century policymaking is increasingly defined by the need to respond to major social, environmental, and economic challenges. Sometimes referred to as ‘grand challenges’, these include threats like climate change, demographic, health, and well-being concerns, as well as the difficulties of generating sustainable and inclusive growth. Against this background, policymakers are increasingly embracing the idea of using industrial and innovation policy to tackle these ‘grand challenges’. Examples of challenge-led policy frameworks include the United Nation’s Sustainable Development Goals (SDGs; Borras,­­ 2019), the European Union’s Horizon Europe research and development programme (Mazzucato, 2018a), and the UK’s 2017 Industrial Strategy White Paper (HM Government, 2018).

Challenge-driven policy frameworks are emerging in parallel to well-established modernization and competitiveness frameworks**.** While 1 2 modernization, and in particular competitiveness frameworks, rely on the idea that government should first and foremost fix market failures,3 a challenge-driven agenda does not have such clearly defined theoretical origins and analytical lenses. As Richard Nelson argued in 1977 in his seminal book The Moon and the Ghetto, getting man to the moon and back is not the same as solving the problem of ghettos in American cities. Put differently, the nature of our knowledge about socio-economic challenges differs from our perception of strictly technical challenges. We can discover answers to technical puzzles; socio-economic issues do not have a single correct discoverable solution. Such issues require continuous discussion, experimentation, and learning.

We believe challenge-led growth requires a new conceptual and analytical framework that has at its core the idea of confronting the direction of growth with growth that is, for example, more inclusive and sustainable. Such a framework should focus on market shaping and market co-creating (Mazzucato, 2016). This is a question of both theory and policy practice. In theory, challenge-driven innovation policy questions both established neoclassical and evolutionary concepts (Schot and Steinmueller, 2018). In policy practice, directed policies require rethinking what is meant by ‘vertical policies’.

Industrial policies have always been composed of both a horizontal and a vertical element. Horizontal policies have historically been focused on skills, infrastructure, and education, while vertical policies have focused on sectors like transport, health, energy, or technologies. These two traditional approaches roughly embody differing schools of economics: neoclassical economics-inspired horizontal policies focusing on supply-side factors and inputs; and evolutionary economics-inspired policies putting emphasis on demand-side factors and systemic interactions (Nelson and Winter, 1974; Hausmann and Rodrik, 2006 for a synthesis). Although certain sectors might be more suited to sectorspecific vertical strategies, the ‘grand challenges’ expressed in SDGs are cross-sectoral by nature and hence we cannot simply apply a vertical approach to them. Both neoclassical and evolutionary approaches to industrial policy have relied on the idea that the best policy outcome is economy-wide development, without specifying its nature. In policy this has led to managing economies according to GDP growth rates, competitiveness indices and rankings, or other macro indicators (e.g. exports, patents) (Drechsler, 2019). Yet, many SDGs are only indirectly related to the economy and hence many of the key issues around SDGs have not been theorized in the context of innovation and industrial policy (see, e.g., Zehavi and Brenzitz, 2017).

In this chapter we argue that through well-defined goals, or more specifically ‘missions’, that are focused on solving important societal challenges, policymakers have the opportunity to determine the direction of growth by making strategic investments, coordinating actions across many different sectors, and nurturing new industrial landscapes that the private sector can develop further (Mazzucato, 2017; Mazzucato and Penna, 2016). The result would be an increase in cross-sectoral learning and macroeconomic stability. This ‘mission-oriented’ approach to industrial policy is not about top-down planning by an overbearing state; it is about providing a direction for growth, increasing business expectations about future growth areas, and catalysing activity—self-discovery by firms (Hausmann and Rodrik, 2003)—that otherwise would not happen (Mazzucato and Perez, 2015). It is not about de-risking and levelling the playing field, nor about supporting more competitive sectors over less (Aghion et al., 2015), since the market does not always know best, but about tilting the playing field in the direction of the desired societal goals, such as the SDGs. However, we argue, to achieve this requires a new analytical framework based on the idea of public value and a policymaking framework aimed at shaping markets in addition to fixing various existing failures. Indeed, we argue that if we want to take grand challenges such as the SDGs seriously as policy goals, market shaping should become the overarching approach followed in various policy fields.

### Advantage CP – 1NC

#### The United States federal government, including the Patent and Trademark Office and International Trade Commission, should:

#### Establish that the sham exception to Noerr-Pennington antitrust immunity requires findings of both objective baselessness and subjective intent to act anticompetitively and that serial litigation is not sufficient to trigger antitrust liability without a finding of objective baselessness.

#### Apply the doctrine of patent law to restrict unfair methods of competition by Patent Assertion Entities

#### Limit citizen petitioning of the Food and Drug Administration via parallel review, defined time frames for submission and review of petitions by brand-name manufacturers, required disclosures of conflicts of interest, and automatic dismissal of petitions based on fraud and misrepresentation.

#### Overturn *Citizens United v. FEC*, increase funding for Congressional staffing, and prohibit members of Congress from lobbying after returning to the private sector.

#### The first plank has the court codify the status quo – that provides certainty and resolves circuit splits.

#### The patent plank allows the ITC to restrict unfair complaints by patent trolls – solves the advantage

Donahey ’16 [Teague; intellectual property litigator in the Boise, Idaho office of Holland & Hart; July/August 2016; “Expanding horizon of Section 337 jurisdiction”; <https://www.hollandhart.com/files/36919_IPM_July_Aug_2016-Feat.pdf>; accessed 10/28/21; TV]

Under 19 USC § 1337 (“Section 337”), the US International Trade Commission (ITC) is authorised to investigate and adjudicate international trade disputes involving imported products. For many years, the ITC has been one of the most popular venues in the US for patent litigation, and contentious patent infringement disputes have consumed the vast majority of the ITC’s § 337 bandwidth over the years. Parties involved in cross-border business disputes, however, should recognise that the scope of the ITC’s § 337 jurisdiction is much broader than just patents. Indeed, under the express language of § 337, the statute operates to address any number of “unfair methods of competition” and “unfair acts” related to products imported into the US, and the precise contours of this ambiguous language have never been determined.

The ITC’s popularity as a forum for patent infringement disputes

The ITC’s popularity as a patent infringement forum derives from several key factors. First, the ITC is statutory mandated to complete its investigations in an expeditious fashion – approximately 18 months, which is much faster than the typical case in the federal court system – placing enormous practical and financial pressures on defendants, who are termed respondents in ITC parlance. Such pressures are often sufficient to drive early settlement, thereby avoiding what can seem like endless litigation in federal court.

Secondly, § 337 offers US complainants powerful statutory remedies: exclusion orders barring infringing products from being imported into the US, which are enforced by US Customs and Border Protection (CBP), as well as cease-and-desist orders prohibiting related conduct (eg, product-marketing activities) within the US. These remedial orders are effectively injunctive relief, which has become more difficult to obtain in US courts given developments in patent infringement case law.

Thirdly, although proper notice must be given to all respondents, § 337 proceedings are ultimately adjudicated on an in rem basis against the imported products. This is significant, given that US complainants often face enforcement challenges when required to proceed on an in personam basis in US courts against overseas infringers.

Fourthly, in contrast to US courts, the ITC is unlikely to stay its § 337 proceedings during co-pending inter partes review (IPR) proceedings before the US Patent & Trademark Office involving the same patent or patents. Thus, an ITC respondent is typically unable to block the enforcement proceeding by filing an IPR petition – a typical defence tactic.

ITC § 337 proceedings apply to essentially all IP disputes involving imported goods

The ITC’s historical focus on patents, however, has obscured the fact that § 337 is, at heart, a trade provision covering a much broader range of unfair trade practices. In addition to patent infringement, § 337 expressly reaches disputes involving trademark or copyright infringement, as well as infringement of statutory rights with respect to semiconductor mask works and vessel hull designs. Section 337 also covers other “unfair methods of competition and unfair acts”, which language has been understood to include such practices as trade secret misappropriation, unfair competition and passing off, false advertising and false designation of origin, trademark dilution, trade dress infringement and antitrust violations.1

One recent and prominent example of a non-patent § 337 adjudication was Converse’s 2014 complaint2 against 31 different respondent entities alleging trademark infringement related to Converse’s All Star/Chuck Taylor shoe line, along with claims for false designation of origin, unfair competition under the Lanham Act and trademark dilution. The ITC Administrative Law Judge ruled in Converse’s favour and recommended an exclusion order. Several years earlier, in a landmark 2012 case, Louis Vuitton was similarly successful in obtaining an ITC exclusion order against counterfeit handbags and luggage.3

In another highly publicised § 337 investigation,4 the ITC issued an exclusion order in 2009 barring the importation of cast steel railway wheels from China. The ITC’s determination was based on its finding that a misappropriation of trade secrets had occurred and an exclusion order was issued against the implicated products on an in rem basis even though the misappropriation had occurred abroad, in China.

The full breadth of the ITC’s § 337 jurisdiction remains untested

Notwithstanding the diverse nature of such decisions, § 337’s disjunctive reference to both unfair methods of competition and, separately, unfair acts indicates that the ITC’s § 337 jurisdiction is likely even broader. Indeed, it has long been recognised that the statutory unfair acts language provides a distinct basis for jurisdiction over and above the statute’s reference to unfair methods of competition.5

When § 337’s predecessor statute – the Tariff Act of 1922 – was originally enacted, the Senate Finance Committee reported that the provision was “broad enough to prevent every type and form of unfair practice”.6 Similarly, an early appellate decision explained that the provision’s language “is broad and inclusive and should not be held to be limited to acts coming within the technical definition of unfair methods of competition as applied in some decisions… Congress intended to allow wide discretion in determining what practices are to be regarded as unfair.”7

Although the concept of unfairness is inherently vague, the ITC has attempted to define the scope of unfair acts under § 337 as being “within the general range of practices ‘heretofore regarded as opposed to good morals because characterised by deception, bad faith, fraud or oppression, or as against public policy because of their dangerous tendency unduly to hinder competition or create monopoly’.”8 The ITC has further indicated that “the concept of an unfair act involves some sense of an intentional tort which constitutes an offence not merely against the immediate victim, but against the values of society as well”– in summary: “intentionally tortious behaviour contrary to public morals”.9

The ITC and the courts have also occasionally sought guidance from § 5 of the Federal Trade Commission Act (15 USC § 45), which, using language almost identical to § 337, empowers the Federal Trade Commission (FTC) to prohibit “unfair methods of competition” and “unfair or deceptive acts or practices”. In this regard, the FTC, somewhat cryptically, has interpreted the FTC Act’s reference to unfair methods of competition as including “not only those acts and practices that violate the Sherman or Clayton Act but also those that contravene the spirit of the antitrust laws and those that, if allowed to mature or complete, could violate the Sherman or Clayton Act.”10 The FTC Act’s separate reference to unfair acts is currently understood to be directed to consumer unfairness, with ‘unfairness’ being evaluated in light of the following factors: whether the practice injures consumers; whether it violates established public policy; and whether it is unethical or unscrupulous.11 Courts have emphasised that § 5 is intended to be flexible and that unfairness should be determined on case-by-case basis in light of the facts.

Going forward, it remains to be seen how far the ITC will permit the unfairness envelope to be pushed. Section 337 litigants have raised claims such as breach of contract and tortious interference, for example, although the jurisdictional viability of such claims has not been conclusively resolved. Could such claims ever constitute the required “intentionally tortious behaviour contrary to public morals”, or do they constitute merely private offences directed at the immediate victim alone – offences less likely to give rise to § 337 jurisdiction? Recent observers have gone further and proposed that § 337 could cover circumstances rarely conceived as being relevant to the statute. For example, it has been surmised that § 337 could be invoked to prevent the importation of products manufactured overseas in circumstances involving: human rights violations; child labour; violations of environmental norms; food and drug safety violations; endangered plant or animal species; and/or conflict minerals.12 All of these types of conduct could arguably provide the foreign manufacturer of imported goods an unfair cost advantage over US competitors and, as such, constitute unfair methods of competition and unfair acts within the spirit of § 337. But any such claims would move § 337 well beyond its traditional frame of reference.

Regardless, it is clear that the ITC’s § 337 jurisdiction is not limited to patent infringement disputes, despite past practice before the Commission. Indeed, essentially any intellectual property dispute involving products imported into the US would be a strong candidate for § 337 enforcement before the ITC.

#### Reducing Noerr immunity to solve patent trolls distorts antitrust law and links to every disad – using patent law alone is comparatively more effective

Sipe ’17 [Matthew G; J.D., Yale Law School; B.A., University of Virginia; 2017; “Patents v. Antitrust: Preempting Conflict”; <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1958&context=aulr>; American University Law Review, Vol. 66, Issue 2; accessed 10/12/21; TV]

The analysis in Part IV examines the extent that conflicting guidance and requirements are likely to emerge if antitrust law and patent law are permitted to overlap. That analysis focused primarily on the damage that overlap would do to patent law: from disrupting the “fine, complex, detailed line[s]” of patent doctrines to improperly interpreting patents due to a lack of requisite “expertise.”298 But as antitrust law increasingly attempts to supervise patent activity, antitrust law itself is at risk of warping as well.

For example, antitrust courts have attempted in recent years to police patent trolls: entities that acquire and enforce patents without actually practicing them.299 The troll business model—acquiring licensing fees from entities that actually do create goods and services— has led many academics and policymakers to characterize them as a pure anticompetitive nuisance worthy of antitrust intervention.300 But there are “clear doctrinal . . . roadblocks to leveraging antitrust law” to police much of patent troll behavior, ranging from “quasiconstitutional” protections to textual limitations.301

In terms of constitutional protections, the Supreme Court has established that the First Amendment’s protection of the right to petition grants presumptive immunity from liability under the antitrust laws for “attempts to influence the passage or enforcement of laws,” such as patent infringement suits.302 This immunity applies even when a suit is brought with anticompetitive intent:

Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act. The jury should have been so instructed and, given the obviously telling nature of this evidence, we cannot hold this lapse to be mere harmless error.303

The only exception to this immunity is where a lawsuit is a “sham,” determined by a two-prong test: (1) the suit “must be objectively baseless,” such that “no reasonable litigant could realistically expect success on the merits,” and (2) the suit must be brought with the “subjective motivation” to interfere with a competitor through “governmental process—as opposed to the outcome of that process.”304

However, neither prong is likely to be met in many troll cases. With regard to the first prong, the patent quality of troll portfolios is generally at least as high as portfolios owned by non-trolls,305 and patents owned by trolls tend to fare no better or worse on average in reexamination proceedings.306 With regards to the second prong, troll plaintiffs genuinely hope to succeed on the merits. Trolls, by definition, do not participate in the actual product market—and hence are not in competition with the product sellers—so merely hurting producers through nuisance litigation does them no good. A successful infringement suit, on the other hand, grants them damages. As a result, for antitrust law to reach patent trolls, arguably the most important carve-out from antitrust liability307 would need to be eroded.

In terms of textual limitations, in the types of patent troll cases where immunity does not apply, commentators have frequently suggested using section 5 of the Federal Trade Commission Act as the doctrinal hook for antitrust enforcement.308 The scope of section 5— prohibiting any “unfair or deceptive acts or practices in or affecting commerce”309—is quite broad. This breadth makes it a seemingly natural tool against a novel threat like patent trolls, who do not appear to implicate other antitrust laws.310 But the use of section 5 as a catchall to expand antitrust law’s reach has significant drawbacks. Critics rightly point out the “apparent absence of limiting principles” in both section 5’s language311 and interpretation,312 and the commensurate risk of uncertainty and rent-seeking generated by its application in novel contexts.313 Attempts to police patent trolls only exacerbate this increasingly atextual approach to antitrust enforcement.

Hence, if antitrust law is to play a role in policing patent troll activity, it would first have to “distort” antitrust law in order to do so,314 whether by overriding key doctrinal carve-outs or by permitting atextual expansion. Either way, the existing risk of false antitrust positives and chilling effects associated with antitrust intervention is increased significantly. In comparison, patent law may already have the tools to curtail troll behavior.315 Where, as in the context of patent trolls, antitrust law must be stretched or distorted in order to reach patent activity, the benefits of preemption as an alternative are therefore substantial.

#### The FDA regulation plank solves citizen petitions

Lee 10 – Stacey B. Lee, Assistant Professor, Johns Hopkins University Carey School of Business, “Is a Cure on the Way? – The Bad Medicine of Generics, Citizen Petitions, and *Noerr-Pennington* Immunity,” 2010, 20 KAN. J.L. & PUB. POL'y 98

Regulatory reforms are necessary to safeguard the citizen petition process. 259 First, the Agency should define what constitutes a delaying petition. Second, the FDA should automatically dismiss serial petitions and petitions based on fraud or misrepresentations. Third, the FDA should classify petitions dismissed under these categories as "objectively baseless." If the FDA has determined a petition is objectively baseless, courts should accept that determination and hold that the objectively baseless element of the sham exception test is satisfied.

Abusing government processes will continue so long as there is no penalty for engaging in this type of conduct. The FDA could discourage the most rampant abuse of sham petitions by exercising its discretion to refer unsuccessful citizen petitions to the FTC or Department of Justice. The Citizen Petition Fairness and Accuracy Act of 2006 would have given the Department of Health and Human Services the power to sanction those who abuse the citizen petition process.260 Possible sanctions would have included a fine of up to $1 million, a suspension or permanent revocation of the right of the violator to file future citizen petitions, and a dismissal of the petition.2 61 However, there was not sufficient support in Congress to pass this legislation. 262 Congress should refer to this legislation for guidance in drafting a new bill to protect the citizen petition process from abuse.

Another area that must be improved is the adherence to the 180-day regulatory review requirement. Divorcing the ANDA approval process from the review process of citizen petitions has improved efficiency, but more must be done. In 2009, the FDA still did not complete all citizen petition reviews within the required 180 days.263 Stricter agency adherence to the regulatory time frames would increase efficiency and decrease brand-name manufacturers' ability to benefit from unofficial patent extensions due to the delay incurred during the FDA review process.

Additionally, the FDA should seek to improve the speed of its internal review process. Rather than the current system of consecutive reviews by legal and scientific experts, the Agency should route a petition based on an initial determination as to whether it raised valid legal or scientific concerns. 264 If the petition raised both valid legal and scientific issues, the FDA could forward the petition to the appropriate legal and scientific offices simultaneously to allow for parallel review of the concerns.265

The FDA could make an additional regulatory improvement by imposing a time frame for citizen petition submissions. Similar to the predefined comment period for citizens to respond to a proposed FDA rule,266 citizens should be given a defined forty-five day comment period to raise health and safety concerns in response to ANDA applications. This would avoid eleventh-hour petitions and enable the FDA to rule in time for an approved generic to go to market without an unjust delay. These regulatory reforms would decrease the incentives for brand-name companies to submit sham petitions and help to safeguard the citizen petition process.

#### The democracy reform plank solves their lobbying advantage – from their internal link card!

Mounk 18 – Harvard aff author, “America Is Not A Democracy,” https://www.theatlantic.com/magazine/archive/2018/03/america-is-not-a-democracy/550931/

Mair and Crouch, Krein and Bannon are right to recognize that the people have less and less hold over the political system, an insight that can point the way to genuine reforms that would make our political system both more democratic and better functioning. One of the reasons well-intentioned politicians are so easily swayed by lobbyists, for example, is that their staffs lack the skills and experience to draft legislation or to understand highly complex policy issues. This could be addressed by boosting the woefully inadequate funding of Congress: If representatives and senators were able to attract—and retain—more knowledgeable and experienced staffers, they might be less tempted to let K Street lobbyists write their bills for them.

Similarly, the rules that currently govern conflicts of interest are far too weak. There is no reason members of Congress should be allowed to lobby for the companies they were supposed to regulate so soon after they step down from office. It is time to jam the revolving door between politics and industry.

Real change will also require an ambitious reform of campaign finance. Because of Citizens United, this is going to be extremely difficult. But the Supreme Court has had a change of heart in the past. As evidence that the current system threatens American democracy keeps piling up, the Court might finally recognize that stricter limits on campaign spending are desperately needed.

### States CP – 1NC

#### The fifty states and relevant subnational entity should substantially increase antitrust scrutiny of practices immunized under the federal Noerr-Pennington antitrust exemption.

#### States solve.

Arteaga & Ludwig ’21 [Juan; 1/28/21; Partner @ Crowell & Moring LLP, JD @ Columbia; and Jordan; Partner @ Crowell & Moring LLP, JD @ Loyola Law School, Los Angeles; “The Role of US State Antitrust Enforcement,” *Global Competition Review*; https://globalcompetitionreview.com/guide/private-litigation-guide/second-edition/article/the-role-of-us-state-antitrust-enforcement; AS]

During the 1980s, for example, state attorneys general once again emerged as vigorous antitrust enforcers, especially with respect to the prosecution of resale price maintenance practices and other vertical restraints. The rise in the level and prominence of state antitrust enforcement during this period was largely due to a perceived enforcement void at the federal level, where the DOJ and FTC had mostly limited their focus to ‘prohibiting cartels and large horizontal mergers’. No longer content with ceding antitrust enforcement to federal enforcers, state attorneys general expanded their antitrust dockets from prosecuting purely ‘local matters, such as bid-rigging on state contracts’, to actively investigating and litigating matters with multistate and national implications. To help ensure that they had a larger seat at the antitrust enforcement table, state attorneys general also increased the coordination of their enforcement efforts and competition advocacy through organisations such as the National Association of Attorneys General (NAAG), which created a Multistate Antitrust Task Force and issued state Vertical Restraints and Horizontal Merger Guidelines during this period.

Since the reawakening of state antitrust enforcement nearly 30 years ago, state attorneys general have continued to play an important role in the enforcement of both state and federal antitrust laws. During periods of lax federal antitrust enforcement, state attorneys general have often ramped up their enforcement activity in order to protect consumers from anticompetitive transactions and business practices. During periods

of vigorous federal antitrust enforcement, they have often served as strong partners for the DOJ and FTC by, among other things, offering valuable insights about competitive dynamics in local markets, assisting with obtaining information from key market participants (including state governmental entities that are direct purchasers of goods and services), and helping develop and implement litigation strategies for cases being tried before federal judges presiding in their states.

Since January 2017, state attorneys general have increasingly played a leading and independent antitrust enforcement role. State antitrust enforcers have significantly increased their enforcement activity and willingness to act separately from their federal counterparts because many of them believe that there has been ‘under-enforcement’ by the DOJ and FTC. State antitrust enforcers have also been able to enhance their influence over key competition policy issues and the antitrust enforcement agenda within the United States because there appears to have been a significant decline in the coordination and relationship between the DOJ and FTC.

### Innovation DA – 1NC

#### The plan deletes the pharmaceutical industry

Mosier 21 – Mark Mosier, Partner at Covington & Burling LLP, “BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176010/20210419114711882\_Main%20Document.pdf

The key question on which Petitioners seek this Court’s review—what an antitrust plaintiff must prove to establish that an innovator’s patent infringement lawsuit is a “sham” and therefore excepted from Noerr-Pennington immunity—is of critical importance to the biopharmaceutical industry. To continue the extraordinary investments in research and development necessary to offer new life-saving and life-enhancing treatments, innovators must be able to enforce their rights under the patent laws, including through petitioning courts for redress against infringement of their patent rights. The court of appeals erred in applying the sham-litigation exception established in Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49 (1993) (“PRE”), and all but eliminated the requirement that an innovator must subjectively intend to use the judicial process to directly interfere with a competitor’s business interests in order to constitute sham litigation. The court of appeals’ decision thus exposes biopharmaceutical companies to significant antitrust liability for filing good-faith patent infringement lawsuits. As a result, innovators will be deterred from enforcing their patent rights, undermining the constitutional protection of Noerr-Pennington immunity and weakening the robust patent protections necessary to spur the life-saving innovations that the biopharmaceutical industry provides. For these reasons, PhRMA and BIO join Petitioners in asking this Court to grant the petition for a writ of certiorari.

INTRODUCTION AND SUMMARY OF ARGUMENT

Under the Noerr-Pennington doctrine, patent holders are generally immune from antitrust liability for filing lawsuits seeking to enforce their rights. See PRE, 508 U.S. at 56. This immunity is necessary to protect litigants’ First Amendment rights to petition the government for redress of their grievances. See id. at 56-57. This Court has recognized a narrow exception to this rule, but that exception applies only where a litigant has initiated “sham litigation.” Id. The decision below warrants this Court’s review because it misapplied the sham-litigation test, and in so doing, substantially broadened that narrow exception in a way that threatens to encroach on patent holders’ rights under both the patent laws and the First Amendment.

I. The decision below will chill innovation in the biopharmaceutical industry. Biopharmaceutical companies invest billions of dollars annually to develop new life-saving and life-enhancing treatments. These investments make financial sense only because the patent laws reward the developer of a new treatment with a period of exclusivity during which it can recoup its substantial investment. By discouraging patent holders from enforcing their rights, the court of appeals’ decision reduces the incentive for biopharmaceutical companies to invest in developing new treatments, which will have serious negative consequences for scientific progress, public health, and the economy.

#### Pharma innovation solves a laundry list of existential threats

NAS 8, National Academy of Sciences, “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” December 3, 2008, Board on Life Sciences Division on Earth and Life Studies, National Research Council

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could contribute to advances in many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of crops while reducing key inputs like pesticides, fertilizers, and water by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the chemistry of the oceans, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

### FTC DA – 1NC

#### Plan trades off with FTC resources in other areas

Reinhart 21 – Tara Reinhart, head of the Antitrust/Competition Group in Skadden’s Washington, D.C. office, “Lina Khan’s Appointment as FTC Chair Reflects Biden Administration’s Aggressive Stance on Antitrust Enforcement,” 6/18/21, https://www.skadden.com/insights/publications/2021/06/lina-khans-appointment-as-ftc-chair

Second, like all antitrust enforcers, Ms. Khan and the FTC will face resource constraints. Bringing antitrust litigation is an expensive and laborious process, often requiring millions of dollars for expert fees and a large army of FTC staff attorneys and taking many months or even years to accomplish. Typically, the FTC can only litigate a handful of antitrust matters at a time. It seems likely that Congress will provide more funding to the FTC in the current environment, but even with these extra resources, the FTC will still have to pick its cases carefully and cannot challenge every deal or every instance of alleged unlawful conduct.

#### Antitrust resources are key to merger enforcement – that’s key to supply chain resilience

Miller 22 – Sarah Miller, Executive Director and Founder of the American Economic Liberties Project, “To Save Jobs and Slow Inequality, Stop the Merger Frenzy,” January 2022, https://www.economicliberties.us/wp-content/uploads/2022/01/Stop-the-Merger-Frenzy\_Quick-Take\_Final\_1.10.pdf

The creation and preservation of good jobs, the revitalization of small and independent

business, and the promotion of competitive markets are essential to a healthy, resilient, and

just economy. However, COVID-19 and policymakers’ response to it have instead facilitated

a rapid economic restructuring that is exacerbating already extreme levels of corporate

concentration across the economy through a massive increase in mergers.

Policymakers must move quickly to put the brakes on corporate consolidation or risk jeopardizing short- and longer-term efforts to strengthen the American economy. Most immediately, rampant consolidation promises to deliver mass layoffs and further drive down wages in communities around the country if policymakers are unable to adequately intervene.

The merger wave also endangers many Biden administration objectives, from addressing economic inequality and insecurity to strengthening supply chain resiliency, rebalancing bargaining power between labor and employers, and promoting business dynamism and innovation.

A RECORD-BREAKING PACE OF MERGERS AND ACQUISITIONS

Ballooning stock prices have driven up company valuations, resulting in more companies willing to sell at today’s high prices. Corporate buyers, armed with their own high valuations, are on the hunt. Incentivized by cheap capital and huge cash reserves, dealmakers have created an unprecedented merger wave, pushing already overtaxed antitrust enforcement capacity to its limit.

#### Supply chain stability solves emergent catastrophes whose cumulative risk profile outweighs all existential threats.

Piekle ’20 [Roger; Professor of Poli Sci @ UC Boulder; “Catastrophes of the 21st Century” https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3660542]

Emergent catastrophes

Some catastrophes are difficult to place into historical context because there is really no such relevant context. Among them are financial crises, supply-chain disruption or epidemics. For instance, the table below comes from Supply Chain Digest and shows (as of 2006) a ranking of top ten “supply chain disasters.”6 These are not disasters caused by extreme events like a flood (e.g., Bangkok 2011) or an earthquake (e.g., Honshu) 2011 which then have knock-on effects to global supply chains, as important as these are. These disasters are caused by the failure of a system created by humans which displays some unanticipated behavior for which decision makers were unprepared.

An “emergent” phenomena, according to one useful definition is “a large scale, group behavior of a system, which doesn’t seem to have any clear explanation in terms of the system’s constituent parts” (Darley, 1994; cf. Homer-Dixon et al. 2015). In other words, you cannot describe the behavior of the system as simply the additive consequence of its elements – hence the notion of emergence. Emergent systems are “complex” in the sense that its behaviors are “the result of interactions between a large number of relatively simple parts, cannot be predicted simply from the rules of those underlying interactions” (Darley, 1994). Such interactions can be simulated but not generally predicted.

Due to their inherent unpredictability, emergent phenomena pose a particular challenge for the use of insurance as a tool of management. Insurance requires that risks be, to some quantifiable degree, in the sense of being able to characterize their statistics of occurrence (e.g., Berliner, 1982). Emergent phenomena do not meet this criterion of insurability. This does not necessarily mean that insurance cannot be used as a response tool, but rather that any such reinsurance will probably need the backstop of a residual market (see Weinkle, 2015).

With respect to catastrophic risks, perhaps the ultimate irony is that efforts to quantify risk, as a mechanism of responding to risk, itself can lead to emergent phenomena with its own considerable risks. Consider the role of so-called “risk models” in finance and their role in the global financial crisis. Risk models can be valuable tools in the financial industry because they allow decision makers to evaluate the consequences of their assumptions in a rigorous manner. But there are two significant problems with their use in financial decision making.

One is that risk models break down in times of crisis. Well before the global financial crisis, Daníelsson (2002) observed that “The basic statistical properties of market data are not the same in crisis as they are during stable periods; therefore, most risk models provide very little guidance during crisis periods." The same models that make sophisticated financial instruments possible during normal times are virtually useless during times of crisis. They can also create emergent behaviors in financial markets.

A second problem is that the use of risk models encourages a herd mentality among firms. According to an Inspector General's report from the US Securities and Exchange Commission released September 25, 2008, "In times of market stress, trading dries up and reliable price information is difficult to obtain. Models therefore become relatively more important than market price in times of market stress than in times when markets are liquid and trading actively. Such stressed circumstances force firms to rely more on models and less on markets for pricing and hedging purposes."7 Daníelsson (2002) observes that the wide reliance on risk models to make decisions in a crisis can lead to perverse outcomes if “identical external regulatory risk constraints are imposed, regulatory demands may perversely lead to the amplification of the crisis by reducing liquidity." To have many large institutions making bad decisions with flawed information is not a recipe for financial stability.

Daníelsson (2008) cites a Lehmann Brothers' modeler commenting on model performance during the summer of 2007: "Events that models predicted would happen only once in 10,000 years happened every day for three days." As the financial crisis unfolded, decision makers suffered from having little experience in using the complex risk assessments. This was revealed dramatically during the spring of 2008, when the Financial Times reported that an error in a model used by Moody's, one of the world's most respected and widely utilized source for credit ratings, research and risk analysis, led to a far higher credit rating than was deserved by a particular complex derivative product. Upon learning of the error, Moody's adjusted the model to reflect the ratings error, rather than admit the initial mistake.8 Because no one had any experience with the sophisticated financial product being modeled, the presence of the error in the rating virtually escaped notice in the marketplace. Efficient? Hardly.

Effectively using models of complex, emergent systems usually means treating them as one of many approaches to assessing risk. The Inspector General of the SEC recommended that the SEC be "more skeptical" of risk models and that firms be required to develop "informal plans" for scenarios that may not be found in their models. In other words, they should use models heuristically and not as comprehensive tools for assessing risks. This implies that the appropriate use of any risk model is contingent on the decision environment – useful in ordinary times, risky in times of crisis. The sets a rather high bar for their effective use, as the existence of a crisis may not be readily apparent.

Risk models are an important tool and no doubt here to stay as a fundamental part of our 21st century global financial system. But wisdom will be found in using them effectively. Daníelsson (2008) explained,

“The current crisis took everybody by surprise in spite of all the sophisticated models, all the stress testing, and all the numbers. The financial institutions that are surviving this crisis best are those with the best management, not those who relied on models to do the management's job. Risk models do have a valuable function in the risk management process so long as their limitations are recognized. They are useful in managing the risk in a particular trading desk, but not in capturing the risk of large divisions, not to mention the entire institution. For the supervisors the problem is even more complicated. They are concerned with systemic risk which means aggregating risk across the financial system. Relying on statistical models to produce such risk assessments is folly. We can get the numbers, but the numbers have no meaning.”

The global financial crisis provides a perfect example of emergent risks and the challenges of preparing for them. More broadly, dealing with emergent phenomena requires attention to what is possible, rather than the probabilities of possibilities, and strategies of resilience, robustness and responsiveness.

Extraordinary Catastrophes

The third category of 21st catastrophes considered here are the extraordinary. Those hazards that may or may not be foreseen or foreseeable, but for which we are wholly unprepared, such as an asteroid impact, massive solar storm, or even fantastic scenarios found only in fiction, such as the consequences of contact with alien life. Perhaps surprisingly, such extraordinary hazards have received some attention in recent years.

For instance, Towers Watson has focused on a category of “extreme risks” which it defines as “potential events that are very unlikely to occur but that could have a significant impact on economic growth and asset returns, should they happen.”9 Towers Watson provided a ranking of what it concluded to be the top 15 “extreme” risks, shown below (cf., Smil 2008). In a somewhat similar exercise, Bostrom (2013) focuses on the concept of “existential risk” defined as “one that threatens the premature extinction of Earth-originating intelligent life or the permanent and drastic destruction of its potential for desirable future development.” Included in this category are things like nanotechnology or artificial intelligence run amok, global pandemic, nuclear terrorism and extreme climate change. Sandberg and Bostrom (2008) surveyed experts and arrived at an estimate of a 19% probability that humanity goes extinct before 2100, a number that they caution to take “with a grain of salt.”

Even while taking that “grain of salt” with respect the specific risk probabilities, the potential risks of large magnitude are nonetheless interesting. The experts that they surveyed provided median estimates of the likelihood of >1 million deaths by 2100 for each of the following threats: molecular nanotech weapons (25%), superintelligent AI (10%), engineered pandemic (30%), nuclear war (30%), nanotech accident (5%), natural pandemic (60%), nuclear terrorism (15%).

These values are remarkably high In another, similar exercise in 2015 the Global Challenges Foundation produced a list of 12 risks that threaten humanity.10 They identify risks described as “infinite” meaning that they could pose an existential threat. There are of course less intense scenarios associated with these risks that do not rise to the level of existential. The table below shows these risks, ranked by the number of times that each appears in a 22 different “global challenge” surveys identified in the report.

Climate change is ranked most commonly, appearing in 21 out of the 22 surveys. By contrast, the impact of a near-earth object (asteroid, comet etc.) presents a risk which is straight-forward and over the longer-term, a certainty. However, it appears in less than 2/3 of the risk surveys. NASA explains that the probabilities of a large impact are small (e.g., on average a 100m object is expected to hit the Earth once every 10,000 years) and with proper monitoring, the world would have several years advance notice of such an approaching object.11

The differential focus is highlighted by Bostrom (2013) who observes, “it is striking how little academic attention these issues have received compared to other topics that are less important.” The Global Challenges foundation points to the fact that there are about 100 times as many academic articles on the “dung beetle” as there are to “human extinction.” Bostrom (2013) suggests that one reason for the apparent disparity is that “the biggest existential risks are not amenable to plug-and-play scientific research methodologies.” Most notably, they are not often amenable to meaningful prediction or risk quantification. Further, none of these issues are politicized in the sense that climate change is, which provides a demand for evermore studies to buttress ongoing policy debates. No one is debating the risks of an asteroid impact. Google Scholar allows for a simple, quantitative investigation of the focus of academic attention on extraordinary catastrophes. The graph below shows a simple ratio of articles on “climate change” listed by Google Scholar to articles on “asteroid impact risk,” “global pandemic,” “super volcano,” and “extraterrestrial life.”12 The differential is stark.

### DA – Court Politics – 1NC

#### The court has taken up a challenge to EPA climate authority under the non-delegation doctrine, but will refrain from a broad decision because of fear of public backlash

Smith 21 – Lexi Smith, former advisor to the Mayor of Boston on climate policy, currently JD candidate at Yale Law School, “Supreme Court to weigh EPA authority to regulate greenhouse pollutants,” 11/7/21, https://yaleclimateconnections.org/2021/11/supreme-court-to-weigh-epa-authority-to-regulate-greenhouse-pollutants/

The Supreme Court agreed to hear a case, West Virginia v. EPA, challenging the Environmental Protection Agency’s authority to regulate greenhouse gases as pollutants.

The case presents an opportunity for the Court to overturn key climate precedents and potentially change the relationship between federal agencies and Congress. The decision could have far-reaching consequences for federal climate policy and perhaps even for federal agencies more broadly.

How did we get here, how far might the Court go, and what consequences might the case have for climate change regulation and executive branch authority?

EPA’s authority to regulate greenhouse gases: Massachusetts v. EPA

In a groundbreaking decision in 2007, the Supreme Court held 5-4 that EPA has authority to regulate greenhouse gases under the Clean Air Act. During the Bush administration, environmentalists petitioned the agency to issue a rule on the regulation of greenhouse gases. The Bush EPA denied the petition, and environmental groups, states, and local governments challenged that decision in court. The Supreme Court’s decision turned on whether greenhouse gases like carbon dioxide fall under the definition of “air pollutants,” which the Clean Air Act authorizes EPA to regulate.

The Court concluded that carbon dioxide and other greenhouse gases are air pollutants under the Clean Air Act’s definition, and also noted that the EPA cannot refuse to regulate greenhouse gases for policy reasons outside the Clean Air Act itself, as the Bush administration had done. The Court ordered EPA to either issue a finding that greenhouse gases are dangerous to the public health and welfare, the first step toward regulation, or to give a reasoned explanation for why greenhouse gases do not meet the threshold of endangerment outlined in the Clean Air Act. The agency ultimately found that greenhouse gases are dangerous to the public health and welfare, which formed the foundation for EPA’s regulation of greenhouse gases.

That Supreme Court’s ruling in Massachusetts v. EPA was a 5-4 decision, and environmental advocates leading up to it were not at all certain that they would win the case. In fact, the case was controversial at the time because many environmentalists worried that it would result in a harmful adverse ruling. The four liberals on the Court in 2007, Justices Souter, Ginsburg, Breyer, and Stevens, were joined by Justice Kennedy to form a majority. But Chief Justice Roberts and Justices Thomas, Scalia, and Alito dissented.

Chief Justice Roberts’s dissent (joined by Justices Scalia, Thomas, and Alito) argued that the states, local governments, and environmental groups challenging the EPA should not have been allowed to sue in the first place because they lacked standing: One requirement of standing is a “concrete and particularized” injury. Chief Justice Roberts argued that harms from climate change affect everyone, so the injury in question was not sufficiently individualized and personal to support a lawsuit.

Justice Scalia’s dissent (joined by Chief Justice Roberts and Justices Thomas and Alito) focused on the Clean Air Act and argued that the Act is meant to address conventional air pollutants that harm human health directly through exposure, such as inhalation. He maintained that the Act was not meant to address the broader issue of climate change, and that greenhouse gases therefore did not fall under the definition of “air pollutants.”

Of course, the Supreme Court’s composition has changed significantly since 2007. With a 6-3 conservative-liberal divide, the conservative dissenters’ objections to Massachusetts v. EPA may now represent the majority view.

The ‘worst case scenario’: What could West Virginia v. EPA bring?

There are reasons to expect that the Court will show restraint when it hears the upcoming challenge to EPA’s authority in the West Virginia v. EPA case. But first, let’s walk through the worst potential outcomes from the perspective of climate advocates.

As suggested above, the Court could overturn its decision in Massachusetts v. EPA and effectively take away EPA’s authority to regulate greenhouse gases. With such a ruling, EPA could no longer issue rules directly regulating greenhouse gas emissions, and past greenhouse gas rules issued under its Clean Air Act authority would be invalid.

Richard Lazarus, a Harvard Law School professor who recently wrote a book about Massachusetts v. EPA, called the Court’s decision to hear West Virginia v. EPA “the equivalent of an earthquake around the country for those who care deeply about the climate issue.”

The consequences of the case could even reach far beyond climate regulation. The case presents an opportunity for the Court to revive the “nondelegation doctrine,” a mostly defunct principle that purported to limit Congress’s authority to delegate legislative power to executive branch agencies. The doctrine comes from Article I of the Constitution, which says that “[a]ll legislative powers herein granted shall be vested in a Congress of the United States.” The Supreme Court has not used the nondelegation doctrine to strike down agency action in more than 80 years.

Implications of enforcing nondelegation doctrine

The practical consequences of enforcing the nondelegation doctrine would debilitate the current system of executive branch rulemaking and regulation, subject to judicial review and congressional oversight. If Congress were to do all the rulemaking currently done by EPA, for instance, environmental regulation would become virtually impossible to enact. Congress in that case would have to make thousands of granular and technical decisions about environmental policy, even though we know it can barely pass major legislation as it is.

More broadly, nondelegation could mean that much of the work done by all federal agencies would have to be done instead by a clearly ill-equipped Congress. Even without current gridlock on Capitol Hill, the sheer volume of policy decisions Congress would have to make would be completely unworkable.

While this outcome sounds unlikely and illogical to those who support federal agency regulation, several of the current Justices at various times have expressed interest in weakening the administrative state and deregulating industry. For them, the nondelegation doctrine may be an attractive principle.

Notably, for instance, in a case called Gundy v. United States in 2019, four of the conservatives (Chief Justice Roberts and Justices Gorsuch, Thomas, and Alito) showed a willingness to revisit the nondelegation doctrine. At that time, Justice Kennedy had retired, and Justice Kavanaugh had not yet been confirmed, so the case was 4-4. With Justices Kavanaugh and Barrett now on the court, there appears to be some chance that reviving the nondelegation doctrine would garner the support of five or even six Justices.

The petitioners – West Virginia and North American Coal Corporation – that brought the appeal in West Virginia v. EPA explicitly suggested that this case could be an opportunity for the Court to reconsider nondelegation: “Nothing in the statute [the Clean Air Act] approaches the clear language Congress must use to assign such vast policymaking authority – assuming, of course, it can delegate enormous powers like these in the first place.”

In short, the worst-case scenario from the perspective of climate action advocates is that the Supreme Court takes away the EPA’s authority to regulate greenhouse gases and also revives the nondelegation doctrine, which would strip most federal agencies of much of their regulatory power.

Reasons for a less sweeping outcome

Let’s now consider some reasons the Court may be unlikely to completely overturn Massachusetts v. EPA or fully embrace the nondelegation doctrine.

First, Chief Justice Roberts, and increasingly Justices Kavanaugh and Gorsuch, appear keenly mindful and protective of the Court’s reputation and legacy. They have tended to look out for the public perception of the Court and avoid decisions that would have provoked especially strong public backlash. Recent examples include upholding the Affordable Care Act and civil rights protections for the LGBT community.

These cautious impulses may be heightened by the looming threat of court reform, which could gain more momentum if a particularly controversial conservative decision were issued. Given the strong public backlash likely to result from a decision taking away EPA authority to regulate greenhouse gases and/or reviving the nondelegation doctrine, the Court may proceed with caution.

#### The plan’s liberal ruling provides breathing room for a conservative decision on non-delegation

Bazelon 15 – Emily Bazelon, staff writer for the New York Times Magazine, Truman Capote Fellow at Yale Law School, “Marriage of Convenience,” 1/27/2015, https://www.nytimes.com/2015/02/01/magazine/marriage-of-convenience.html

More significant, if the court is seen as transcending partisan politics, Roberts will probably have more chances, over time, to accomplish what appears to be his primary long-term goal: to move the court in a more conservative direction on a range of issues. In particular, Roberts's brand of conservatism has manifested itself in two main areas. The first is in decisions that are sympathetic to corporations. A 2013 study found that he had been more likely to side with businesses than any justice in the previous 65 years, except for Samuel Alito. The second is in decisions that are antagonistic toward the idea of taking race into account in shaping law or policy. Roberts has voted repeatedly against affirmative action, writing last year that it was not hard to conclude that racial preferences may ''do more harm than good.'

When Roberts was nominated to be chief justice 10 years ago by President George W. Bush, he exuded calm neutrality at his confirmation hearing, comparing judges to umpires who call balls and strikes. At the end of his first term, he emphasized the importance of the court's ''credibility and legitimacy as an institution,'' in an interview with the George Washington University law professor Jeffrey Rosen.

But in 2010, Roberts supplied the fifth vote for the court's remarkably unpopular ruling in Citizens United. By striking limits that Congress set on campaign spending by corporations, the court was perceived as favoring the interests of the wealthy. The court's approval rating fell 10 percentage points, to barely break even, from 61 percent.

Since then, the court has fared better with the public when it pairs conservative decisions with progressive ones. And same-sex marriage is part of that equation. In 2013, the term ended with a splashy ruling in which five justices -- Roberts not among them -- struck down part of the Defense of Marriage Act, which restricted federal benefits for spouses to male-female couples. This decision came one day after the court gutted a central component of the Voting Rights Act, in a 5-to-4 decision written by Roberts.

#### Domestic U.S. climate regulations are key to avoiding dangerous climate change globally

Friedman 21 – Lisa Friedman, climate and energy reporter for the New York Times, “At Climate Talks, Biden Will Try to Sell American Leadership to Skeptics,” 10/31/21, https://www.nytimes.com/2021/10/31/climate/climate-change-biden-cop26.html

If Mr. Biden lacks a reliable plan for the United States to significantly cut its emissions this decade, it would “send a signal” to other major emitters that America is still not serious, she said. And it would be difficult for Mr. Biden to urge other countries to take more meaningful steps away from fossil fuels, others said.

“Some of these countries are saying, ‘Oh yeah, but look at what you did guys, and now you’re coming back and demanding after you were away for the past four years?’” said Andrea Meza, the environment and energy minister of Costa Rica.

Tensions were already running high ahead of the summit. China, currently the world’s top emitter, announced a new target on Thursday that was supposed to be a more ambitious plan to curb its pollution but is virtually indistinguishable from what it promised six years ago. President Xi Jinping has indicated he will not attend the summit in person, as have presidents of two other top polluting nations, Vladimir V. Putin of Russia and Jair Bolsonaro of Brazil.

Democrats close to President Biden said he is painfully aware that the credibility of the United States is on the line in Glasgow, particularly after a botched withdrawal from Afghanistan this summer and a dust-up with France over a military submarine contract.

Representative Ro Khanna, Democrat of California, met with the president recently to discuss how to salvage Mr. Biden’s legislative climate agenda.

“He indicated that many world leaders like Putin and Xi are questioning the capability of American democracy to deliver, so we need to show them that we can govern,” Mr. Khanna said.

Mr. Biden, who is accompanied in Glasgow by 13 Cabinet members, insists they have a story of success to tell, starting with his decision on his first day on the job to rejoin the 2015 Paris Agreement, an accord of nearly 200 countries to fight climate change, from which Mr. Trump had withdrawn the United States.

Since then, Mr. Biden has taken several steps to cut emissions, including restoring and slightly strengthening auto pollution regulations to levels that existed under President Barack Obama but were weakened by Mr. Trump. He has taken initial steps to allow the development of large-scale wind farms along nearly the entire coastline of the United States, and last month finalized regulations to curb the production and use of potent planet-warming chemicals called hydrofluorocarbons, which are used in air-conditioners and refrigerators.

But Mr. Biden is likely to emphasize the $555 billion that he wants Congress to approve as part of a huge spending bill. The climate provisions would promote wind and solar power, electric vehicles, climate-friendly agriculture and forestry programs, and a host of other clean energy programs. Together, those programs could cut the United States’ emissions up to a quarter from 2005 levels by 2030, analysts say.

That’s about halfway to Mr. Biden’s goal of cutting the country’s emissions 50 to 52 percent below 2005 levels. “We go in with a fact pattern that is pretty remarkable, as well as real momentum,” Ali Zaidi, the deputy White House national climate adviser, told reporters.

Mr. Biden plans to release tough new auto pollution rules designed to compel American automakers to ramp up sales of electric vehicles so that half of all new cars sold in the United States are electric by 2030, up from just 2 percent this year. His top appointees have also promised new restrictions on carbon dioxide emissions from coal and gas-fired power plants. And earlier this year, Biden administration officials said they would roll out a draft rule by September to regulate emissions of methane, a powerful planet-warming gas that leaks from existing oil and natural gas wells.

So far, the administration has not offered drafts of any of those rules. Several administration sources said that delay has been due in part to staff shortages, as well as an effort not to upset any lawmakers before they vote on Mr. Biden’s legislative agenda.

But time is running out. It can take years to complete work on such complex and controversial government policies, and several are likely to face legal challenges. On Friday, the U.S. Supreme Court, which has a conservative majority, said it would review the E.P.A.’s authority to regulate greenhouse gas emissions, potentially complicating Mr. Biden’s plans.

The U.S. track record

For three decades, American politics have complicated global climate efforts.

Former President Bill Clinton, a Democrat, joined the first global effort to tackle climate change, the 1997 Kyoto Protocol. His Republican successor, President George W. Bush, renounced the treaty. Mr. Obama, another Democrat, joined the 2015 Paris Agreement and rolled out dozens of executive orders to help meet his promises to cut emissions. His Republican successor, Mr. Trump, abandoned the accord, repealed more than 100 of Mr. Obama’s regulations and took steps to expand fossil fuel drilling and mining.

Mr. Biden is facing similar resistance. No Republicans in Congress back his current climate effort. Representative Frank Lucas of Oklahoma, the top Republican on the House science committee, said the international community should be skeptical of the Biden administration’s promises. “I think they’ll roll their eyes just as people will continue to do in the United States,” Mr. Lucas said.

The president has also struggled to win over two pivotal players within his own party. Senator Joe Manchin III, Democrat of West Virginia, has been steadfastly opposed to a central feature of Mr. Biden’s climate plan: a program that would have rapidly compelled power plants to switch from burning coal, oil and gas, to using wind, solar and other clean energy. Mr. Manchin’s state is a top coal and gas producer, and he has personal financial ties to the coal industry. He was able to kill the provision. Senator Kyrsten Sinema, Democrat of Arizona, has also withheld her support, saying she wants a more modest spending bill.

Environmental leaders said America’s past inconsistency on climate action makes it more important for Mr. Biden to succeed now.

“The U.S. has had to be dragged kicking and screaming to the climate table and has slowed down action that was needed to tackle the climate crisis,” said Mohamed Adow, director of Power Shift Africa, a Nairobi-based environmental think tank. “That is the legacy Biden has to deal with.”

What’s at stake

Average global temperatures have already risen about 1.1 degrees Celsius (2.7 degrees Fahrenheit), compared with preindustrial levels, locking in an immediate future of rising seas, destructive storms and floods, ferocious fires and more severe drought and heat.

At least 85 percent of the planet’s population has already begun to experience the effects of climate change, according to research published in the journal Nature Climate Change. This summer alone, more than 150 people died in violent flooding in Germany and Belgium. In central China, the worst flooding on record displaced 250,000 people. In Siberia, summer temperatures reached as high as 100 degrees, feeding enormous blazes that thawed what was once permanently frozen ground.

“Clearly, we are in a climate emergency. Clearly, we need to address it,” Patricia Espinosa, head of the U.N. climate agency, said Sunday as she welcomed delegates to Glasgow. “Clearly, we need to support the most vulnerable to cope. To do so successfully, greater ambition is now critical.”

If the planet heats even a half-degree more, it could lead to water and food shortages, mass extinctions of plants and animals, and more deadly heat and storms, scientists say.

#### Unchecked warming causes extinction

Peter Kareiva 18, Ph.D. in ecology and applied mathematics from Cornell University, director of the Institute of the Environment and Sustainability at UCLA, Pritzker Distinguished Professor in Environment & Sustainability at UCLA, et al., September 2018, “Existential risk due to ecosystem collapse: Nature strikes back,” Futures, Vol. 102, p. 39-50

In summary, six of the nine proposed planetary boundaries (phosphorous, nitrogen, biodiversity, land use, atmospheric aerosol loading, and chemical pollution) are unlikely to be associated with existential risks. They all correspond to a degraded environment, but in our assessment do not represent existential risks. However, the three remaining boundaries (climate change, global freshwater cycle, and ocean acidification) do pose existential risks. This is because of intrinsic positive feedback loops, substantial lag times between system change and experiencing the consequences of that change, and the fact these different boundaries interact with one another in ways that yield surprises. In addition, climate, freshwater, and ocean acidification are all directly connected to the provision of food and water, and shortages of food and water can create conflict and social unrest.

Climate change has a long history of disrupting civilizations and sometimes precipitating the collapse of cultures or mass emigrations (McMichael, 2017). For example, the 12th century drought in the North American Southwest is held responsible for the collapse of the Anasazi pueblo culture. More recently, the infamous potato famine of 1846–1849 and the large migration of Irish to the U.S. can be traced to a combination of factors, one of which was climate. Specifically, 1846 was an unusually warm and moist year in Ireland, providing the climatic conditions favorable to the fungus that caused the potato blight. As is so often the case, poor government had a role as well—as the British government forbade the import of grains from outside Britain (imports that could have helped to redress the ravaged potato yields).

Climate change intersects with freshwater resources because it is expected to exacerbate drought and water scarcity, as well as flooding. Climate change can even impair water quality because it is associated with heavy rains that overwhelm sewage treatment facilities, or because it results in higher concentrations of pollutants in groundwater as a result of enhanced evaporation and reduced groundwater recharge. Ample clean water is not a luxury—it is essential for human survival. Consequently, cities, regions and nations that lack clean freshwater are vulnerable to social disruption and disease.

Finally, ocean acidification is linked to climate change because it is driven by CO2 emissions just as global warming is. With close to 20% of the world’s protein coming from oceans (FAO, 2016), the potential for severe impacts due to acidification is obvious. Less obvious, but perhaps more insidious, is the interaction between climate change and the loss of oyster and coral reefs due to acidification. Acidification is known to interfere with oyster reef building and coral reefs. Climate change also increases storm frequency and severity. Coral reefs and oyster reefs provide protection from storm surge because they reduce wave energy (Spalding et al., 2014). If these reefs are lost due to acidification at the same time as storms become more severe and sea level rises, coastal communities will be exposed to unprecedented storm surge—and may be ravaged by recurrent storms.

A key feature of the risk associated with climate change is that mean annual temperature and mean annual rainfall are not the variables of interest. Rather it is extreme episodic events that place nations and entire regions of the world at risk. These extreme events are by definition “rare” (once every hundred years), and changes in their likelihood are challenging to detect because of their rarity, but are exactly the manifestations of climate change that we must get better at anticipating (Diffenbaugh et al., 2017). Society will have a hard time responding to shorter intervals between rare extreme events because in the lifespan of an individual human, a person might experience as few as two or three extreme events. How likely is it that you would notice a change in the interval between events that are separated by decades, especially given that the interval is not regular but varies stochastically? A concrete example of this dilemma can be found in the past and expected future changes in storm-related flooding of New York City. The highly disruptive flooding of New York City associated with Hurricane Sandy represented a flood height that occurred once every 500 years in the 18th century, and that occurs now once every 25 years, but is expected to occur once every 5 years by 2050 (Garner et al., 2017). This change in frequency of extreme floods has profound implications for the measures New York City should take to protect its infrastructure and its population, yet because of the stochastic nature of such events, this shift in flood frequency is an elevated risk that will go unnoticed by most people.

4. The combination of positive feedback loops and societal inertia is fertile ground for global environmental catastrophes.

Humans are remarkably ingenious, and have adapted to crises throughout their history. Our doom has been repeatedly predicted, only to be averted by innovation (Ridley, 2011). However, the many stories of human ingenuity successfully addressing existential risks such as global famine or extreme air pollution represent environmental challenges that are largely linear, have immediate consequences, and operate without positive feedbacks. For example, the fact that food is in short supply does not increase the rate at which humans consume food—thereby increasing the shortage. Similarly, massive air pollution episodes such as the London fog of 1952 that killed 12,000 people did not make future air pollution events more likely. In fact it was just the opposite—the London fog sent such a clear message that Britain quickly enacted pollution control measures (Stradling, 2016). Food shortages, air pollution, water pollution, etc. send immediate signals to society of harm, which then trigger a negative feedback of society seeking to reduce the harm.

In contrast, today’s great environmental crisis of climate change may cause some harm but there are generally long time delays between rising CO2 concentrations and damage to humans. The consequence of these delays are an absence of urgency; thus al

though 70% of Americans believe global warming is happening, only 40% think it will harm them (http://climatecommunication.yale.edu/visualizations-data/ycom-us-2016/). Secondly, unlike past environmental challenges, the Earth’s climate system is rife with positive feedback loops. In particular, as CO2 increases and the climate warms, that very warming can cause more CO2 release which further increases global warming, and then more CO2, and so on. Table 2 summarizes the best documented positive feedback loops for the Earth’s climate system. These feedbacks can be neatly categorized into carbon cycle, biogeochemical, biogeophysical, cloud, ice-albedo, and water vapor feedbacks. As important as it is to understand these feedbacks individually, it is even more essential to study the interactive nature of these feedbacks. Modeling studies show that when interactions among feedback loops are included, uncertainty increases dramatically and there is a heightened potential for perturbations to be magnified (e.g., Cox, Betts, Jones, Spall, & Totterdell, 2000; Hajima, Tachiiri, Ito, & Kawamiya, 2014; Knutti & Rugenstein, 2015; Rosenfeld, Sherwood, Wood, & Donner, 2014). This produces a wide range of future scenarios.

Positive feedbacks in the carbon cycle involves the enhancement of future carbon contributions to the atmosphere due to some initial increase in atmospheric CO2. This happens because as CO2 accumulates, it reduces the efficiency in which oceans and terrestrial ecosystems sequester carbon, which in return feeds back to exacerbate climate change (Friedlingstein et al., 2001). Warming can also increase the rate at which organic matter decays and carbon is released into the atmosphere, thereby causing more warming (Melillo et al., 2017). Increases in food shortages and lack of water is also of major concern when biogeophysical feedback mechanisms perpetuate drought conditions. The underlying mechanism here is that losses in vegetation increases the surface albedo, which suppresses rainfall, and thus enhances future vegetation loss and more suppression of rainfall—thereby initiating or prolonging a drought (Chamey, Stone, & Quirk, 1975). To top it off, overgrazing depletes the soil, leading to augmented vegetation loss (Anderies, Janssen, & Walker, 2002).

Climate change often also increases the risk of forest fires, as a result of higher temperatures and persistent drought conditions. The expectation is that forest fires will become more frequent and severe with climate warming and drought (Scholze, Knorr, Arnell, & Prentice, 2006), a trend for which we have already seen evidence (Allen et al., 2010). Tragically, the increased severity and risk of Southern California wildfires recently predicted by climate scientists (Jin et al., 2015), was realized in December 2017, with the largest fire in the history of California (the “Thomas fire” that burned 282,000 acres, https://www.vox.com/2017/12/27/16822180/thomas-fire-california-largest-wildfire). This catastrophic fire embodies the sorts of positive feedbacks and interacting factors that could catch humanity off-guard and produce a true apocalyptic event. Record-breaking rains produced an extraordinary flush of new vegetation, that then dried out as record heat waves and dry conditions took hold, coupled with stronger than normal winds, and ignition. Of course the record-fire released CO2 into the atmosphere, thereby contributing to future warming.

Out of all types of feedbacks, water vapor and the ice-albedo feedbacks are the most clearly understood mechanisms. Losses in reflective snow and ice cover drive up surface temperatures, leading to even more melting of snow and ice cover—this is known as the ice-albedo feedback (Curry, Schramm, & Ebert, 1995). As snow and ice continue to melt at a more rapid pace, millions of people may be displaced by flooding risks as a consequence of sea level rise near coastal communities (Biermann & Boas, 2010; Myers, 2002; Nicholls et al., 2011). The water vapor feedback operates when warmer atmospheric conditions strengthen the saturation vapor pressure, which creates a warming effect given water vapor’s strong greenhouse gas properties (Manabe & Wetherald, 1967).

Global warming tends to increase cloud formation because warmer temperatures lead to more evaporation of water into the atmosphere, and warmer temperature also allows the atmosphere to hold more water. The key question is whether this increase in clouds associated with global warming will result in a positive feedback loop (more warming) or a negative feedback loop (less warming). For decades, scientists have sought to answer this question and understand the net role clouds play in future climate projections (Schneider et al., 2017). Clouds are complex because they both have a cooling (reflecting incoming solar radiation) and warming (absorbing incoming solar radiation) effect (Lashof, DeAngelo, Saleska, & Harte, 1997). The type of cloud, altitude, and optical properties combine to determine how these countervailing effects balance out. Although still under debate, it appears that in most circumstances the cloud feedback is likely positive (Boucher et al., 2013). For example, models and observations show that increasing greenhouse gas concentrations reduces the low-level cloud fraction in the Northeast Pacific at decadal time scales. This then has a positive feedback effect and enhances climate warming since less solar radiation is reflected by the atmosphere (Clement, Burgman, & Norris, 2009).

The key lesson from the long list of potentially positive feedbacks and their interactions is that runaway climate change, and runaway perturbations have to be taken as a serious possibility. Table 2 is just a snapshot of the type of feedbacks that have been identified (see Supplementary material for a more thorough explanation of positive feedback loops). However, this list is not exhaustive and the possibility of undiscovered positive feedbacks portends even greater existential risks. The many environmental crises humankind has previously averted (famine, ozone depletion, London fog, water pollution, etc.) were averted because of political will based on solid scientific understanding. We cannot count on complete scientific understanding when it comes to positive feedback loops and climate change.

## Innovation Advantage

### Innovation High – 1NC

#### Innovation high now

Lincicome 21 – Scott Lincicome, senior fellow in economic studies at the Cato Institute, “U.S. R&D Spending Continues to Climb (Somebody Should Tell Congress),” 5/21/21, https://www.cato.org/blog/us-rd-spending-continues-climb

[Graphs excluded]

As I noted on Wednesday, the Senate is now considering “The United States Innovation and Competition Act of 2021” (formerly known as the “Endless Frontier Act”), which is primarily\* intended to boost federal funding for research and development in the United States by tens of billions of dollars. If you were to listen to the bill’s advocates, you’d think that the United States was suffering from a dramatic decline in R&D spending over the last several decades, and that other countries — particularly China — had raced ahead. New data from the U.S. and National Center for Science and Engineering Statistics (NCSES) and the OECD, however, paint a different picture.

First, the NCSES’ latest report on R&D expenditures shows that total U.S. spending reached an all‐​time high in 2019, both in total, inflation‐​adjusted dollars ($584.4 billion) and as a share of GDP (3.06%):

That same dataset shows that all forms of R&D — basic, applied, and experimental development — also hit all‐​time highs in 2019:

The OECD, meanwhile, shows that the United States still leads the world in gross R&D expenditures and is among the top 10 in R&D intensity (GDP share), still well above China in both categories:

Of course, total dollar amounts alone can’t tell us everything we need to know about a nation’s innovative capacity. However, the data above should at least warrant skepticism about the need for tens of billions of taxpayer dollars in new federal R&D spending and likewise demand hard proof from advocates that government funds will actually boost American innovation. On the latter score, for example, we know that massive semiconductor subsidies in China (the legislation’s clear target) haven’t produced a cutting‐​edge, world‐​beating industry, and that — as Cato adjunct Terence Kealey and others have written — government R&D spending risks crowding out private spending (and thus not boosting national R&D expenditures overall). The first chart above, showing private and federal R&D spending moving in opposite directions, provides some support for the crowd‐​out thesis. As I’ve discussed here, moreover, various data and anecdotal evidence indicate that private R&D expenditures in key U.S. manufacturing industries — such as semiconductors, electric vehicles (and batteries, in particular), and pharmaceuticals — are solid, if not world‐​class.

### Patent Trolls Defense – 1NC

#### No impact to patent trolling

Giudici 17 – Emiliano Giudici, Associate Professor of Finance, Rusche College of Business, Stephen F. Austin State University, “Evaluating Market Reactions to Non-Practicing Entity Litigation,” 2017, <https://scholarship.law.vanderbilt.edu/cgi/viewcontent.cgi?article=1083&context=jetlaw>

[NPEs = non-practicting entities = patent trolls]

An ongoing and important debate in patent law concerns the actions of "non-practicing entities" or "patent assertion entities," which are sometimes pejoratively referred to as "patent trolls" (hereinafter collectively referred to as "NPEs").1 Generally, NPEs are individuals or entities that own a patent, either through invention or acquisition, but do not use it to produce or manufacture anything. 2 Most NPEs referred to as patent trolls do not invent-their typical business model is to license or purchase patent rights and assert them through litigation against entities that make products that allegedly infringe upon their patent rights. 3 Depending upon whom you ask, NPEs are either valid, useful actors in the market for innovation or leeches that feed off the innovation of others.4

This Article seeks to add to the literature on this debate by analyzing what the market has to say about NPE litigation through an event study.5 Many of the targets of NPE litigation are publicly traded companies. If the market exhibits at least some level of efficiency, and if NPE litigation in fact stifles innovation and creates costs for product-producing companies, one would expect to see some effect on the market when new patent litigation is filed. 6 Using the RPX Corporation patent litigation database,7 this study analyzes the effect that NPE patent litigation brought by the ten largest NPEs had on the stock price of the eight largest targets of NPE patent litigation claims to determine whether and to what extent the market reacts to the filing of these claims.8 Based upon this analysis, it appears the market largely ignores the filing of NPE patent claims against large companies, calling into question the damaging effect on innovation and the economy claimed by the opponents of NPEs.

#### Their internal links are pure hype with terrible methodologies

Katznelson 16 – Ron D. Katznelson, president of Bi-Level Technologies, a signal and image processing technology firm, “The $83 Billion Patent Litigation Fallacy,” Spring 2016, https://www.cato.org/sites/cato.org/files/serials/files/regulation/2016/4/regulation-v39n1-3.pdf

These patent owners (e.g., universities, research and development consortia, patent intermediaries, individual inventors, etc.) are variously called non-practicing Entities (NPEs) or patent Assertion Entities (PAEs), but most pejoratively, “patent trolls.” The apparent purpose of this last, mythological name is to evoke the specter of dangerous, subhuman creatures that live in the dark and exact tribute on all who pass by. it’s clever spin, but it’s grotesquely false. The Wright Company was not a patent troll; it held a pioneer aviation patent and sought to expand, not restrict, the domain in which the Wright brothers’ inventions could improve American society and its economy. The same goes for many of today’s NPEs.

in 2013, the White House Office of Science and Technology policy (OSTP) published a report entitled, “Patent Assertion and U.S. innovation,” and more commonly called the PAE report. it purportedly shows that when NPEs seek to protect their legally acquired intellectual property rights, they “act to significantly retard innovation in the United States.” The PAE report further asserts that this results “in economic ‘dead weight loss’ in the form of reduced innovation, income, and jobs for the American economy.”

This follows the same false narrative spun by the navy a century ago, complete with factual claims that lack legitimate foundation. (Indeed, I have submitted a petition for correction of the PAE report to the OSTP under the Information Quality Act [IQA], arguing that the report fails to meet all applicable federal standards for transparency, reproducibility, and perhaps most importantly, objectivity. Unlike a century ago, U.S. government agencies like the OSTP are statutorily precluded from disseminating influential information that is demonstrably false, yet, in contravention of the IQA guidelines issued by the Office of Management and Budget, the PAE report relies on studies that have undergone no peer review, relied on opaque or erroneous methods and surveys, lack objectivity, and contain demonstrable bias.

A central claim of the report is that patent lawsuits by NPEs recently caused lost wealth of over $300 billion over four years. For this, the report relies on estimates by James Bessen, Jennifer Ford, and Michael Meurer, published in their Regulation article, “The private and Social Costs of patent Trolls” (Winter 2011–2012). Their paper was the issue’s cover story, promoted with an illustration portraying—as the hoary myth requires—oversized humanoids with visibly malign intent, armed with clubs, holding-up innocent travelers for payment at a toll bridge. The unmistakable message: patent owners who license their intellectual property are evil.

Bessen, Ford, and Meurer’s article examines the economic effects of patent lawsuits by NPEs, which they define as firms that do not produce goods but rather acquire patents in order to license them to others. Their conclusions are startling. They claim losses to defendants in NPE patent suits during a period of four years “average over $83 billion per year in 2010 dollars, which equals over a quarter of U.S. industrial R&D spending per annum.” This, the article says, proves that NPE patent litigation constitutes a “very large disincentive to innovation.” In other words, NPEs destroy the incentive to innovate when they protect innovation from the various high-tech highwaymen who otherwise would misappropriate it.

However, Bessen, Ford, and Meurer’s article suffers from fundamental analytical and inferential shortcomings. As I explain below, its cost estimates and inferences should be dismissed, along with their indictment of NPEs and similar patent holders.

### Asteroids Defense – 1NC

#### Asteroids won’t hit earth, and even if they do they won’t kill us.

**Britt ‘5** – science writer for LiveScience

[Robert Roy Britt, science writer for LiveScience; “The Odds of Dying;” published 1/6/2005; http://www.livescience.com/3780-odds-dying.html ; Jay]

Perceptions of risk factors can change over time simply because more is learned. The chances of an Earth-impacting asteroid killing you have dropped dramatically, for example, from about 1-in-20,000 in 1994 to something like 1-in-200,000 or 1-in-500,000 today. The new numbers -- their range reflecting the need for further research -- were offered up last week by Clark Chapman of the Southwest Research Institute and David Morrison at NASA's Ames Research Center. Why such a dramatic downgrade? Active intervention. "A significant part of it is that we have now discovered, in the last dozen years, a good fraction of the largest, most deadly asteroids and found that they won't hit the Earth," Chapman told LiveScience. Also, projections of the destruction a large space rock would cause have been revised downward a bit. Finally, since Earth is two-thirds water, asteroid risks include the possibility of an impact-induced tsunami. And Chapman says asteroid-generated tsunamis may not be as deadly as once presumed.

#### Asteroid calculations are bad science

**BENNETT 2010** (James, Prof of Economics at George Mason, *The Doomsday Lobby: Hype and Panic from Sputniks, Martians, and Marauding Meteors*, p. 157-158

We should here acknowledge, without necessarily casting aspersions on any of the papers discussed in this chapter, the tendency of scientific journals to publish sexy articles. (Sexy, at least, by the decidedly unsexy standards of scientific journals.) Writing in the Public Library of Science, Neal S. Young of the National Institutes of Health, John P.A. Ioannidis of the Biomedical Research Institute in Greece, and Omar Al-Ubaydli of George Mason University applied what economists call the “winner’s curse” of auction theory to scientific publishing. Just as the winner in, say, an auction of oil drilling rights is the firm that has made the highest estimation — often overestimation — of a reserve’s size and capacity, so those papers that are selected for publication in the elite journals of science are often those with the most “extreme, spectacular results.”63 These papers may make headlines in the mainstream press, which leads to greater political pressure to fund projects and programs congruent with these extreme findings. As The Economist put it in an article presenting the argument of Young, Ioannidis, and Al-Ubaydli, “Hundreds of thousands of scientific researchers are hired, promoted and funded according not only to how much work they produce, but also where it gets published.” Column inches in journals such as Nature and Science are coveted; authors understand full well that studies with spectacular results are more likely to be published than are those that will not lead to a wire story. The problem, though, is that these flashy papers with dramatic results often “turn out to be false.”64 In a 2005 paper in the Journal of the American Medical Association, Dr. Ioannidis found that “of the 49 most-cited papers on the effectiveness of medical interventions, published in highly visible journals in 1990–2004… a quarter of the randomised trials and five of six nonrandomised studies had already been contradicted or found to have been exaggerated by 2005.” Thus, those who pay the price of the winner’s curse in scientific research are those, whether sick patients or beggared taxpayers, who are forced to either submit to or fund specious science, medical or otherwise. The trio of authors call the implications of this finding “dire,” pointing to a 2008 paper in the New England Journal of Medicine showing that “almost all trials” of anti-depressant medicines that had had positive results had been published, while almost all trials of anti-depressants that had come up with negative results “remained either unpublished or were published with the results presented so that they would appear ‘positive.’” Young, Ioannidis, and Al-Ubaydli conclude that “science is hard work with limited rewards and only occasional successes. Its interest and importance should speak for themselves, without hyperbole.” Elite journals, conscious of the need to attract attention and stay relevant, cutting edge, and avoid the curse of stodginess, are prone to publish gross exaggeration and findings of dubious merit. When lawmakers and grant-givers take their cues from these journals, as they do, those tax dollars ostensibly devoted to the pursuit of pure science and the application of scientific research are diverted down unprofitable, even impossible channels. The charlatans make names for themselves, projects of questionable merit grow fat on the public purse, and the disconnect between what is real and what subsidy-seekers tell us is real gets ever wider.65 The matter, or manipulation, of odds in regards to a collision between a space rock and Earth would do Jimmy the Greek proud. As Michael B. Gerrard writes in Risk Analysis in an article assessing the relative allocation of public funds to hazardous waste site cleanup and protection against killer comets and asteroids, “Asteroids and comets are… the ultimate example of a low-probability/high-consequence event: no one in recorded human history is confirmed to have ever died from one.” Gerrard writes that “several billion people” will die as the result of an impact “at some time in the coming half million years,” although that half-million year time-frame is considerably shorter than the generally accepted extinction-event period.66 The expected deaths from a collision with an asteroid of, say, one kilometer or more in diameter are so huge that by jacking up the tiny possibility of such an event even a little bit the annual death rate of this never-beforeexperienced disaster exceeds deaths in plane crashes, earthquakes, and other actual real live dangers. Death rates from outlandish or unusual causes are fairly steady across the years. About 120 Americans die in airplane crashes annually, and about 90 more die of lightning strikes. Perhaps five might die in garage-door opener accidents. The total number of deaths in any given year by asteroid or meteor impact is zero — holding constant since the dawn of recorded time.

## Lobbying Advantage

### Alt Causes – 1NC

#### Petitions not key to democracy – Capitol riot, voting rights, economic disenfranchisement thump.

#### Alt causes – regulatory agencies and the Supreme Court – their evidence

Mounk 18 – Harvard aff author, “America Is Not A Democracy,” https://www.theatlantic.com/magazine/archive/2018/03/america-is-not-a-democracy/550931/

The massive influence that money yields in Washington is hardly a secret. But another, equally important development has largely gone ignored: More and more issues have simply been taken out of democratic contestation.

In many policy areas, the job of legislating has been supplanted by so-called independent agencies such as the Federal Communications Commission, the Securities and Exchange Commission, the Environmental Protection Agency, and the Consumer Financial Protection Bureau. Once they are founded by Congress, these organizations can formulate policy on their own. In fact, they are free from legislative oversight to a remarkable degree, even though they are often charged with settling issues that are not just technically complicated but politically controversial.

The range of crucial issues that these agencies have taken on testifies to their importance. From banning the use of the insecticide DDT to ensuring the quality of drinking water, for example, the EPA has been a key player in fights about environmental policy for almost 50 years; more recently, it has also made itself central to the American response to climate change, regulating pollutants and proposing limits on carbon-dioxide emissions from new power plants.

While independent agencies occasionally generate big headlines, they often wield their real power in more obscure policy areas. They are now responsible for the vast majority of new federal regulations. A 2008 article in the California Law Review noted that, during the previous year, Congress had enacted 138 public laws. In the same year, federal agencies had finalized 2,926 rules. Such rules run the gamut from technical stipulations that affect only a few specialized businesses to substantial reforms that have a direct impact on the lives of millions. In October 2017, for example, the Consumer Financial Protection Bureau passed a rule that would require providers of payday loans to determine whether customers would actually be able to pay them back—potentially saving millions of people from exploitative fees, but also making it more difficult for them to access cash in an emergency.

The rise of independent agencies such as the EPA is only a small piece of a larger trend in which government has grown less accountable to the people. In the latter half of the 20th century, the Federal Reserve won much greater independence from elected politicians and began to deploy far more powerful monetary tools. Trade treaties, from NAFTA to more-recent agreements with countries such as Australia, Morocco, and South Korea, have restricted Congress’s ability to set tariffs, subsidize domestic industries, and halt the inflow of certain categories of migrant workers. At one point I planned to count the number of treaties to which the United States is subject; I gave up when I realized that the State Department’s “List of Treaties and Other International Agreements of the United States” runs to 551 pages.

Most of these treaties and agreements offer real benefits or help us confront urgent challenges. Whatever your view of their merit, however, there is no denying that they curtail the power of Congress in ways that also disempower American voters. Trade treaties, for example, can include obscure provisions about “investor–state dispute settlements,” which give international arbitration courts the right to award huge sums of money to corporations if they are harmed by labor or environmental standards—potentially making it riskier for Congress to pass such measures.

This same tension between popular sovereignty and good governance is also evident in the debates over the power of the nine unelected justices of the Supreme Court. Since the early 1950s, the Supreme Court has ended legal segregation in schools and universities. It has ended and then reintroduced the death penalty. It has legalized abortion. It has limited censorship on television and the radio. It has decriminalized homosexuality and allowed same-sex marriage. It has struck down campaign-finance regulations and gun-control measures. It has determined whether millions of people get health insurance and whether millions of undocumented immigrants need to live in fear of being deported.

Whether you see judicial review as interpreting the law or usurping the people’s power probably depends on your view of the outcome. The American right has long railed against “activist judges” while the American left, which enjoyed a majority on the Court for a long stretch during the postwar era, has claimed that justices were merely doing their job. Now that the Court has started to lean further right, these views are rapidly reversing. But regardless of your politics, there’s no question that the justices frequently play an outsize role in settling major political conflicts—and that many of their decisions serve to amplify undemocratic elements of the system.

Take Citizens United. By overturning legislation that restricted campaign spending by corporations and other private groups, the Supreme Court issued a decision that was unpopular at the time and has remained unpopular since. (In a 2015 poll by Bloomberg, 78 percent of respondents disapproved of the ruling.) It also massively amplified the voice of moneyed interest groups, making it easier for the economic elite to override the preferences of the population for years to come.

### Democracy Defense – 1NC

#### Democracy solves nothing.

Doorenspleet 19 Renske Doorenspleet, Politics Professor at the University of Warwick. [Rethinking the Value of Democracy: A Comparative Perspective, Palgrave Macmillan, p. 239-243]

The value of democracy has been taken for granted until recently, but this assumption seems to be under threat now more than ever before. As was explained in Chapter 1, democracy’s claim to be valuable does not rest on just one particular merit, and scholars tend to distinguish three different types of values (Sen 1999). This book focused on the instrumental value of democracy (and hence not on the intrinsic and constructive value), and investigated the value of democracy for peace (Chapters 3 and 4), control of corruption (Chapter 5) and economic development (Chapter 6). This study was based on a search of an enormous academic database for certain keywords,6 then pruned the thousands of articles down to a few hundred articles (see Appendix) which statistically analysed the connection between the democracy and the four expected outcomes. The frst fiding is that a reverse wave away from democracy has not happened (see Chapter 2). Not yet, at least. Democracy is not doing worse than before, at least not in comparative perspective. While it is true that there is a dramatic decline in democracy in some countries,7 a general trend downwards cannot yet be detected. It would be better to talk about ‘stagnation’, as not many dictatorships have democratized recently, while democracies have not yet collapsed. Another fnding is that the instrumental value of democracy is very questionable. The feld has been deeply polarized between researchers who endorse a link between democracy and positive outcomes, and those who reject this optimistic idea and instead emphasize the negative effects of democracy. There has been ‘no consensus’ in the quantitative literature on whether democracy has instrumental value which leads some beneficial general outcomes. Some scholars claim there is a consensus, but they only do so by ignoring a huge amount of literature which rejects their own point of view. After undertaking a large-scale analysis of carefully selected articles published on the topic (see Appendix), this book can conclude that the connections between democracy and expected benefts are not as strong as they seem. Hence, we should not overstate the links between the phenomena. The overall evidence is weak. Take the expected impact of democracy on peace for example. As Chapter 3 showed, the study of democracy and interstate war has been a fourishing theme in political science, particularly since the 1970s. However, there are four reasons why democracy does not cause peace between countries, and why the empirical support for the popular idea of democratic peace is quite weak. Most statistical studies have not found a strong correlation between democracy and interstate war at the dyadic level. They show that there are other—more powerful—explanations for war and peace, and even that the impact of democracy is a spurious one (caveat 1). Moreover, the theoretical foundation of the democratic peace hypothesis is weak, and the causal mechanisms are unclear (caveat 2). In addition, democracies are not necessarily more peaceful in general, and the evidence for the democratic peace hypothesis at the monadic level is inconclusive (

caveat 3). Finally, the process of democratization is dangerous. Living in a democratizing country means living in a less peaceful country (caveat 4). With regard to peace between countries, we cannot defend the idea that democracy has instrumental value. Can the (instrumental) value of democracy be found in the prevention of civil war? Or is the evidence for the opposite idea more convincing, and does democracy have a ‘dark side’ which makes civil war more likely? The findings are confusing, which is exacerbated by the fact that different aspects of civil war (prevalence, onset, duration and severity) are mixed up in some civil war studies. Moreover, defining civil war is a delicate, politically sensitive issue. Determining whether there is a civil war in a particular country is incredibly diffcult, while measurements suffer from many weaknesses (caveat 1). Moreover, there is no linear link: civil wars are just as unlikely in democracies as in dictatorships (caveat 2). Civil war is most likely in times of political change. Democratization is a very unpredictable, dangerous process, increasing the chance of civil war significantly. Hybrid systems are at risk as well: the chance of civil war is much higher compared to other political systems (caveat 3). More specifcally, both the strength and type of political institutions matter when explaining civil war. However, the type of political system (e.g. democracy or dictatorship) is not the decisive factor at all (caveat 4). Finally, democracy has only limited explanatory power (caveat 5). Economic factors are far more significant than political factors (such as having a democratic system) when explaining the onset, duration and severity of civil war. To prevent civil war, it would make more sense to make poorer countries richer, instead of promoting democracy. Helping countries to democratize would even be a very dangerous idea, as countries with changing levels of democracy are most vulnerable, making civil wars most likely. It is true that there is evidence that the chance of civil war decreases when the extent of democracy increases considerably. The problem however is that most countries do not go through big political changes but through small changes instead; those small steps—away or towards more democracy—are dangerous. Not only is the onset of civil war likely under such circumstances, but civil wars also tend to be longer, and the confict is more cruel leading to more victims, destruction and killings (see Chapter 4). A more encouraging story can be told around the value for democracy to control corruption in a country (see Chapter 5). Fighting corruption has been high on the agenda of international organizations such as the World Bank and the IMF. Moreover, the theme of corruption has been studied thoroughly in many different academic disciplines—mainly in economics, but also in sociology, political science and law. Democracy has often been suggested as one of the remedies when fghting against high levels of continuous corruption. So far, the statistical evidence has strongly supported this idea. As Chapter 5 showed, dozens of studies with broad quantitative, cross-national and comparative research have found statistically signifcant associations between (less) democracy and (more) corruption. However, there are vast problems around conceptualization (caveat 1) and measurement (caveat 2) of ‘corruption’. Another caveat is that democratizing countries are the poorest performers with regard to controlling corruption (caveat 3). Moreover, it is not democracy in general, but particular political institutions which have an impact on the control of corruption; and a free press also helps a lot in order to limit corruptive practices in a country (caveat 4). In addition, democracies seem to be less affected by corruption than dictatorships, but at the same time, there is clear evidence that economic factors have more explanatory power (caveat 5). In conclusion, more democracy means less corruption, but we need to be modest (as other factors matter more) and cautious (as there are many caveats). The perceived impact of democracy on development has been highly contested as well (see Chapter 6). Some scholars argue that democratic systems have a positive impact, while others argue that high levels of democracy actually reduce the levels of economic growth and development. Particularly since the 1990s, statistical studies have focused on this debate, and the empirical evidence is clear: there is no direct impact of democracy on development. Hence, both approaches cannot be supported (see caveat 1). The indirect impact via other factors is also questionable (caveat 2). Moreover, there is too much variation in levels of economic growth and development among the dictatorial systems, and there are huge regional differences (caveat 3). Adopting a one-size-ftsall approach would not be wise at all. In addition, in order to increase development, it would be better to focus on alternative factors such as improving institutional quality and good governance (caveat 4). There is not suffcient evidence to state that democracy has instrumental value, at least not with regard to economic growth. However, future research needs to include broader concepts and measurements of development in their models, as so far studies have mainly focused on explaining cross-national differences in growth of GDP (caveat 5). Overall, the instrumental value of democracy is—at best—tentative, or—if being less mild—simply non-existent. Democracy is not necessarily better than any alternative form of government. With regard to many of the expected benefts—such as less war, less corruption and more economic development—democracy does deliver, but so do nondemocratic systems. High or low levels of democracy do not make a distinctive difference. Mid-range democracy levels do matter though. Hybrid systems can be associated with many negative outcomes, while this is also the case for democratizing countries. Moreover, other explanations—typically certain favourable economic factors in a country—are much more powerful to explain the expected benefts, at least compared to the single fact that a country is a democracy or not. The impact of democracy fades away in the powerful shadows of the economic factors.8

## Petitions Advantage

### Generics Bad – 1NC

#### Pharma innovation and generic drugs are both high now, but the aff goes too far – it crushes innovation and causes a shift to more expensive drug development which turns prices

Branstetter 14 – Lee Branstetter, professor of economics and public policy at Carnegie Mellon University, “Starving (or Fattening) the Golden Goose? Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation,” September 2014, https://www.nber.org/system/files/working\_papers/w20532/w20532.pdf

In his provocative paper, “The Health of Nations,” Yale University economist William Nordhaus (1999) argues that the advances in human welfare generated by better medical science over the past half century have been equal in value to the consumption increases from all other sources put together. Victor Fuchs (1982) has suggested that most of the real improvement in human health generated over this period stems from modern medicine’s expanding arsenal of pharmaceutical products. While documenting these claims in a way that meets modern evidentiary standards is challenging, the work of scholars such as Frank Lichtenberg (2001, 2004, 2007) has provided evidence suggesting that the gains from pharmaceutical innovation have been very large. In the long run, global investments in pharmaceutical research have proven to be very good ones.

These benefits have come with significant costs; pharmaceutical innovation is risky and expensive. These costs are passed on to consumers in the form of higher prices for branded pharmaceuticals. In recent years, prescription drug spending in the U.S. has exceeded $300 billion, an increase of $135 billion since 2001. Consumption of prescription drugs now accounts for approximately 12 percent of total health care spending (GAO, 2012). However, over this time period, generic products have accounted for an increasing share of prescription drug expenditures, saving consumers an estimated $1 trillion (GAO, 2012). Current regulation attempts to strike a balance between access to lower cost generics on the one hand and adequate incentives to promote pharmaceutical innovation on the other. While the rise in generic penetration has brought substantial benefits to consumers (Branstetter et al., 2013), some have argued that the regulatory "balance" has shifted so far in the direction of access to inexpensive drugs that it has undermined the incentives for new drug development (Higgins and Graham, 2009; Knowles, 2010). Such a shift could have strong implications, even for drug companies outside the United States, because the global industry relies disproportionately on the U.S. market as a source of its profits. Has the increase in generic entry affected pharmaceutical innovation? Our study attempts to address this question and quantify, for the first time, the impact of generic entry on early-stage drug development.

We start by constructing a novel and unique dataset that allows us to analyze this issue at the level of narrowly defined therapeutic areas. Instead of relying on patents as measures of innovation, we focus on early-stage drug development. While patenting is certainly important in the pharmaceutical industry, it can occur anytime throughout the drug development process, and it often occurs long before the actual therapeutic value of a compound has been demonstrated. Our outcome variable, on the other hand, allows us to measure what is actually happening in the early stages of the clinical development process. We also utilize comprehensive data on branded and generic drug sales across all therapeutic categories in the U.S. market1 , obtained at the firm-product-year level, such that we can measure the differential exposure of individual firms to generic competition across these different therapeutic markets. Finally, we seek to control for changes in scientific opportunity by building a comprehensive database of citation-weighted scientific journal articles in the medical sciences and mapping them to our pharmaceutical product market categories.

Using these data, we find that the aggregate level of new drug development has not declined as generic penetration in the U.S. market has risen; the total number of new compounds (including both small and large molecules) in early stage development has risen over our sample period (Figure 1). However, rising generic competition has had a statistically and economically significant impact on how pharmaceutical product development is undertaken and where those efforts are focused. We show this by using an empirical framework that models the flow of early-stage pharmaceutical innovations as a function of generic entry and penetration, as well as scientific opportunity and challenges, firm innovative capability and a vector of additional controls. Using this framework, we document a negative and significant relationship between generic entry (penetration) and early-stage innovation at the ATC 2-digit therapeutic category level. The elasticity from our specification implies that a 10% increase in generic penetration in a particular market will lower early-stage innovations, in that same market, by 7.9%.

The interpretation that an increase in generic penetration within a market lowers early-stage innovation is strengthened by a series of alternative specifications and robustness checks. First, we limit our sample to a set of therapeutic categories where substitution between generics and branded products is limited for clinical reasons, and we find that our measured effect attenuates to the point of insignificance, as expected. Second, we show that our estimated effect is strongly negative for early-stage innovation, where it is possible to redirect R&D in response to market shifts, but much weaker for late-stage innovation, where firms have stronger incentives to deploy products that have survived the clinical trials process, even if generic competition is limiting the addressable market. Third, we show that our baseline effect is robust to inclusion of (therapeutic market \* year) interaction terms that effectively remove all the unobserved market-specific effects that change in a common way across firms.

Finally, we consider the possibility that, within therapeutic markets, a shift is occurring out of chemical-based (small molecule) products and into biologic-based (large molecule) products. The regulatory mechanisms that have accelerated generic entry in chemical-based drugs do not extend to biologics. Additionally, the pathways by which biologic-based generics (known in the industry as ‘biosimilars’) could enter the U.S. market have yet to be finalized.2 Exploiting this regulatory difference between chemical-and biologic-based innovations, we find a positive relationship between generic entry and a shift towards biologic-based products within therapeutic categories. As conjectured by Golec et al. (2010), this movement suggests that the nature of innovation taking place in the pharmaceutical industry is changing.

Is this shift in the direction and nature of drug development socially beneficial or socially harmful? At this stage in the research process, it is not yet possible to produce a definitive answer to this question. On the one hand, one could argue that current regulation is ‘pushing’ innovation toward therapeutic markets for which significant numbers of viable generics do not exist. In other words, R&D efforts and expenditures could be flowing to therapeutic areas that are relatively underserved, thereby generating welfare gains. On the other hand, our evidence of a significant movement in the data from development of chemical-based to biologic-based products may have important implications for the future, especially since biologics tend to be more expensive, on average, than chemical-based products. Until current regulatory challenges are resolved, these higher prices may persist for long periods of time. As the regulatory playing field tilts sharply in the direction of biologics, and firms respond rationally to the incentives they confront, we cannot rule out the possibility that recent efforts to balance access with incentives for innovation will give us cheaper drugs today, but more expensive drugs tomorrow.

### Circumvention – 1NC

#### New antitrust is circumvented and watered down – durable fiat doesn’t solve judicial disregard and congressional inaction

Crane 21 – Frederick Paul Furth Sr. Professor of Law at UMich (Daniel, Antitrust Antitextualism, 96 Notre Dame L. Rev. 1205 (2021). Available at: <https://scholarship.law.nd.edu/ndlr/vol96/iss3/7>

As first the antitrust agencies through their merger guidelines and then the courts through endorsement of the agencies’ approach systematically shifted merger policy away from the incipiency standard and began requiring formal market definition and probability of adverse price effects, Congress acquiesced through inaction. Whatever else it said in 1950, Congress has thus far shown itself willing to let the courts and antitrust agencies reshape merger law in a form far more favorable to business consolidation. \* \* \* In sum, from the courts’ earliest forays into interpreting the Sherman Act up through contemporary antitrust jurisprudence, the courts have manifested a systematic tendency to interpret the substantive antitrust statutes contrary to their texts, legislative histories, and often their spirit.236 Sometimes, as with the rule of reason and labor exemption, the judicial disregard of text and purpose has occurred fairly immediately. In other cases, as with the Robinson-Patman and Celler-Kefauver Acts, an initial period of statutory fidelity has slipped gradually into a period of statutory infidelity. In some cases, as with respect to section 5 of the FTC Act and section 3 of the Clayton ct, the courts continue to proclaim their fidelity after they functionally move to infidelity. In many cases, the courts stop pretending after a while and admit quite candidly that they are taking liberties with the statute. If this antitrust antitextualism is merely the product of common-law methodology, one would expect to see movement away from the statute’s text in both permissive and restrictive directions, or, to put it more crassly, both in favor of big capital and against it. But the movement has all been in one direction: loosening a congressional check on big capital. Thus, the rule of reason allowed courts to bless large combinations of capital that the courts deemed reasonable; narrowing the labor exemption frustrated labor’s ability to countervail capital’s power; restricting the private right of action for treble damages significantly curtailed the private-litigation check on business; judicial narrowing of the Clayton Act’s exclusive dealing and tying restrictions allowed (mostly big) firms to exploit market power; reading “unfair” out of the FTC Act eliminated section 5 as a check on business morality; eviscerating the Robinson-Patman Act protections for small and independent businesses favored large and powerful businesses; and requiring proof of likely price increases and technical relevant market definition in merger cases immunized many large-scale mergers from legal challenge. Throughout the history of American antitrust law, the courts have shown a systematic tendency to read down the antitrust statutes in favor of big capital. But the story of antitrust antitextualism is not simply one of conservative/progressive ideological struggle between Congress and the courts. Much of the action away from statutory text and purpose was accomplished by, or with the support of, judges of the political left. Unlike in other fields, Congress has not responded with statutory overrides. And far from buttressing its atextual statutory readings of the antitrust laws through veiled constitutional warnings about congressional overreaching, the Court has repeatedly pulled in the opposite direction, asserting quasi-constitutional reverence for antitrust law.237 Despite ample opportunity to do so, the Court has not removed antitrust law from the reach of congressional reconsideration by constitutionalizing its atextual readings. Antitrust antitextualism does not follow a conventional left/right ideological pattern. Its actual pattern is more subtle III. THE IDEALISTIC CONGRESS, PRAGMATIC COURTS THESIS AND ITS IMPLICATIONS Thus far, this Article has made an empirical observation—that, from the beginning of antitrust history, the courts have atextually read down the antitrust statutes in favor of big business and considered and rejected a potential explanation: that this phenomenon primarily represents an ideological tugof-war between a progressive Congress and more conservative courts. This final Part searches for an alternative understanding, one that is perhaps less obvious but more fitting, and then considers its systemic implications for the antitrust enterprise. A. The Idealistic/Pragmatic Thesis Congress writes expansive statutes reining in business power, the courts (either immediately or over time) disregard the plain text of the statutes and trim them down in favor of capital, and Congress acquiesces through inaction. Why? The best-fitting explanation is this: the antitrust laws reside in perennial tension between two fundamental impulses of the American political psyche—the romantic and idealistic attachment to smallness over bigness, and the pragmatic and often grudging realization that large-scale organization may be necessary to achieve material advantages. The romanticism and idealism of the anti-bigness impulse pushes it to the fore in the popular political arena. Congress legislates on the popular aspiration for an egalitarian economy organized around small proprietors and independent local businesses and freedom from economic dominance. When the statutes come to the courts or antitrust agencies, judges and antitrust enforcers play the pragmatic role of balancing those popular aspirations against the contending impulse for efficiency and material benefit. This balancing act induces them to give less effect to the statutes than the broad statutory texts suggest. So long as the judicial decisions achieve results that strike a politically acceptable outcome between the aspirational and pragmatic impulses, Congress is content to leave the judicial and enforcement decisions alone.

### Generics Defense – 1NC

#### Generics inevitable – enter the market but do so *later* – no impact to differenntial.

#### Generics fail – require patented innovative drugs to enter the market before the generic can be released.

# 2NC

## CP

### AT: PDB

#### The perm links to the net benefit because it still imposes antitrust liability – all of our links are specific to the imposition of antitrust remedies like treble damages

#### The plan and perm involve judicial interference with FDA processes – the counterplan alone is more effective and quicker

Avery 13 – Matthew Avery, Associate at Baker Botts LLP, “The Antitrust Implications of Filing “Sham” Citizen Petitions with the FDA,” 2013, 65 Hastings L.J. 113

A judicial approach to overseeing the citizen petition process should come from both judicial deference and a new look at the sham exception in light of the abuse of the petition process.249 The courts should generally defer to the FDA,250 which has broad discretion to establish and apply rules for public participation in Agency matters.251 This discretion gives the FDA broad authority to create and enforce its procedural rules on citizen petitions. The courts should also defer to the FDA when reviewing its factual determinations related to evaluating citizen petitions.

1. Reduce Judicial Participation

Courts may set aside agency action, findings, and conclusions if they are found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”252 In order to avoid such arbitrary and capricious rulings, the FDA should issue guidelines on the meaning of the terms “main purpose of delaying ANDA approval,” “intent to delay,” or “delaying petition,” as discussed previously in Part VI.A.4.253 Absent clear guidelines, any FDA decision would likely need to define the meaning of “intent to delay” in order to avoid being found arbitrary or capricious. Such guidelines would streamline FDA decisions and create a baseline for the courts to review citizen petitions under the antitrust laws.

Nonetheless, courts should not, in the interim, analyze such determinations to see whether they should be set aside. Agencies are granted broad deference because they are considered best equipped to respond to “changing circumstances.”254 Recent cases suggest, however, that courts have come to ad hoc conclusions regarding the merits of eleventh-hour citizen petitions and that the sham exception is not consistently applied to Noerr-Pennington cases.255

It is possible that the current legal climate for citizen petitions consists of those “changing circumstances.”256 The fact that the FDA issued a new rule suggests that the Agency has been taking notice of the hole it needs to plug.257 Both judges and academics have pointed out the failings of the legislation currently in place.258 If the FDA or the legislature pays greater attention to sham petitions and delineates the difference between what constitutes “sham” and “not sham,” it could speed up the process in which meritless petitions are deemed a sham. Allowing the FDA to determine whether a petition constitutes a sham would shift the responsibilities to the better-suited entity and increase the efficiency and certainty of labeling petitions as sham. Given the FDA’s greater expertise in evaluating scientific methodologies, judicial deference to FDA’s determination of whether a petition is a sham creates an effective system of deterrence.259 Alternatively, the FDA could promulgate clear guidelines regarding the definition of “sham,” and courts could rely on those guidelines in their analysis of alleged sham petitions.

### AT: PDCP

#### 1. The counterplan PICS out of “core antitrust law” because it doesn’t expand the three federal “core antitrust laws” – prefer contextual evidence defining conjunctive phrases. Severance is a voting issue for neg ground.

Sonia Kuester Pfaffenroth et al, Justin Hedge and Monique N. Boyce Arnold & Porter, ‘21 “ A Comparison Of Proposed Antitrust Legislation In 2021: Federal And New York State”

At the federal level, there are three core antitrust laws: (1) the Sherman Act, in which Section 1 outlaws "every contract, combination, or conspiracy in [unreasonable] restraint of trade," and Section 2 outlaws any "monopolization, attempted monopolization, or conspiracy or combination to monopolize";1 (2) the Federal Trade Commission Act, which prohibits "unfair methods of competition" and "unfair or deceptive acts or practices";2 and (3) Section 7 of the Clayton Act, which prohibits mergers and acquisitions where the effect "may be substantially to lessen competition, or to tend to create a monopoly."3 Criminal violations of the Sherman Act carry a maximum penalty of a $100 million fine for corporations, and a maximum penalty of 10 years in prison and a $1 million fine for individuals. A prevailing plaintiff in a civil suit can recover treble damages and attorneys' fees. But federal law currently does not provide for civil penalties when the government brings an antitrust case, only injunctive relief.

#### 2. Their definition of “scope” is unlimiting and would allow affs to expand CFIUS, the 14th amendment, or any regulatory prohibition as a topical mechanism. A more limiting definition of scope refers only to the total number of prohibited business practices.

Keith N. Hylton, Professor of Law, Boston University, and Fei Deng, and Consultant, NERA Economic Consulting, ‘7, “ANTITRUST AROUND THE WORLD: AN EMPIRICAL ANALYSIS OF THE SCOPE OF COMPETITION LAWS AND THEIR EFFECTS” Antitrust Law Journal [Vol. 74 2007] https://www.jstor.org/stable/pdf/27897550.pdf?refreqid=excelsior%3A424f12ccaeba1aa8d4150377ebe7192d

We turn our attention now to dominance law – or, in the language of American antitrust specialists, monopolization law. The Dominance Score is an attempt to measure the number of types of conduct specified in a country's competition law as unlawful abuse of a dominant position. For those familiar with American law, the dominance measure is an attempt to measure the scope of laws equivalent to Section 2 of the Sherman Act. One can think of the Dominance Score as the size of the net specifically designed to capture dominant firms that engage in anticompetitive con duct.3

#### 3. Antitrust and patent law are conceptually and legally distinct.

Feldman 8 - Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation at UC Hastings. (Robin, "Patent and antitrust: Differing shades of meaning." Va. JL & Tech. 13 (2008): 1. <https://web.stanford.edu/dept/law/ipsc/pdf/feldman-robin.pdf>) //S.He

The relationship between patent law and antitrust law has challenged legal minds since the emergence of antitrust law in the late 19th century. In reductionist form, the two concepts pose a natural contradiction: One encourages monopoly while the other restricts it. The inherent tension can be framed in the following manner: Can a body of case law that grants monopoly opportunities be reconciled with a body of case law that curtails monopolization.2

To avoid uncomfortable dissonance, the trend across time has been to try to harmonize patent and antitrust law. Since the 1930s, for example, the Supreme Court has ruled that antitrust law operates only when patent holders reach beyond the boundaries inherent in the patent grant. 3

It is an inspired attempt at reconciling the two bodies of case law. Unfortunately, no one has been able to determine what boundaries are inherent in the patent grant, a confusion that has spawned almost a century of consternation and conflict over what exercise of power lies within the patent grant and what lies outside. In recent decades, harmonization efforts have led Congress and the courts to engage in a series of attempts, some aborted and some half-formed, to graft antitrust doctrines onto patent law. 4 In addition, many scholars have advocated various harmonization approaches. 5

These efforts, too, have failed to resolve the conflicts. This piece argues that the deviations between patent law and antitrust law run far deeper than courts and commentators recognize. The problem isn't just that one encourages monopoly while the other limits it. Rather, patent law and antitrust law often use the same concepts and terminology with differing meanings and contexts. In other words, it may appear that they are talking about the same things, and yet, they are not.

Our tendency to assume parallel meanings threatens any attempt to reconcile the two bodies of law. Most importantly, ignoring asymmetries can lead to both underprotection and overprotection of patent rights, as well as the improper application of antitrust laws. To highlight the problem, this piece explores a number of examples of differing meanings in hopes of promoting a more subtle understanding of the patent/antitrust terrain.

The relationship between patent and antitrust is particularly important at this moment in time. Patent law is experiencing a moment in the sun, both in the courts and in the public eye. In particular, after accepting relatively few patent cases over the last decade, the Supreme Court accepted a record number of patent cases last term and this term, including ones that touch on the boundaries of the exercise of power permitted to patent holders6 . The Supreme Court also has accepted an unusually large number of antitrust cases. As both patent and antitrust law enjoy the spotlight of focus, it is particularly important to develop a more nuanced understanding of the shades of meaning in patent law and how those differ from antitrust.

#### [ ] Their Bradford and and Chilton is a negative card. It says that prohibitions expand the scope of the law. The counterplan expands the scope of patent and contract law, not antitrust law.

### AT: Links to DA – General

#### Ex ante patent law protects innovation far more than ex post application of antitrust.

Lim ’14 [Daryl; Assistant Professor, The John Marshall Law School; 2014; “Patent Misuse and Antitrust: Rebirth or False Dawn?”; <https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1191&context=mttlr>; Michigan Telecommunications and Technology Law Review; accessed 10/28/21; TV]

The Supreme Court forged patent misuse as a tool to prevent abuses of the patent system, regardless of a demonstrable effect on competition.91 It begins with the premise that the patent grant is not a property right as such, but a privilege conferred by the patent office to promote technological progress.92 Patentees found to be misusing their patents are not allowed to enforce their patents.93

Patent misuse may be analogized to the fair use defense in copyright law. Fair use permits use of copyrighted works “to fulfill copyright’s very purpose, ‘[t]o promote the Progress of Science and useful Arts.’”94 Like patent misuse, fair use is “an open-ended and context-sensitive inquiry”.95 Bath fair use and patent misuse are rooted in IP policy despite its inquiry into aspects of market competition.96 As noted earlier, misuse contains a blend of competition and innovation policies. In the case of fair use, the crucial inquiry is “whether the new work merely supersedes the original work, or instead adds something new with a further purpose or of a different character.”97

Ramsey Hanna observed that, in contrast to “copyright and patent law [which] recognize the importance of encouraging socially beneficial innovation,” antitrust law “lacks similar sensitivity to the central role of innovation.”98 Hanna partly attributes this to “a dearth of economic literature dealing with determinants, mechanics, and dynamic effects of innovation”99 as well as “the difficulty in defining markets in industries with differentiated but highly substitutable goods.”100

Antitrust law is concerned about economic monopoly power and of patentees using that power to raise prices and stifle output.101 It works ex post to create a competitive environment taking into account the need to incentivize innovation. Although the antitrust laws purport to take into account dynamic efficiencies that include innovation concerns, commentators like Marshall Leaffer are concerned that it does not do so “adequately”102 because antitrust policy has a “natural bias” toward static analysis, which is more measurable.103

The differences between antitrust and patent policy led Robin Feldman to conclude that antitrust law is “designed to address only particular types of harm, and it cannot reach everything that patent policy addresses.”104 As examples of these unreachable aspects, she cites the following: preventing economic loss that occurs in defensive research activities in patent circumvention; the negative effects on innovation caused by an excess of patent rights, and the impediments to innovation from awarding patents to earlystage inventors at the expense of late-stage inventors.105

Julie Cohen, Brett Frischmann, Dan Moylan and a number of others agree, and they have argued that misuse provides a more relevant answer to harms to market innovation.106 These may include the lack of ability to use and the diminished position of licensees that results from the ability to meter uses.107 These fundamental differences in policy explain why different or additional elements may be required to prove an antitrust violation from a case of patent misuse.

### AT: Links to DA – Patent Suits

#### The key distinction is that the counterplan deals with suits more effectively, but doesn’t expose companies to liability for even filing them – the link is about the chilling effect of antitrust liability, not about whether the suits succeed or not

Mosier 21 – Mark Mosier, Partner at Covington & Burling LLP, “BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, <https://www.supremecourt.gov/DocketPDF/20/20-1293/176010/20210419114711882_Main%20Document.pdf>

[Modified for gendered language]

Hatch-Waxman litigation is fraught with uncertainty and is enormously costly to innovator pharmaceutical companies. See Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) (recognizing that “[n]o one can be certain that ~~he~~ [they] will prevail in a patent suit”) (emphasis in original). Given the technical complexities inherent in these lawsuits, the existing case law hardly provides a reliable guide for the likelihood that an innovator will ultimately succeed in enforcing its rights. See TM Patents, L.P. v. Int’l Bus. Machs. Corp., 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999) (noting that “nearly 40 percent of claims constructions are changed or overturned by the Federal Circuit”); see also, e.g., Purdue Pharma L.P. v. Endo Pharm. Inc. 438 F.3d 1123, 1125-26 (Fed. Cir. 2006) (initially affirming a ruling in favor of a generic challenger, only to vacate and remand on reconsideration). Moreover, as discussed above, by design, the Hatch-Waxman Act incentivizes innovators to act quickly to enforce their rights in order to be eligible for a stay of up to 30 months. Consistent with this, a party bringing a patent infringement lawsuit before concluding that it is certain to win the case does not act in bad faith. See Asahi Glass Co., 289 F. Supp. 2d at 993 (“It is not bad faith . . . to assert patent rights that one is not certain will be upheld in a suit for infringement . . .”).

If allowed to stand, the decision below would penalize innovators for filing suit in the face of this uncertainty. The standard for subjective intent that the court of appeals applied would deter innovators faced with potential generic infringers from asserting their rights based on the prospect of treble-damage antitrust liability. While parties typically seek the advice of counsel to avoid taking any actions that could result in antitrust liability, the decision below discourages that approach by treating a patent holder’s decision to rely on advice from experienced attorneys to bring ultimately unsuccessful suits as a reason for treating the suit as a sham. Pet. App. 66a-70a. Even for patent holders who decide to bring suit to enforce their rights, the decision below will serve as a powerful deterrent to making reasonable arguments for the development or modification of patent law principles. That outcome is in sharp tension with PRE’s statement that an “objectively good faith argument for the extension, modification, or reversal of existing law” cannot render a lawsuit baseless. 508 U.S. at 65.

Penalizing patent owners for asserting uncertain but presumptively valid patent rights undermines a critical element of the patent protections on which innovators depend to protect their enormous investments in developing life-saving drugs. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1369 (Fed. Cir. 1998) (innovators “must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent’s validity or infringement not survive litigation”). Absent robust patent protections, biopharmaceutical innovators face diminished prospects of recouping the high costs of developing new treatments, and are consequently less likely to make the necessary R&D investments.15 As a former Acting Chairman of the FTC has observed, “innovation in the life sciences industry would suffer catastrophic decline without patent protection.”16

### Solvency – Patent Trolls – 2NC

#### Given all of this, the counterplan is clearly sufficient to solve patent misuse

Lim ’14 [Daryl; Assistant Professor, The John Marshall Law School; 2014; “Patent Misuse and Antitrust: Rebirth or False Dawn?”; <https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1191&context=mttlr>; Michigan Telecommunications and Technology Law Review; accessed 10/28/21; TV]

Patent misuse is an extension of the equitable doctrine of unclean hands where courts exercising their discretion will deny enforcement even if infringement is found.25 It acts as a public injunction against abuses of the privilege granted under patent law, and balances public and private interests.26 Examples of patent misuse include tying,27 package licensing,28 and horizontal price-fixing29 and territorial allocatfions30 under the guise of sham patent licenses.31

A judge finding patent misuse has the discretion to withhold damages or injunctive relief even if the patents themselves have not yet been enforced.32 The patents in question are rendered unenforceable until the effects of the misuse have been purged.33 Purging requires patentees to show that they have completely abandoned the misconduct, and that their “baleful effects” have dissipated.34

Abandonment of the misconduct may occur at any time, even after the filing of the suit in which the question of misuse is raised. The standard is an objective one, and the abandonment need not take the particular form desired by the defendant.35 At the same time, “[t]here is no set time period for purging; the time will vary with the facts of each case,” since “whether a purge has been accomplished is a factual matter and is ‘largely discretionary with the trial court.’”36 Additionally, successful defendants may recover expenses in defending the action in an award for damages.37

Patent misuse and the antitrust laws both seek to restrain the myriad of ways that a patentee’s exclusive right can be abused.38 Indeed, at a sufficiently high level of abstraction, the goals of promoting innovation and competition pursued by both the antitrust and patent laws are similar39 Authorized under the Commerce Clause,40 the antitrust laws promote vigorous competition in the marketplace so that consumers benefit from a variety of goods and services at competitive prices.41 The Supreme Court heralded the antitrust laws as “the Magna Carta of free enterprise,”42 and explained that they “are as important to the preservation of economic freedom and our free enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms. And the freedom guaranteed to each and every business, no matter how small, is the freedom to compete.”43

Early courts observed an “obvious tension” between the patent law and the antitrust laws, because one “creates and protects monopoly power while the other seeks to proscribe it.”44 Later courts were more conciliatory, recognizing that patent and antitrust laws serve the public in complementary but different ways. Specifically, the patent system facilitates invention by ensuring a return on risky investments, while the antitrust laws foster market competition.45 Despite the latter view prevailing today, the intersection between the patent and antitrust laws remains “a source of confusion and controversy.”46 Patent misuse rests at the heart of the patent-antitrust interface and has inherited all of that “confusion and controversy.”47 In 1957, the Ninth Circuit observed that patent misuse was “one of the most important and unsettled aspects of patent law.”48 That sentiment continues to echo on today.49

According to a 2013 patent litigation study conducted by PricewaterhouseCoopers (the PwC Study), patent litigation in America is rising, nearly tripling in the last ten years (see Figure 1 below). Part of the reason stems a higher number of patent filings and grants. Figure 1 shows the strong correlation between the spike in litigation and patent grants.50 As the number of issued patents increase, companies anxious to avoid these “patent thickets”51 will contribute to a higher frequency of licensing agreements and therefore increase the likelihood that misuse might result.52

### AT: Antitrust Key to Deterrence

#### The counterplan’s reforms solve deterrence

Avery 13 – Matthew Avery, Associate at Baker Botts LLP, “The Antitrust Implications of Filing “Sham” Citizen Petitions with the FDA,” 2013, 65 Hastings L.J. 113

The FDA should implement a multi-level review process to screen out improper or unfounded petitions based on disclosed conflicts. For example, to help the FDA evaluate whether a petition’s main objective is to delay approval of an ANDA, the Agency could require submission of more information concerning the circumstances under which a petition is filed. Five requirements would be particularly useful to the FDA’s initial review: (1) an accurate statement of procedural history, (2) an indication of any pending ANDAs or NDAs the citizen petition would affect, (3) a statement of financial interest, including financial relationships of any kind to the stakeholders, (4) a statement of likely financial impact, and (5) a corporate disclosure statement indicating any corporate relationships between affected parties. With this screening information at the outset, the FDA could quickly identify “suspect” petitions—such as those having a main purpose of delay— for secondary screening. Petitions involving large sums of money or that are filed shortly before ANDA approval is expected on a blockbuster drug might be subject to additional review to weed out clearly improper petitions, or to designate pressing petitions for immediate review to avoid financial loss. Falsification of screening information could be subject to harsh fines and outright denial of the citizen petition.

In concert with the screening process, the FDA should require petitioners to provide full disclosure of conflicts of interest, such as financial interests as noted above, in the approval or submission of the petition.230 For example, petitioners could be required to certify that: (1) petitioners have submitted all information the petition relies on, (2) the petition is legally and factually well grounded, (3) it is submitted in good faith, and (4) the petition includes all available information that is unfavorable to the petition.231 Although these additional certifications would burden all petitioners, they may also deter improperly motivated citizen petitions. Further, the proposed certification requirement could be given teeth by imposing a bond or potential penalties where delay of ANDA approval is sought. As noted above, this process would allow the FDA to identify and potentially screen out the petitions that are likely to be improperly motivated.

2. Adopt More Efficient Methods of Review

The FDA should adopt more efficient methods of review to improve response rates under the new proposed rule, or other changes that would urge adherence to the timeframe for all petitions rather than most petitions. The FDA currently reviews a citizen petition’s legal and scientific issues consecutively.232 Instead, the petitions should be routed based on whether they raise legal issues, scientific issues, or both.233 If a petition raises both legal and scientific issues, both issues should be reviewed in parallel by appropriate personnel.234 The review process could also be improved by implementing a tracking system to monitor how the FDA handles citizen petitions, which would help to identify systemic deficiencies or potential improvements.235

3. Time Restrictions on Submitting Citizen Petitions

Imposing a deadline to submit citizen petitions prior to ANDA approval could further deter abuse of the process. For example, the FDA could refuse to consider, for purposes of ANDA approval, citizen petitions submitted less than nine months from the pioneer’s patent expiration date.236 Alternatively, the Agency could provide would-be petitioners with a comment period consisting of a predetermined number of days in which they could submit citizen petitions concerning a submitted ANDA, similar to the predefined comment period for citizens to respond to a proposed FDA rule.237 Limiting opportunities to interfere with the ANDA approval process through such restrictions would stop dubious eleventh-hour citizen petitions and require petitioners to put forth their best arguments in a timely manner. Under this system, the FDA could review citizen petitions with fewer delays and thus determine whether to approve generic entry more rapidly.238

Another option is for the FDA to implement some type of “abbreviated citizen petition” process that would put the FDA on notice about concerns without making formal requests for action. The Agency could respond to an abbreviated petition by determining whether the concerns are prima facie legitimate, prioritizing them based on legitimacy, and then requesting a more formal “non-abbreviated” citizen petition for the highest priority concerns. This would essentially make the filing of a citizen petition an organic process that would raise all concerns at the outset and allow the FDA to engage in a conversation with the filer. The FDA could then specify what further evidence would be required to warrant the relief requested, strictly control the review schedule, and eliminate the need to review evidence that cannot support such relief.

4. Prima Facie Review of Intent

The FDA should exercise its discretion to determine whether citizen petitions concerning ANDA review appear to be anticompetitive by determining whether such petitions are filed with an intent to delay ANDA approval. Under 505(q)(1)(E), if the Agency finds that a petition’s main purpose is to delay ANDA approval, then it may deny the petition at any time.239 However, the FDA has never actually denied a petition based on such a finding and has refused to issue guidance on how such an intent to delay might be determined.240 Consequently, it is not at all clear and when a citizen petition could be summarily denied based on the Agency’s finding of intent to delay.

In order to give 505(q)(1)(E) some teeth, the FDA should issue guidelines defining what it means for a petition to have a “main purpose of delay,” “intent to delay,” or when a petition is a “delaying petition,” then refer dubious petitions to the Federal Trade Commission or Department of Justice for antitrust analysis or criminal investigation.241 Because the FDA is capable of determining factual issues for agencies and judges, such a referral could create a presumption that the FDA’s determinations regarding delaying intent are correct. Such a presumption may be justified given the FDA’s experience in reviewing citizen petitions and its history of maintaining the dialogue between industry and the government. This would lead to deterrence in the courts as well because of the presumption against sham petitioners.

A consequence of the FDA’s free reign to deny citizen petitions is that brand-name manufacturers who petitioned to keep generics off the market may vigorously challenge such denials. However, the Agency is in a favorable position to deny petitions while simultaneously fending off any suits from aggrieved petitioners. It has long been established that a purely legal challenge to a “final agency action” may not be fit for judicial review.242 Denial of a petition that could affect the approval of a related ANDA submitted by a generic competitor constitutes “final agency action,” and a challenge to such denial may not be ripe until the Agency makes a concrete determination on the related generic application.243 Consequently, the FDA can indefinitely defend or dismiss suits by petitioners who are denied until it approves the generic drug that the petitioners opposed in the first place. This gives the Agency maneuvering room to issue clarifying guidance or exercise its discretion.

5. Lengthen and Enforce the Time Period for Response

The source of the problem with citizen petition misuse is the time it takes to approve or deny the petitions and the FDA’s failure to act on ANDAs in the interim. The FDA has increasingly failed to meet the statutory response time, which was previously 180 days and has now been reduced to 150 days. Now that the FDA has even less time to respond to citizen petitions, it seems even more likely that the Agency will fail to respond in a timely manner. Consequently, changes in regulations should first target this aspect of the citizen petition process.244

One option arises from the rule that requires the FDA to notify an ANDA applicant within thirty days if the FDA’s response to an ANDA will be delayed beyond 180 days.245 If the FDA imported a similar rule requiring the Agency to notify ANDA applicants of anticipated delays caused by citizen petitions in a timely manner, it may encourage the FDA to stop ignoring the time limit and increase the response rate.

A second solution would be to require a response to a citizen petition even if the FDA has not completed its review within the imposed response period or has not acted on related ANDAs. While this solution is supported by the recently amended law prohibiting the FDA from delaying ANDA approval in response to citizen petitions unless the delay is necessary to protect the public health, it carries the risk that the FDA will release superficial or incomplete responses.246

A third alternative would be to expand, rather than reduce, the time limit.247 However, petitions that did not receive a response within 180 days were typically delayed for more than a year.248 Expanding the time limit for the sake of the relatively few petitions that receive late responses could increase the average response time and create more delays in the otherwise-timely petition process.

A two-pronged approach—extending the period to make review more feasible and giving the requirement teeth to make it a hard deadline—could significantly improve the current system. Legitimate petitions would be less likely to get shortchanged, and improper petitions would have to be denied in a timely manner.

### Solvency – Citizen Petitions – 2NC

#### It’s comparatively more effective than the plan

Lee 10 – Stacey B. Lee, Assistant Professor, Johns Hopkins University Carey School of Business, “Is a Cure on the Way? – The Bad Medicine of Generics, Citizen Petitions, and *Noerr-Pennington* Immunity,” 2010, 20 KAN. J.L. & PUB. POL'y 98

This Article explores the regulatory and adjudicatory impact of brand-name drug manufacturers' use of the governmental processes to delay the availability of generic drugs. In the current environment, brand-name drug manufacturers can engage in a two-tiered approach to extend their market share with little fear of facing antitrust liability. On the administrative agency level, manufacturers can file baseless petitions that can delay a generic drug's approval for six months or longer. If the FDA determines the petition is meritless, these manufacturers can avoid antitrust liability by relying on Noerr- Pennington immunity. While this Article recommends a robust application of the sham exception, even a reconfigured Noerr-Pennington doctrine cannot provide a complete solution. This Article argues that agency reforms are necessary to effectively curb this type of abuse. The Food and Drug Administration Amendments Act of 2007 ("FDAAA") is an initial step in that direction.' 2 This Article suggests ways to build on that foundation and more fully engage the FDA in actively policing the integrity of its own processes.

Given the unique regulatory framework for encouraging the development and market introduction of generic drugs, Part II of this Article provides an overview of the generic drug industry. It describes the Hatch-Waxman Act of 1984-the legislation that modified antitrust laws and enabled production of generic drugs.' 3 Part III describes the Abbreviated New Drug Application ("ANDA") process for generic drugs. 14 Furthermore, it describes the original intent behind the establishment of the citizen petition process and its role in generic drug approvals.'5 Finally, this section discusses how FDA regulations and policies allow some brand-name drug manufacturers to manipulate this process.

Part IV examines the trilogy of cases that define the basic parameters and principles of the Noerr-Pennington doctrine.'6 Additionally, it examines the doctrine's two-part inquiry on which courts rely to determine applicability of the sham exception.17 In particular, this Article comments on the difficulty courts have had policing the conduct of defendant manufacturers; many manufacturers have been accused of filing petitions that are both objectively baseless and born of predatory intent, but the cases addressing their delaying petitions go unpunished.18 As part of that examination, Part IV analyzes Louisiana Wholesale Drug Co. v. Sanofi-Aventis, a recent federal district court opinion.' 9 This case illustrates that even after the FDA determines a petition is baseless and without legal merit, it is still possible for a court to hold that the facts are insufficient to meet the sham exception criteria. This Article posits that Louisiana Wholesale is significant because it strongly suggests that under the court's current interpretation of the sham exception, regardless of the facts and agency determinations, the filing of baseless citizen petitions will remain immune from liability.

Finally, Part V considers other alternatives to discourage drug manufacturers from abusing the citizen petition process. These alternatives include regulatory and procedural reforms that build on the recently passed FDAAA citizen petition provisions. These proposals would enable the FDA to respond more directly and effectively to anticompetitive abuses of the regulatory process. In addition, this Article recommends ways for courts to incorporate FDA citizen petition determinations when evaluating the objectively baseless prong of the sham exception. The goal of these proposals is to strike an appropriate balance between preserving the intent of citizen petitions and maintaining a regulatory pathway for generic drugs to enter the market that is unimpeded by bad-faith barriers.

### AT: First Amendment Overwhelms (Chen 16)

#### This card is two lines of garbage – it just says people have a right to petition the FDA – we agree – but they don’t have a right to have their petitions approved – the counterplan just streamlines the review and denial of bad petitions

#### The FDA is allowed to summarily dismiss petitions

Zhang 17 – Sarah Zhang, health and science writer for the Atlantic, “How Pharma Companies Use 'Citizen Petitions' to Keep Drug Prices High,” 3/8/17, https://www.theatlantic.com/health/archive/2017/03/pharma-citizen-petitions-drug-prices/518544/

Gaming the FDA’s citizen petition this way puts the agency in a tricky spot. “The FDA’s number one job is safety. That’s what they’re good at. They’re not designed as a competition policing agency,” says Robin Feldman, a law professor at UC Hastings and a co-author of the paper. For example, the FDA can summarily deny petitions that it finds frivolous—but it never has. The agency tends to err on the side of caution because the consequences of approving an unsafe drug are so high.

## State

#### Farming is rapidly becoming sustainable---all environmental metrics are improving

Michael Shellenberger 20, Founder and President of Environmental Progress, Former President of the Breakthrough Institute, Apocalypse Never: Why Environmental Alarmism Hurts Us All, ISBN: 0063001705,9780063001701

As farms become more productive, grasslands, forests, and wildlife are returning. Globally, the rate of reforestation is catching up to a slowing rate of deforestation.19

Humankind’s use of wood has peaked and could soon decline significantly.20 And humankind’s use of land for agriculture is likely near its peak and capable of declining soon.21 All of this is wonderful news for everyone who cares about achieving universal prosperity and environmental protection.

The key is producing more food on less land. While the amount of land used for agriculture has increased by 8 percent since 1961, the amount of food produced has grown by an astonishing 300 percent.22

Though pastureland and cropland expanded 5 and 16 percent, between 1961 and 2017, the maximum extent of total agriculture land occurred in the 1990s, and declined significantly since then, led by a 4.5 percent drop in pastureland since 2000.23 Between 2000 and 2017, the production of beef and cow’s milk increased by 19 and 38 percent, respectively, even as total land used globally for pasture shrank.24

The replacement of farm animals with machines massively reduced land required for food production. By moving from horses and mules to tractors and combine harvesters, the United States slashed the amount of land required to produce animal feed by an area the size of California. That land savings constituted an astonishing one-quarter of total U.S. land used for agriculture.25

Today, hundreds of millions of horses, cattle, oxen, and other animals are still being used as draft animals for farming in Asia, Africa, and Latin America. Not having to grow food to feed them could free up significant amounts of land for endangered species, just as it did in Europe and North America.

As technology becomes more available, crop yields will continue to rise, even under higher temperatures. Modernized agricultural techniques and inputs could increase rice, wheat, and corn yields five-fold in sub-Saharan Africa, India, and developing nations.26 Experts say sub-Saharan African farms can increase yields by nearly 100 percent by 2050 simply through access to fertilizer, irrigation, and farm machinery.27

If every nation raised its agricultural productivity to the levels of its most successful farmers, global food yields would rise as much as 70 percent.28 If every nation increased the number of crops per year to its full potential, food crop yields could rise another 50 percent.29

Things are headed in the right direction regarding other environmental measures. Water pollution is declining in relative terms, per unit of production, and in absolute terms in some nations. The use of water per unit of agricultural production has been declining as farmers have become more precise in irrigation methods.

High-yield farming produces far less nitrogen pollution run-off than lowyield farming. While rich nations produce 70 percent higher yields than poor nations, they use just 54 percent more nitrogen.30 Nations get better at using nitrogen fertilizer over time. Since the early 1960s, the Netherlands has doubled its yields while using the same amount of fertilizer.31

High-yield farming is also better for soils. Eighty percent of all degraded soils are in poor and developing nations of Asia, Latin America, and Africa. The rate of soil loss is twice as high in developing nations as in developed ones. Thanks to the use of fertilizer, wealthy European nations and the United States have adopted soil conservation and no-till methods, which prevent erosion. In the United States, soil erosion declined 40 percent in just fifteen years, between 1982 and 1997, while yields rose.32

## Case

### Defense

#### They cause increased access now but decreased access in the future

Branstetter 14 – Lee Branstetter, professor of economics and public policy at Carnegie Mellon University, “Starving (or Fattening) the Golden Goose? Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation,” September 2014, https://www.nber.org/system/files/working\_papers/w20532/w20532.pdf

The possibility that rising generic penetration could undermine the incentives to undertake new drug development has been recognized in prior work. For example, Hughes et al. (2002) show in a theoretical model that providing greater access to a current stock of branded prescription drugs yields large benefits to existing customers. However, this access comes at a cost in terms of lost consumer benefits from reductions in the flow of future drugs. Other papers have also discussed this possibility, including Grabowski and Kyle (2007), Higgins and Graham (2009), Knowles (2010), and Panattoni (2011). This research stream has provided (mostly indirect or anecdotal) evidence suggesting that an intensification of generic competition has undermined incentives for R&D. However, to the best of our knowledge, no published study has yet provided direct econometric evidence demonstrating that generic 11 entry has caused a change in the rate or direction of new drug development.8 The extent to which this occurs in practice remains an open question.

#### Investors have adapted to patent trolls, and they don’t have long-term effects on innovation

Giudici 17 – Emiliano Giudici, Associate Professor of Finance, Rusche College of Business, Stephen F. Austin State University, “Evaluating Market Reactions to Non-Practicing Entity Litigation,” 2017, <https://scholarship.law.vanderbilt.edu/cgi/viewcontent.cgi?article=1083&context=jetlaw>

[NPEs = non-practicing entities = patent trolls]

Overall, the empirical results of this study are in sharp contrast with the findings of Bessen, Ford, and Meurer. They examined a large sample of firms across six industries, with firms of a wide range of market capitalizations. 16 7 Their findings indicate that for the period spanning 1990-2010, markets reacted negatively to the filing of lawsuits by NPEs. 168 Bessen, Ford, and Meurer suggest technology and software are more likely targets because patents in that sector tend to be more vulnerable to inadvertent breaches. 169 This study, by contrast, selects firms among the most targeted in those sectors and spans more recent times. Consistent with Bessen, Ford, and Meurer, this study finds the number of filings has increased over time; however, we find that equity investors do not react as sharply as they suggest. The negative skewness of aggregate abnormal returns the day after the filing indicates that in some instances investors' reactions are quite strong; 170 however, this also indicates parametric statistical tests could be inappropriate. 171 The nonparametric tests conducted in this study confirm the weak reactions of investors.

A number of hypotheses could be consistent with these findings of weak abnormal returns and negative skewness. Suppose with the passage of time, investors now realize that the lawsuits will be quickly settled and the NPEs do not have a real intention to halt the production of a particular product of the target firm; then, filing would produce no abnormal returns and no visible change in the skewness, as a technology-based firm's stock price may already reflect its investors' expectation that it will have to settle some patent lawsuits. This would ameliorate the impact of any information that another NPE patent lawsuit has been filed, as long as that lawsuit is of the type to which investors have become accustomed.

The negative skew at the aggregate level, however, suggests two alternative hypotheses: either some lawsuits are associated with significant sell-off or investors in some firms perceive the lawsuits as being detrimental in the long run. The tests at the firm level demonstrate that, using parametric and nonparametric tests, the majority of the firms do not experience significant negative returns on the day of filing. 172 All except one of the firms (VZ) experience negative skew the day after the filing.173 These two findings support the second of the previous hypotheses: investors perceive some filings as being a threat to the target's future profitability and others as nonthreats. These findings suggest further event studies may need to focus on the types of patent filings that are most likely to be used opportunistically by NPEs and could potentially cause unnecessary economic harm.

These findings do not completely contradict those of Bessen, Ford, and Meurer, but shed a different light. Perhaps the increased media coverage on NPEs' activity has educated investors, who realize the true intent of these organizations is to collect monetary compensation rather than prevent the development of a product in its entirety. Investors would perceive this as a one-time expense rather than a permanent hurdle to the firm's ability to innovate and benefit from R&D. The skewness of the results suggests that perhaps investors have become more sophisticated over the years, and instead of initiating selloffs large enough to depress the price of the target's common stock, they evaluate each case and react more conservatively.

#### Patent trolls cause design-around innovations that generate net benefits

Katznelson 16 – Ron D. Katznelson, president of Bi-Level Technologies, a signal and image processing technology firm, “The $83 Billion Patent Litigation Fallacy,” Spring 2016, https://www.cato.org/sites/cato.org/files/serials/files/regulation/2016/4/regulation-v39n1-3.pdf

The authors also miscalculate the social cost of patent litigation because they overlook fundamental economic effects of patent enforcement and because they do not include the wealth effects on parties other than the specific defendants in the lawsuits they covered. “Costs” are net reductions in aggregate welfare. Failing to net them is an obvious error. The authors dismiss, and thus do not properly account for, transfers to other patentees (as described above), to the defendant’s product competitors, to other third parties licensed under the asserted patents, and to third-party patentees having patents in the same technology class as those litigated in the dataset sample. When patents in a given technology area are litigated, the valuation of other patents in the particular technology class often increase as a result of heightened strategic interest in the pertinent technology market. The authors’ analysis of firms in the same SiC 3-digit industry class is too coarse for distilling effects on product or technology classes.

Bessen, Ford, and Meurer also ignore substantial efficiency gains from the indirect benefits of patent enforcement when firms are encouraged to “design around” the asserted patent claims. When design-arounds are commercially successful, they often result in substantial increases in social welfare. My colleague John Howells and I have documented empirical evidence showing how design-around patents spur new manufacturers’ entry into the market, unleash fierce price competition, spur robust price reductions, and reduce deadweight losses of the patentee’s monopoly pricing. We found that from a dynamic efficiency perspective, the greatest potential social welfare enhancement from design-arounds appears downstream over years, even in areas other than the patented technology.

### 2NC – Innovation

#### Innovation high now.

Accenture, global professional services company, 2-2-2022, "Global Industrial Companies Ramp Up R&D Spending Following Covid Shock, Accenture Study Finds," automation, https://www.automation.com/en-us/articles/february-2022/global-industrial-companies-r-d-spending-covid

Growth in R&D spending by over 200 of the world’s largest electrical, machinery and medical equipment companies has been on the rise since mid-2020, according to new research conducted by Capital Economics and Accenture. As a whole, industrial company spend on R&D grew by 17.5% in the third quarter of 2021 compared with the same period a year earlier. The rebound is particularly evident in the electrical sector, where spending grew by over 25% in Q3.

The findings confirm a trend of growing R&D investment. The report “R&D and Innovation across Industry”, also looks at the spending of a larger sample of industrial companies across 12 countries. This shows that R&D spend increased by over 35% in real terms between 2012-2019. On average global R&D investment has been growing at an annual pace of 3.6% in the 5 years up to 2019, outpacing growth in the wider economy of 2.1%. Across a sample of the largest industrial firms, 1.6-11% of revenue was invested in R&D.

Austria claimed the number one spot in the ranking, thanks to its high absolute R&D spend as a share of industry output. France, Sweden and the US trailed closely behind. At the end of the ranking table was the UK and Norway, whose R&D efforts are weaker in both absolute spending terms and research intensity.

Digitisation was identified as the key focus of R&D efforts, particularly given the Covid-19 pandemic wreaking havoc in working arrangements, supply chains and demand patterns. Software and data skills remain in high demand, with google searches for “software engineer jobs” rising fourfold since 2005. For reference, this is a much faster pace than hardware engineers or even solicitors or accountants, where searches have not even doubled over this time period.

Commenting on the findings, Thomas Rinn, Accenture’s Global Lead for Industrials, said: “Far from derailing investment in R&D, the pandemic has accelerated it. More firms across the industrial sector are recognising its direct correlation with higher production efficiency and elevated business agility. AI, cloud computing, digital twins and automation has skyrocketed across the sector, allowing businesses to respond quickly to disruption and changing demand to generate sustainable returns. As Covid-19 continues to accelerate new social and economic trends, as well as radically impacting supply chains, it is vital that industrial firms continue to invest in R&D to stay ahead of the curve. Those that fail to do so risk being left behind.”

#### Patent innovation high now

Andrew G. Isztwan BSE, JD, VP of Litigatation @ Interdigital (25+ years as counsel) , ’19, BRIEF OF AMICUS CURIAE OF INTERDIGITAL, INC. IN SUPPORT OF NEITHER PARTY Case: 19-16122, 08/30/2019, ID: 11417354, DktEntry: 87, Page 1 of 18 https://www.qualcomm.com/media/documents/files/amicus-brief-filed-by-interdigital-inc-in-support-of-neither-party.pdf

Cellular wireless technology has advanced to incredible levels of speed, quality, and ubiquitous adoption. It is no exaggeration to say that the advent of cellular devices has been revolutionary, changing countless aspects of how people experience their daily lives. Cellular adoption began with the first widespread 2G (second generation) cellular phones in the 1990s. Companies like InterDigital and others made enormous investments of time and engineering work to enable steady improvements in technology via the development of 3G standards that became available in the 2000s and 4G standards that became available in the 2010s. Over time, these efforts led to improved stability and data throughput to the point where it is now commonplace to stream high quality video over wireless networks. Looking forward to the 2020s, the move toward 5G standards is now well underway, the culmination of many years of research and development. 5G represents the next widespread deployment of even faster and more robust cellular technology. 5G standards will deliver these improvements through numerous innovations, including expansion into the millimeter wave spectrum and advanced spectrum sharing techniques. The use cases that can be enabled by 5G go far beyond those that have been implemented with current 4G technology. For example, new uses of 5G technology are expected to include:  Virtual reality (VR) and augmented reality (AR) applications via cellular-enabled devices;  Broad expansion of the capabilities of self-driving and autonomous vehicles;  Interconnection of household and commercial products such as large appliances and smart home devices;  Telehealth applications, such as remote surgery; Remote control of critical infrastructure for businesses and governmental users;  Smart city initiatives to integrate traffic, public safety, first response, and more; and  Options for home internet beyond those offered by legacy providers. Rollouts of 5G cellular networks in the United States are currently underway, with a handful of 5G-compatible phones available on the market and infrastructure in place in a few large cities. Within the next one to two years, 5G adoption is expected to quickly accelerate.

### 2NC – AT Stroids

#### No stroids impacts – 1NC evidence indicates its too far off and wont hit earth. Amount of water on earth means will simply cause tsunami

#### There’s no imminent threat to the Earth and we would have centuries of warning in the status quo

**BENNETT 2010** (James, Prof of Economics at George Mason, *The Doomsday Lobby: Hype and Panic from Sputniks, Martians, and Marauding Meteors*, p. 168-169

Cooler heads intervened. Donald Yeomans of the Jet Propulsion Laboratory said, “The comet will pass no closer to the Earth than 60 lunar distances [14 million miles] on August 5, 2126. There is no evidence for a threat from Swift-Tuttle in 2126 nor from any other known comet or asteroid in the next 200 years.”96 Even Brian Marsden concurred. He retracted his prediction, though he held out the possibility that in the year 3034 the comet could come within a million miles of Earth. Surveying this very false and very loud alarm, Sally Stephens, writing in the journal of the Astronomical Society of the Pacific, observed, “Marsden’s prediction, and later retraction, of a possible collision between the Earth and the comet highlight the fact that we will most likely have century-long warnings of any potential collision, based on calculations of orbits of known and newly discovered asteroids and comets. Plenty of time to decide what to do.”97

# 1NR

### impact – 1nr

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror

Marjanovic and Feijao 20 [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html]

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### That causes extinction.

Millett & Snyder-Beattie ‘17. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

### 1 – AT: but daaaartmouth you have no cards about the plaaaaaan – 1nr

#### Damages – the threats of treble damages and disgorgement have a unique chilling effect

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

Companies face significant enforcement and litigation risks without Noerr-Pennington immunity— risks that will undoubtedly deter their exercise of First Amendment protected activity absent intervention by this Court to establish clear rules for the doctrine’s scope and the narrow “sham” litigation exception.

In the antitrust context, companies face liability for treble damages in suits brought by government enforcers, their competitors, or customers. Octane Fitness, 572 U.S. at 556 (observing the “chilling” effect of the threat of treble damages pursuant to 15 U.S.C. 15). The $500 million dollar disgorgement award obtained by the FTC in this case, on top of a private settlement, demonstrates the substantial risks a company faces when deciding whether it may proceed with efforts to petition the courts or other governmental agencies.

Additionally, unfair competition laws similarly may impose punitive and substantial liability. See, e.g., ADP, LLC v. Ultimate Software Grp., Inc., No. 16-8664-KM-MAH, Dkt. Entry No. 119 (D.N.J., Mar. 5, 2018) (assessing Noerr Pennington immunity in light of claimed punitive damages and attorneys’ fees under various federal and state trade secret and unfair competition laws); Boydstun Equip. Mfg., LLC v. Cottrell, Inc., No. 3:16-cv-790-SI, 2017 WL 4803938, at \*9-\*13 (D. Or. Oct. 24, 2017) (applying Noerr-Pennington immunity to alleged violations of state and federal anti-monopolization laws and “Walker Process” fraud, citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965), which permits treble damages).

The FTC, moreover, has vigorously asserted its claimed right not only to damages, but also to disgorgement. See Shari Ross Lahlou, Greg Luib, & Michael Weiner, HIGH STAKES AT THE HIGH COURT: THE FTC’S DISGORGEMENT AUTHORITY COMES BEFORE THE SUPREME COURT, 35 Antitrust 71, 72 (Fall 2020) (“Since 2012, however, the FTC has routinely sought disgorgement in antitrust cases”); see also AMG Cap. Mgmt., LLC v. Fed. Trade Comm’n, 141 S. Ct. 194, No. 19-508 (argued Jan. 13, 2021).6 Regardless of how this Court decides that question in AMG, private parties may be able to seek disgorgement and other equitable remedies under state law, resulting in substantial exposure. Such a risk is particularly dangerous, when the “sham” exception has been traditionally limited to “those rare instances where other conduct or incriminating documents” show bad faith. Lars Noah, Sham Petitioning as a Threat to the Integrity of the Regulatory Process, 74 N.C. L. REV. 1, 41 (1995).

#### The current objectively baseless standard is good precisely because it’s very hard to overcome – that’s key to the patent system – the aff changes this!

Mosier 21 – Mark Mosier, Partner at Covington & Burling LLP, “BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176010/20210419114711882\_Main%20Document.pdf

The court of appeals held that Petitioners subjectively intended to file a lawsuit in bad faith based on its determination that the objective prong was satisfied and the existence of two unremarkable facts present in nearly every patent infringement suit filed by a biopharmaceutical company under the Hatch- Waxman Act: (1) the lawsuit was approved by experienced in-house patent attorneys who, the court concluded, should have known the suit was objectively baseless; and (2) the filing of the lawsuits benefited Petitioners by triggering an automatic stay of Perrigo’s FDA applications under the Hatch-Waxman Act. This misconstruction of PRE’s subjective intent requirement greatly expands the reach of the sham litigation exception to Noerr-Pennington immunity and is inconsistent with the showing required under PRE.

A. The Sham Litigation Exception to Noerr- Pennington Immunity Requires Exacting Proof of Both Objective Baselessness and Subjective Bad Faith

This Court has recognized a narrow exception to Noerr-Pennington First Amendment immunity where the petitioning activity is a “sham”—i.e., where it “is not genuinely aimed at procuring favorable government action, as opposed to a valid effort to influence government action.” PRE, 508 U.S. at 58 (internal citation and quotation marks omitted); Octane Fitness 572 U.S. at 556 (describing sham litigation as a “narrow exception” to Noerr-Pennington immunity). In order for litigation to be a sham, it must first “be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” PRE, 508 U.S. at 60. This Court, however, has been clear that objective baselessness alone is insufficient to qualify litigation as a sham. See PRE, 508 U.S. at 60 (outlining “a two-part definition of ‘sham’ litigation”); id. (if litigation is objectively baseless, court must go on to “examine the litigant’s subjective motivation”); BE & K Constr. Co. v. NLRB, 536 U.S. 516, 526 (2002) (“For a suit to violate the antitrust laws . . . it must be a sham both objectively and subjectively.”) (emphasis in original). Instead, a court must also examine the defendant’s subjective motivation for filing the suit 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 opposed to the outcome of that process—as an anticompetitive weapon.” PRE, 508 U.S. at 60-61 (internal citations and quotation marks omitted) (emphasis in original); see also Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 500 n.4 (1988) (sham requires that the activity is “not genuinely aimed at procuring favorable government action” at all).

Courts of appeals have properly interpreted this Court’s two-step test in PRE as “exacting” and as “plac[ing] a heavy thumb on the scale in favor of the defendant.” Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc., 806 F.3d 162, 180 (3d Cir. 2015); see also U.S. Futures Exch., L.L.C. v. Bd. of Trade of Chicago, 953 F.3d 955, 963 (7th Cir. 2020) (“The sham exception is extraordinarily narrow.”) (internal citation omitted). This is particularly true with respect to patent infringement lawsuits. As courts have recognized, “a principal purpose of the patent system is to provide innovators with a property right upon which investment and other commercial commitments can be made”; as such, the patentee “must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent’s validity or infringement not survive litigation.” C.R. Bard, 157 F.3d at 1369.

To safeguard this central goal of the patent system, “[t]he law recognizes a presumption that the assertion of a duly granted patent is made in good faith.” Id. (citing Virtue v. Creamery Package Mfg. Co., 227 U.S. 8, 37-38 (1913)). Thus, to overcome this presumption and establish the subjective bad faith necessary to prove that a patent infringement lawsuit is a sham, an antitrust plaintiff must produce affirmative evidence of bad faith such as, for example, the defendant’s actual knowledge that it could not have prevailed. See, e.g., C.R. Bard, 157 F.3d at 1369 (citing PRE); In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009) (reinstating sham litigation claim given allegations that defendants “knew their misconduct before the PTO had rendered the patent invalid”); Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282, 1288 (9th Cir. 1984) (affirming jury verdict that defendant had engaged in sham litigation based on evidence showing that defendant “actually knew that the . . . patent was invalid”).

#### Expansion – the plan converts a narrow exception into a routine cause of action – that broadly chills patent enforcement

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

The number of sham-litigation cases has increased in recent years, as plaintiffs have sought to convert a “narrow” exception to Noerr-Pennington immunity into a routine cause of action. Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 556 (2014) (“We crafted the Noerr-Pennington doctrine— and carved out only a narrow exception for ‘sham’ litigation— to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances.”); see, e.g., United Food & Com. Workers Unions & Emps. Midwest Health Benefits Fund v. Novartis Pharms. Corp., 902 F.3d 1, 13-16 (1st Cir. 2018); In re Wellbutrin, 868 F.3d at 147-53; In re Humira, 465 F. Supp. 3d at 833; UFCW v. Novartis Pharms. Corp., No. 15-cv-12732, 2017 U.S. Dist. LEXIS 102389, at \*30-39 (D. Mass. June 30, 2017). Given this rise of sham-litigation suits, allowing the Third Circuit’s decision to stand would severely discourage pharmaceutical patent owners from enforcing their intellectual property rights under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), 21 U.S.C.   355 and 35 U.S.C.   271. When confronted with potential infringement of its patent by a generic drug manufacturer, the patent owner would have to decide between allowing such infringement to continue or quickly bringing suit against the infringer—as intended under the Hatch-Waxman Act—and possibly facing ruinous damages if a court later deemed its suit objectively baseless and inferred from that a subjective intent to directly harm competition through the litigation process by activating the automatic thirty-month stay.

#### Settlement – most patent litigation gets settled now, which provides efficient payouts, but limiting Noerr makes settlement into an implicit admission of guilt – that creates a Catch-22 that waxes innovation

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

Also, because the Hatch-Waxman Act encourages expeditious resolution of patent-infringement suits and these suits involve complex issues of patent validity and high stakes, most parties opt for the certainty of settlement. See Lex Machina, Hatch-Waxman ANDA Litigation Report 2017 at 14 (Apr. 2017) (finding that 56.5% of Hatch-Waxman cases filed 2009 to 2017 settled); RBC Capital Markets, Pharmaceuticals: Analyzing Litigation Success Rates (Jan. 15, 2010) (noting that over half of Hatch-Waxman suits filed 2000 to 2009 were settled or dropped); see also Bureau of Competition, Overview of Agreements Filed in FY 2011 (Jan. 2012) (summarizing key information on the 156 final patent settlement agreements filed with the FTC during fiscal year 2011). Such settlements should be encouraged, not penalized. See Actavis, 570 U.S. at 154 (acknowledging “a general legal policy favoring the settlement of disputes,” including in the context of Hatch-Waxman litigation); Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (Posner, J.) (“The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”). Under the Third Circuit’s decision, however, innovators would be dissuaded from settling Hatch-Waxman suits because if later faced with sham-litigation allegations, a settling innovator would be unable to defend the objective reasonableness of its suit by pointing to a win on the merits and unable to rely on its proper subjective motivation for filing suit. See PRE, 508 U.S. at 60 n.5 (“A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.”).

This Catch-22 would stymie pharmaceutical innovation. Developing new drugs is expensive, time-consuming, and risky. See Actavis, 570 U.S. at 142 (providing that the FDA NDA approval process is “long, comprehensive, and costly”); Gail A. Van Norman, Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, 2016 JACC: Basic to Translational Sci. 170, 171 (finding that the average time between drug discovery and FDA approval is ten to fifteen years); Joseph A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 23, 25- 26 (2016) (estimating that the average cost of developing a new drug and obtaining FDA approval was approximately $2.6 billion in 2013, and that only around 12% of drugs that enter Phase 1 clinical trials end up receiving final FDA approval). Given the high costs and significant risks involved in pharmaceutical research and development, branded pharmaceutical companies must be able to rely on patent protection— including the right to sue for possible infringement and settle such suits—to recoup past R&D efforts and to fund further R&D in the future. Pharmaceutical companies would have no incentive to invest billions of dollars in the development of life-saving and life-enhancing technologies if upon entry of a generic competitor they must choose between allowing infringement of their patents, which were the product of significant time and resources, or filing suit and possibly facing bet-the-company damages in the form of treble damages paid to multiple classes of plaintiffs.

#### The courts – judges are generalist and non-expert – the counterplan’s expert regulator is best

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

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

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

### 3 – AT: antitrust is so hard – 1nr

#### Have a low threshold for the link – expansive patent protections are key to provide funding for R&D and recoup massive up-front investments

Mosier 21 – Mark Mosier, Partner at Covington & Burling LLP, “BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI,” 4/19/21, https://www.supremecourt.gov/DocketPDF/20/20-1293/176010/20210419114711882\_Main%20Document.pdf

The process of developing and bringing to market a new drug is incredibly costly. On average, developing and obtaining FDA approval of a new medicine takes ten to fifteen years and costs $2.6 billion.4 As such, biopharmaceutical companies must devote enormous resources to research and development in order to bring a new drug to market. By any measure, the biopharmaceutical industry is one of the most R&D-intensive industries in the world. It accounts for 18% of all self-funded research and development spend in the United States, and the United States accounts for approximately half of all global spend on biopharmaceutical R&D.5 The biopharmaceutical industry has the highest percentage of R&D reinvestment of any U.S. industry as a percentage of revenue. In fact, on a per-employee basis, the pharmaceutical industry invests $196,000 in R&D—13 times the overall manufacturing industry average in the United States.6 PhRMA's member companies collectively invest nearly 25% of their total annual domestic sales in research and development.7 And small, emerging companies represented by BIO are contributing significantly to the search for new cures and therapies, conducting 70 percent of clinical trials.8 Most of these innovative companies have no products yet on the market. Given the research-intensive nature of drug development, more than 90 percent of biopharmaceutical companies are not profitable, and must rely on private investment, not sales, to fund research and development. 9

Such large investments in inventing and commercializing new drugs are particularly noteworthy because there is a very high likelihood that any individual drug will fail to result in a commercially viable product. Pharmaceutical companies may consider tens of thousands of compounds before identifying a handful that might have a potential commercial use.10 Even of those drugs that make it to a Phase I clinical trial, fewer than 12% are ultimately approved by the FDA.11

Patent protection is thus critical to incentivize the industry to continue to pursue both research and development of new drugs and improvements to existing therapies because it ensures that a certain amount of financial reward will accrue to the owner of a new or improved drug product that, against the odds, successfully navigates these obstacles. As the Federal Trade Commission (“FTC”)—Respondent in this case—has explained, “[p]harmaceutical companies . . . rely on patents to prevent free riding, recoup their R&D investments, and learn about new technological breakthroughs.”12 A former Acting Chairman of the FTC recently surveyed the available empirical evidence and concluded that “[t]he strength of IP rights positively correlates with R&D investment, at least in developed countries,” and “empirical evidence that patents drive innovation in pharmaceuticals is especially strong.”13 Others have noted that “it is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection.”14

#### Declines in pharmaceutical patents cause free riding and catastrophic declines in innovation

Ohlhausen 16 – Maureen K. Ohlhausen, Commissioner, FTC, “Patent Rights in a Climate of Intellectual Property Rights Skepticism,” *Harvard Journal of Law & Technology*, Fall 2016, Volume 30, Number 1, https://jolt.law.harvard.edu/assets/articlePDFs/v30/30HarvJLTech103.pdf

The essential question is whether patents enhance innovation. Theory suggests that patents may variously boost and hinder R&D depending on a host of factors. Econometric and survey evidence hint at an answer but do not establish it irrefutably. The uncertainty is unfortunate and feeds debate, but it does not excuse ignorance or guess work in formulating innovation policy. Combined with economic theory and common sense, existing empirical evidence can support at least partially informed decision-making. As explained below, econometric work does not answer every material question — or even most of them — but it does allow policymakers to reject calls for outright patent abolition and permits them to make more informed judgment calls at the margin of patent policy.

A. The Economic Relationship Between Patents, Innovation, and Welfare

A basic economic premise underlies the patent system: technologies are expensive to invent but easy to copy. Thus, absent a Pigouvian subsidy or a property right,79 positive externalities will cause suboptimal investment in innovation.80 This is the classic “public goods” narrative, which warns that easily appropriated information will be under- produced in a free market. One solution is a patent that allows an inventor to prevent third parties from copying her technology. That preventative rationale underlies patent systems around the world, perhaps also reflecting an intuition that inventors deserve exclusive rights against free riders who would rather take others’ ideas than create their own.

In some important industries, public-goods theory accurately captures the nature of invention. The standout example is pharmaceuticals, in which private firms pour billions of dollars into R&D.81 Successful drugs are susceptible to reverse engineering at relatively modest cost by generic firms. It is widely understood that, absent an alternative reward structure like regulatory exclusivity or suitably tailored prizes, innovation in the life sciences industry would suffer catastrophic decline without patent protection.82

#### Patents are key to pharma commercialization even if they’re not key to invention

Holman 18 – Christopher Holman Professor at the University of Missouri-Kansas City School of Law, “Patentability Standards for Follow-On Pharmaceutical Innovation,” *Biotechnology Law Report*, 6/1/2018, Number 3, 10.1089/blr.2018.29073.cmh131

With respect to inventions categorized as “secondary,” in the same way as “primary” inventions, there are significant costs and risks associated with translating these inventions into approved drugs. It is important to bear in mind that patents are not only important for incentivizing invention, but also for incentivizing the substantial investment needed to turn an invention into a useful product. As pointed out by Professor Rob Merges, “patents may have a greater impact on incentives to develop as on incentives to invent,”36 and this is particularly the case with respect to pharmaceuticals, given the huge uncertainty as to whether a promising invention will actually prove viable in the market. Extensive and expensive human clinical trials are needed to assure the safety and efficacy of follow-on pharmaceutical inventions if they are going to provide any benefit to the public and, to the extent available, test data protection alone is often not sufficient to incentivize the funding of such trials.

### 4 – AT: scams bad for pharma – 1nr

#### Applying antitrust spills over – litigants will seize the opportunity to further erode IP protections.

Lim ’14 [Daryl; Assistant Professor, The John Marshall Law School; 2014; “Patent Misuse and Antitrust: Rebirth or False Dawn?”; <https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1191&context=mttlr>; Michigan Telecommunications and Technology Law Review; accessed 10/28/21; TV]

Actavis ushered in an age of more vigorous antitrust scrutiny of patent rights. Even a valid and infringed patent did not give the patentee carte blanche to do as it pleased. Antitrust law could limit the exercise of patent rights if it harmed market competition and consumer welfare. To support its conclusions, the Court dusted off its older decisions from the 1940s to the 1970s.317 The view that patent rights were vulnerable to antirust scrutiny was a view accepted by courts as recently as the turn of the millennium.318 Although the Actavis dissent accused the majority of “announc[ing] a new rule,”319 this more qualified view of patents echoes the Court’s recent decision in eBay v. MercExchange, where it held that patents do not confer an automatic right to exclude but instead needs to be considered in the context of broader equities and concerns.320

Actavis also stood out from recent antitrust decisions favoring defendants.321 The Court noted that, although “avoided litigation costs or fair value for services” may indicate that settlements should survive a rule of reason scrutiny, defendants may have less success with motions to dismiss going forward.322 Settling parties may point to co-marketing arrangements as a justification for the reverse payment, but they are unlikely to win their case on summary judgment.323 Parties on both sides will be compelled to marshal robust economic valuations to support or oppose the challenged payments.324

However, there are also two risks involved in increased antitrust scrutiny—first, that patentees may be less willing to invest in new drugs, and second, that generics may be less willing to mount patent challenges because the likelihood of obtaining a settlement needs to be further discounted postActavis. 325 Even supporters of the majority’s decision must concede that it carries its own hefty price, and without any guarantee that it will achieve its intended results. Described by Robin Feldman as “ground zero” for pharmaceutical development and sales, the impact of Actavis on drug prices and innovation—for better or worse—will be felt in the United States and far beyond.

In short, Actavis has reactivated antitrust scrutiny of patent rights. Courts will see more antitrust challenges within the Hatch-Waxman context and with patent matters more generally. This will in turn generate more debate about how innovation and competition policies are balanced in the exercise of patent rights. In time, this debate will spill-over to patent misuse.

The defense lies at crossroads of patent and antitrust law, and a revitalization of antitrust scrutiny should cause more misuse cases, such as those in Kimble, to be brought as well.

No one is immune to a change of heart. In 2003, Judge Posner became an unlikely advocate of misuse. In SmithKline Beecham Corp. v. Apotex Corp., he concluded it would be a “travesty of equity” to permit the plaintiff an extension of its patent beyond the patent term.326 In so doing, he acknowledged that was effectively reaching the same result as if he had found misuse and refused to enforce the patent against Apotex because it had already expired.327 If one of the Chicago School’s best-known personalities is prepared to look beyond antitrust policy and invoke its equitable basis, a new dawn may yet come to those hoping for a measured revitalization of patent misuse.

While one judge interviewed emphasized that there was no judicial hostility toward misuse, it was difficult for him to “sense vigor beyond antitrust case law.”328 Litigants have added that “[n]or is there any reason to expand the misuse defense to reach alleged collateral anticompetitive conduct, when the antitrust laws already provide any party that suffers competitive injury with powerful means of redress.”329 Other interviewees noted that patent misuse should not become a free-floating ‘get out of jail free’ card.330 In light of these concerns, the first step to any revitalization of patent misuse must be to answer these and other key concerns.

### 5 – AT: generics solve – 1nr

#### The case can’t turn the DA – even if they solve access in the short term, declining innovation crushes health care and drug access long term

Holman 18 – Christopher Holman Professor at the University of Missouri-Kansas City School of Law, “Patentability Standards for Follow-On Pharmaceutical Innovation,” *Biotechnology Law Report*, 6/1/2018, Number 3, 10.1089/blr.2018.29073.cmh131

The high nonobviousness standard promoted in the Guidelines are unabashedly policy-driven; in the view of their author, the extreme importance of immediate access to pharmaceuticals justifies a uniquely rigorous nonobviousness standard for follow-on pharmaceutical inventions. However, the underlying premise that healthcare would be improved by effectively reducing the availability of patents for pharmaceutical inventions fails to account for the high risk, cost, and uncertainty attendant to the development of an approved drug capable of delivering potentially huge improvements in health. When the entire drug development process is properly considered, some commentators actually argue in favor of a relatively permissive standard of nonobviousness that accounts for the unusually high cost and risk associated with drug development, compared to other types of patent eligible innovations. In that regard, it is important to bear in mind that while a reduction in the availability of patent protection for pharmaceuticals might promote access in the short term, the resultant decrease in the incentive for pharmaceutical development will ultimately harm medium and long-term access.

#### The whole point of generic drugs is that they are first developed as brand-name innovations by pharma companies, so the DA turns the case and not the other way around

Schacht 12 – Wendy Schacht, Specialist in Science and Technology Policy, “Drug Patent Expirations: Potential Effects on Pharmaceutical Innovation,” 3/2/12, https://ipmall.law.unh.edu/sites/default/files/hosted\_resources/crs/R42399\_120302.pdf

While many factors contribute to innovation in the brand pharmaceutical industry and its ability to bring new and inventive products to the marketplace, this sector is facing significant issues associated with the loss of revenue available for additional R&D due to patent expirations and generic competition. Generic versions of brand pharmaceuticals benefit the public due to their lower cost and greater availability. However, experts point out that without the research, development, and testing performed by the brand name pharmaceutical companies, generic drugs would not exist. Thus, there is ongoing congressional interest in striking the proper balance between lower cost drugs and maintaining an innovative domestic pharmaceutical sector.

#### They may strengthen pre-existing innovations, but they destroy key future innovation

McDole 21 – Jaci McDole, senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation, “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic,” 4/29/21, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through>

[Italics in original]

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some *pre-existing innovations*, but it would absolutely limit *future innovations*. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.