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Weaponizing Citizen Suits: Second Circuit Revises the Burden of Proof for Proving Sham Citizen Petitions in *Apotex v. Acorda Therapeutics*

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WEAPONIZING CITIZEN SUITS: SECOND CIRCUIT REVISES THE BURDEN OF PROOF FOR PROVING SHAM CITIZEN SUITS IN *APOTEX v. ACORDA THERAPEUTICS*

Abstract: In 2016, in *Apotex Inc. v. Acorda Therapeutics, Inc.*, the United States Court of Appeals for the Second Circuit held that a generic drug company could not rely solely on the timing of the Food and Drug Administration’s (“FDA’s”) disposition of a citizen suit and approval of a generic application to state a claim under the Sherman Act based on sham litigation. By contrast, in 2009, in *In re DDAVP Direct Purchaser Antitrust Litigation*, the Second Circuit held that precisely such evidence was sufficient to state a Sherman Act claim. This Comment argues that the Second Circuit’s revision of the burden of proof for showing a sham citizen suit incentivizes brand-name drug companies to file sham citizen suits as a means to extend their monopolies, which would harm both generic drug manufacturers and the American public. Given the competitive and public health ramifications associated with regulating prescription drugs, it is crucial that U.S. courts give sufficient weight to the underlying policies behind consumer-protection statutes such as the Hatch-Waxman Act and the Sherman Act in order to avoid unintentionally harming the public.

INTRODUCTION

In the United States, brand-name drugs are typically sold at a significantly higher price than their generic counterparts.¹ The separate approval processes at the Food and Drug Administration (“FDA”) for marketing brand-name and generic drugs are one reason for this price discrepancy.²

¹ See *Facts About Generic Drugs*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> [https://perma.cc/62V8-JLMR] (setting out basic facts with respect to generic drugs). The average price of a generic drug is between eighty and eighty-five percent cheaper than the price of its brand-name counterpart. *Id.*; see also U.S. GOV’T ACCOUNTABILITY OFF., GAO-12-371R, SAVINGS FROM GENERIC DRUG USE 1, 4 (2012) (reporting on the amount generic drugs have saved the public compared to brand-name drugs); Aaron S. Kesselheim & Jonathon J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y, L. & ETHICS 293, 293, 295 (2015) (explaining that lower-cost generic drugs, which make up eighty-four percent of all U.S. drugs prescribed but account for less than twenty percent of drug costs, have saved over one trillion dollars in healthcare costs from 1999–2010).

² See *Facts About Generic Drugs*, *supra* note 1 (distinguishing the market approval process for generic drugs from that required of brand-name makers). Unlike brand-name drugs, the Food

One crucial difference between the brand-name and generic approval processes is that an application to market a generic cannot legally be filed with the FDA until after the corresponding brand-name drug's exclusivity period has expired.³ As a result of this regulatory dichotomy, brand-name drug manufacturers retain a monopoly in the market until the first generic competitor is able to receive FDA approval to enter the market.⁴ This creates a strong incentive for brand-name manufacturers to interfere with the generic approval process in order to preserve their monopolies, whether through filing meritless lawsuits to tie up the generic drug manufacturer's resources or by paying the generic manufacturer to delay filing its applications with the FDA.⁵

In May 2016, in *Apotex Inc. v. Acorda Therapeutics, Inc.*, the United States Court of Appeals for the Second Circuit affirmed the United States District Court for the Southern District of New York's dismissal of a generic competitor's claim that a brand-name manufacturer had filed a sham citizen petition with the FDA in order to delay its generic drug's application before the FDA, which would constitute an anticompetitive act in violation of Sec-

and Drug Administration ("FDA") only requires generic manufacturers to show that their drug has the same effects in the human body as the brand-name drug (a feature known as "bioequivalence"). *Id.* Thus, generic manufacturers need not submit clinical trial data, which are both extremely time-consuming and expensive to gather. *Id.* Moreover, generic manufacturers also typically face lower advertising and marketing costs compared to brand-name manufacturers. *Id.*

³ Richard B. Racine, *The Interplay Between U.S. Pharmaceutical Patents and FDA Law*, FINNEGAN: MANAGING INTELLECTUAL PROPERTY (Dec. 2010), <http://www.finnegan.com/resources/articles/articleDetail.aspx?news=ad4b058b-0150-4ec7-90f4-57e6641272a6> [<https://perma.cc/N3JF-VDT5>]. Exclusivity rights were originally designed to strike an important balance between promoting innovative research and development for brand-name drugs and allowing for competition from generics upon expiration of the brand-name drug's exclusivity period. *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments): Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 1 (2003) (statement of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration).

⁴ See *Generic Drugs: Questions and Answers*, FDA, <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> [<https://perma.cc/4SKK-VZKD>] (noting that most brand-name drugs are protected for twenty years under a patent and that as a result, other drug companies may not begin making or selling the protected drug until after its patent has expired).

⁵ See FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1-3 (2010) (summarizing the economic costs "pay-for-delay" agreements impose on consumers and recommending federal legislation to prohibit pay-for-delay agreements). The Federal Trade Commission ("FTC") has recently cracked down on pay-for-delay cases involving brand-name companies who offer generic competitors lucrative payments in exchange for delaying the filing of their generic applications. *Id.* at 1, 3; Robert A. Lipstein et al., *Observations on Brand Name-Generic Sham Litigation Disputes and Settlements*, AIPLA ANTITRUST NEWS (AIPLA Comm. on Antitrust Law), May 2008, at 15 (exploring the tension between brand-name and generic drug manufacturers that Congress created by enacting the Hatch-Waxman Act in 1984); see also *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 430 (E.D. Pa. 2015) (detailing FTC allegations against patent holder of a brand-name testosterone drug that patent litigation was sham litigation initiated in order to delay entry of a generic into the market).

tion Two of the Sherman Act.⁶ A citizen petition directs the FDA's attention to specific concerns over a drug's safety or efficacy and asks the FDA to take some particular action with respect to that drug.⁷ Relying on recent FDA guidance, the Second Circuit conceded that, although it was conceivable that the brand-name manufacturer's citizen petition might have been a sham filing, dismissal of the Sherman Act claim was nevertheless proper because the generic competitor had not pled sufficient facts in support of its antitrust claim.⁸

This Comment argues that, notwithstanding the fact that the FDA ultimately denied the brand-name manufacturer's citizen petition, the Second Circuit's decision is likely to incentivize brand-name drug companies to file self-interested sham citizen suits for the sole purpose of delaying or altogether precluding generic competition.⁹ If brand-name manufacturers file citizen suits with greater frequency and volume, generic competitors would suffer direct harm, but the public at large would also be harmed in the form of higher drug prices and diminished choice.¹⁰ Part I of this Comment addresses the FDA's treatment of generic and brand-name drugs, citizen petitions in the pharmaceutical context, relevant U.S. antitrust doctrine, and the factual and procedural history of *Apotex*.¹¹ Part II reviews the status of the law in the Second Circuit regarding sham citizen suits pre-*Apotex*, and the manner in which recent FDA guidance factored into the Second Circuit's most recent sham citizen suit decision.¹² Finally, Part III examines the likely fallout from *Apotex*, including its prospective impact on generic and brand-name pharmaceutical manufacturers, U.S. antitrust law, and public health.¹³

⁶ 823 F.3d 51, 61–62 (2d Cir. 2016). In the same case, the Second Circuit also affirmed the District Court with respect to *Apotex*'s second claim against *Acorda*, holding *Acorda* was not liable for violating the Lanham Act's prohibition on false advertising as the company had not made any representations that were literally false or likely to mislead consumers. *Id.* at 67–68.

⁷ Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 251 (2012); see also 21 C.F.R. § 10.30 (2016) (authorizing parties to submit a citizen petition to the FDA upon meeting certain requirements).

⁸ See *Apotex*, 823 F.3d at 60–62 (explaining that the FDA Guidance for Industry tends to undermine any inference drawn based on timing that the citizen petition was a sham and was deployed anticompetitively); FDA, OMB 0910-0679, CITIZEN PETITIONS AND PETITIONS FOR STAY OF ACTION SUBJECT TO SECTION 505(Q) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY 13–14 (2014) [hereinafter GUIDANCE FOR INDUSTRY] (explaining that the FDA prefers not to rule on a citizen petition until after it has decided whether or not to approve the associated Abbreviated New Drug Application (“ANDA”) to preserve the procedural rights of generic applicants).

⁹ See *infra* 75–88 and accompanying text.

¹⁰ See *infra* 85–88 and accompanying text.

¹¹ See *infra* 14–54 and accompanying text.

¹² See *infra* 55–74 and accompanying text.

¹³ See *infra* 75–88 and accompanying text.

I. THE PHARMACEUTICAL DRUG INDUSTRY AND ANTITRUST LITIGATION

The pharmaceutical industry is heavily regulated and features a great deal of litigation between brand-name and generic drug companies at the confluence of intellectual property law and antitrust law.¹⁴ Section A of this Part briefly examines the role of the FDA, explains the crucial differences between the approval processes for brand-name and generic drugs, and explores the incentives that brand-name drug manufacturers have in light of the current regulatory regime.¹⁵ Section B of this Part explains the role of citizen petitions within the pharmaceutical industry and how brand-name drug companies have strategically deployed these petitions to extend their monopolies.¹⁶ Section C of this Part provides an overview of U.S. antitrust law with a focus on the Sherman Act and one of its major exceptions, the *Noerr-Pennington* immunity doctrine.¹⁷ Finally, Section D of this Part summarizes the procedural history of *Apotex*, a recent Second Circuit case involving allegations of anticompetitive sham litigation in the prescription drug context.¹⁸

A. *The FDA and Drug Regulation in the United States*

In the United States, the FDA is tasked with safeguarding the nation's health by reviewing human drugs, medical devices, and food to ensure that they are both safe and effective.¹⁹ For its review purposes, the FDA distinguishes between new brand-name drugs and generic drugs with unique approval processes in place for evaluating each.²⁰ To receive U.S. marketing

¹⁴ See Carrier & Wander, *supra* note 7, at 251 (noting that some of the pharmaceutical industry's greatest challenges come with respect to patent terms and the onset of generic competition).

¹⁵ See *infra* 19–28 and accompanying text.

¹⁶ See *infra* 29–34 and accompanying text.

¹⁷ See *infra* 35–45 and accompanying text.

¹⁸ See *infra* 46–54 and accompanying text.

¹⁹ *About FDA: What We Do*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> [<https://perma.cc/RN9N-SYYA>] (setting out the FDA's mission statement and regulatory responsibilities). The FDA, a federal administrative agency, is also responsible for ensuring the safety and efficacy of biological products, veterinary drugs, cosmetics, and radiation-emitting products. *Id.*

²⁰ See *The Drug Development Process*, FDA, <https://www.fda.gov/ForPatients/Approvals/Drugs/default.htm> [<https://perma.cc/BHJ8-9LAH>] (explaining that the typical process for a brand-name manufacturer involves preclinical trials to determine a potential compound's safety and efficacy, followed by four graduated stages of clinical trials involving a greater number of human participants and longer terms of observation); see also *Abbreviated New Drug Application (ANDA)*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/> [<https://perma.cc/8VJ2-BKM6>] (providing a high-level overview of the Abbreviated New Drug Application). To avoid duplicating the efforts of brand-name drug developers, a generic applicant need only demonstrate as part of its ANDA that its generic produces the same results as the brand-name drug in the human body, a feature known as “bioequivalence.” *Id.*

approval, brand-name drugs must provide years of data from pre-clinical (animal) and clinical (human) trials to prove that their drug products are safe and effective.²¹ In contrast, generic drug manufacturers can avoid submitting their own pre-clinical and clinical data altogether and need only show that their drug contains the same active ingredient and has the same effect in the human body as their brand-name counterpart.²²

The presence of generic drugs provides a lower cost alternative to brand-name drugs and the prevalence of generics decreases prescription drug costs overall, an effect that Congress intended in 1984 when it passed the Drug Price Competition and Patent Term Restoration Act of 1984 (popularly known as the “Hatch-Waxman Act”).²³ The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetics Act (“FDCA”) to, among other things, facilitate and expedite generic entry into the market by creating a new, quicker approval process for generics known as the Abbreviated New Drug Application (“ANDA”).²⁴ In passing the Hatch-Waxman Act, Congress sought to strike a balance between two competing public policy goals: protecting brand-name drug manufacturers’ return on investment on the one hand, and ensuring consumer access to lower cost alternatives upon the expiration of the brand-name drug’s exclusivity period on the other.²⁵

Owing to the higher degree of risk and expense inherent to filing an Investigative New Drug Application (“IND”), brand-name manufacturers are rewarded with a limited (in time only) exclusivity period free from generic competition upon receiving FDA market approval for their brand-

²¹ See 21 C.F.R. § 312.20–.38 (2016) (setting out the Investigational New Drug Application (“IND”) process and describing the phases of investigational studies required for new drugs); see also Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, J. HEALTH ECON., May 2016, at 20–22 (estimating that in 2013, the average total cost to obtaining FDA marketing approval for a brand-name drug was approximately \$2.6 billion, with the vast majority of the out-of-pocket costs attributable to conducting pre-clinical and clinical trials).

²² See 21 U.S.C. § 355(j) (2012) (creating the ANDA, an expedited system for approving generics).

²³ Kesselheim & Darrow, *supra* note 1, at 297, 301. The Hatch-Waxman Act arose out of Congress’s frustration with the existing regulatory framework for prescription drugs, which made it relatively difficult for generic manufacturers to get their lower-cost copies approved for sale in the market. *Id.* at 297. Congress, in passing the Hatch-Waxman Act, also sought to lower drug costs in order to mitigate adverse health outcomes caused by patients who tried to save money on high-cost brand-name drugs by reducing their normal drug regimens. *Id.* at 300.

²⁴ See 21 U.S.C. § 355(j) (creating the ANDA approval process for generics). In filing an ANDA, a generic drug company must show that their drug contains the same active ingredient as the brand-name drug and is bioequivalent to the brand-name drug. *Id.* § 355(j)(2)(A)(iv).

²⁵ *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, *supra* note 3. The Hatch-Waxman amendments also created a limited 180-day period of market exclusivity for generics that meet certain criteria, in effect immunizing these generics from competition for a period of time from subsequent generic versions of the same drug. *Id.* at 3–4; see also 21 U.S.C. § 355(j)(5)(B)(iv) (defining the 180-day exclusivity period).

name drug.²⁶ The duration of a brand-name drug company's monopoly depends in part upon the length of their exclusivity period, which is determined based upon the type of chemical compound the brand-name drug contains and is expressly set out in FDA regulations.²⁷ After the exclusivity period expires, a brand-name drug company can retain its monopoly until the FDA approves a generic competitor's ANDA.²⁸

B. Citizen Petitions

A citizen petition is a submission to the FDA which requests that the agency take some action in light of a particular drug's safety or efficacy.²⁹ Specifically, citizen petitions allow any "interested person" to ask the Commissioner of the FDA to "issue, amend, or revoke a regulation or order" or "take or refrain from taking any other form of administrative action."³⁰ Citizen petitions may be filed to challenge a product on scientific or legal bases, before or after the FDA has reviewed the product.³¹

Brand-name drug manufacturers are the most common filers of citizen petitions with the FDA, and usually request that the FDA deny a generic

²⁶ See Racine, *supra* note 3 (explaining that once a brand-name drug company receives approval from the FDA, they are awarded with an exclusivity period). The exclusivity period that the FDA grants is independent from any patent monopoly the U.S. Patent and Trademark Office ("PTO") grants, and essentially allows the brand-name drug company to enjoy a limited monopoly for a period of years completely free from generic competition. *Id.*; see also 21 C.F.R. § 314.108 (2016) (setting out the technical requirements to be considered in deciding the length of the exclusivity period for different drug products).

²⁷ See 21 C.F.R. § 314.108(b)(2) (stating that brand-name drugs that contain a "new chemical entity" enjoy five years of exclusivity from the date of FDA approval); *Frequently Asked Questions on Patents and Exclusivity*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm> [<https://perma.cc/JB88-JF5W>] (stating that drugs intended to treat rare diseases are granted seven years of exclusivity).

²⁸ See 21 U.S.C. § 355 (creating a process by which generic manufacturers can obtain quicker lower-cost approvals than ever before); Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, J. MED. ECON., Dec. 2013, at 1 (finding that the average actual exclusivity period in one study enjoyed by brand-name drugs introduced between 2011 to 2012 was just under thirteen years). Prior to the Hatch-Waxman Act, generic manufacturers were burdened with redundant requirements, engaging in many of the same studies and trials brand-name drug companies already performed in order to generate the safety and efficacy data then required by the FDA for market approval. Grabowski, *supra* at 2.

²⁹ Carrier & Wander, *supra* note 7, at 251; see 21 C.F.R. § 10.30 (2016) (setting out the requirements for the submission of a citizen petition to the FDA).

³⁰ 21 C.F.R. § 10.25(a); see 5 U.S.C. § 553(e) (2012) (requiring government agencies to allow the public to petition for the issuance, amendment, or repeal of a rule); 21 C.F.R. § 10.30 (setting out the requirements for the submission of a citizen petition to the FDA). The citizen petition arose as a byproduct of both the First Amendment's guarantee to the right to petition and the Administrative Procedure Act's requirement that government agencies allow the public certain participatory rights with respect to agency rulemaking. Carrier & Wander, *supra* note 7, at 259–60.

³¹ *Apotex*, 823 F.3d at 57.

competitor's pending ANDA.³² Brand-name drug manufacturers, however, are increasingly utilizing citizen suits for self-interested strategic business and competitive reasons, and not for the purposes for which the citizen petition was originally created.³³ Indeed, there is empirical evidence that generally speaking, citizen petitions filed with the FDA add little if any value to the analysis of a particular drug.³⁴

C. Relevant U.S. Antitrust Laws

In the United States, antitrust law is codified in three federal statutes: the Sherman Act, the Federal Trade Commission Act, and the Clayton Act.³⁵ The earliest of the three, the Sherman Act, was enacted in 1890 and contains two key prohibitions: Section One, which proscribes agreements in restraint of trade, and Section Two, which proscribes unilateral conduct di-

³² See *id.* (stating that citizen suits were originally designed to allow the public to have a voice in the drug approval process, but that a number of pharmaceutical companies have taken advantage of the system to file meritless petitions in order to delay their generic competitors from receiving FDA approvals); *Carrier & Wander*, *supra* note 7, at 252, 271 (finding that from 2001 to 2010, brand-name drug companies filed sixty-eight percent of all citizen petitions with the FDA, seventy-eight percent of which were directed against generic companies).

³³ See *Apotex*, 823 F.3d at 57 (noting the recent misuse of citizen suit petitions by a number of pharmaceutical companies through the filing of meritless petitions in order to delay generic competitors from receiving FDA approval); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 695 (2d Cir. 2009) (holding that plaintiff class of purchasers of a medicinal drug sufficiently stated a claim for sham litigation against the drug's manufacturer and one of its licensees); see also *Carrier & Wander*, *supra* note 7, at 252, 270–71 (noting that one explanation for the fact that only nineteen percent of petitions were successful between 2001 and 2010 was that many petitions were filed to delay generic entry, as was the case for the drug Ambien, whose approval was delayed by 1,225 days as a result of a citizen petition).

³⁴ See *Carrier & Wander*, *supra* note 7, at 261–62 (explaining that many citizen petitions are filed on questionable grounds and that it is very rare that a citizen petition will raise a new issue that has not already been fully considered by the FDA).

³⁵ Sherman Act, 15 U.S.C. §§ 1–7 (2012); Clayton Act, 15 U.S.C. §§ 12–27 (2012); Federal Trade Commission Act, 15 U.S.C. §§ 41–58 (2012); *The Antitrust Laws*, FED. TRADE COMMISSION, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> [<https://perma.cc/RR7P-CUH7>]. The Clayton Act was passed in 1914 and prohibits mergers and acquisitions that tend to create a monopoly. Clayton Act, ch. 323, 38 Stat. 730 (1914) (codified as amended in scattered sections of 15 and 29 U.S.C.). The Federal Trade Commission Act, also passed in 1914, sweeps more broadly, and generally prohibits unfair and anticompetitive methods, acts, or practices. Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41–58 (2012)). Thus, in practice, any behavior that violates the Sherman Act would also be found to violate the Federal Trade Commission Act and would be enforceable by the Federal Trade Commission (“FTC”). See 15 U.S.C. § 45(b) (authorizing the FTC to charge those who are or have been employing unfair methods of competition or deceptive acts or practices affecting commerce in the public interest). See generally Maurice E. Stucke, *Reconsidering Antitrust's Goals*, 53 B.C. L. REV. 551, 552–53 (2012) (noting that U.S. antitrust law is unique compared to other countries in vesting private antitrust plaintiffs with certain advantages to encourage private enforcement of antitrust claims, including broad discovery, the availability of treble damages, and the ability to bring antitrust claims as a class action).

rected towards monopolization of a market.³⁶ Specifically, Section Two confers liability on parties who “shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States.”³⁷

Although the literal text of the Sherman Act seems absolute, the courts have interpreted Section Two with some elasticity to exclude from antitrust liability certain activities that, for example, involve petitioning the legislature or the executive to take action.³⁸ The common-law doctrine excepting certain petitioning activities from antitrust liability under the Sherman Act is known as *Noerr-Pennington* immunity, after the two seminal Supreme Court cases in which the doctrine was developed.³⁹ The *Noerr-Pennington* doctrine in essence ensures that individuals’ First Amendment rights to petition are protected and not infringed by the enforcement of U.S. antitrust laws.⁴⁰ Under the *Noerr-Pennington* immunity doctrine, a party may be exempt from antitrust liability if they petition the government, even if such a petition, if granted, would result in an antitrust violation.⁴¹ *Noerr-Pennington* immunity, however, does not cover petitioning of governmental bodies if they are a mere sham meant to interfere with a competitor’s business.⁴²

In that vein, the United States Court of Appeals for the Second Circuit in 2009 in *In re DDAVP Direct Purchaser Antitrust Litigation* held that, although filing a citizen petition under the FDCA is ordinarily immunized under the *Noerr-Pennington* doctrine, filing a sham citizen petition with the

³⁶ See 15 U.S.C. §§ 1–2 (2012) (codifying the Sherman Act’s prohibitions against agreements in restraint of trade and anticompetitive unilateral conduct). Congress passed the Sherman Act in 1890 as a comprehensive statute aimed at protecting free and unrestrained competition, and Section One of the Sherman Act makes it a felony to engage in contracts, combinations, and conspiracies in restraint of interstate or international trade. *The Antitrust Laws*, *supra* note 35.

³⁷ 15 U.S.C. § 2.

³⁸ See *E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 136 (1961) (emphasizing that associations to persuade government action are different in kind from the price-fixing agreements, boycotts, and market-division agreements that are normally held to be violations of the Sherman Act).

³⁹ *Id.*; see also *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 664–65 (1965) (holding that collective efforts to influence public officials do not constitute an antitrust law violation, even if they were intended to eliminate competition); *In re DDAVP*, 585 F.3d at 685–86 (referring to the immunity as the *Noerr-Pennington* doctrine).

⁴⁰ See FED. TRADE COMM’N, ENFORCEMENT PERSPECTIVES ON THE *NOERR-PENNINGTON* DOCTRINE 3 (2006) (noting that the *Noerr-Pennington* doctrine guides courts in their interpretation of the Sherman Act in a way that promotes democratic government).

⁴¹ Ann K. Wooster, Annotation, “Sham” Exception to Application of *Noerr-Pennington* Doctrine, Exempting from Federal Antitrust Laws Joint Efforts to Influence Governmental Action Based on Petitioning Administrative or Judicial Body, 193 A.L.R. Fed. 139, § 2(a) (2004). The Supreme Court has found *Noerr-Pennington* immunity to apply to petitioning efforts directed at both the legislative and executive branches, and even petitioning before courts and administrative agencies. *Id.*

⁴² *Id.*

FDA is akin to filing sham litigation and is therefore not protected behavior and may constitute a violation of Section Two of the Sherman Act.⁴³ The Second Circuit has stated that in order for a citizen petition to be a sham, a claimant must show that the citizen petition was both an objective and subjective sham.⁴⁴ Thus, in order for the filing of a citizen petition (or litigation) to lose its *Noerr-Pennington* immunity and constitute a sham, in violation of the Sherman Act, it must be both objectively baseless, as judged from the perspective of a reasonable person, and be motivated by the filing party's attempt to directly interfere with a competitor's business.⁴⁵

D. Procedural History of Apotex v. Acorda Therapeutics

In 2007, prior to the filing of the instant lawsuit, Apotex ("the generic manufacturer") submitted an ANDA to the FDA in which it sought approval to market its generic formulation of Zanaflex Capsules.⁴⁶ Zanaflex is the brand-name of tizanidine, a drug used to treat spasticity, a condition common in patients with multiple sclerosis, Parkinson's disease, and other central nervous system injuries.⁴⁷

In early September 2011, while Apotex's ANDA was still pending review with the FDA, Acorda Therapeutics ("the brand-name manufacturer") filed a citizen petition pursuant to 21 C.F.R. § 10.30, challenging Apotex's claims of bioequivalence in its generic application and alleging that its proposed generic label contained misleading or false statements.⁴⁸

In December 2011, Apotex filed a complaint in the United States District Court for the Southern District of New York against brand-name manu-

⁴³ 585 F.3d at 685–86 (holding that a single sham petition may be treated as a single sham litigation). Although a single lawsuit that is both an objective and subjective sham can give rise to antitrust liability, petitions to administrative agencies are within the scope of the sham exception to the *Noerr-Pennington* doctrine so long as they are not "essentially political." *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1062 (9th Cir. 1998).

⁴⁴ *In re DDAVP*, 585 F.3d at 694.

⁴⁵ *Id.*; see *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 61–62 (1993) (explaining that proof of a sham only eviscerates the lawsuit's legal viability and the plaintiff still must prove all of the elements of the antitrust violation in order to prevail on a Sherman claim).

⁴⁶ *Apotex*, 823 F.3d at 57. Zanaflex was first marketed in tablet form and approved by the FDA in 1996. *Id.* at 56. Although Apotex and Acorda Therapeutics each received FDA approval to market their versions of tizanidine tablets, the two companies were motivated to produce a capsule version in order to reduce one of the principal side effects of their tablets, drowsiness. *Id.*

⁴⁷ *Id.* at 57.

⁴⁸ *Id.* at 57–58. Acorda's citizen suit was filed after it lost a 2007 patent-infringement suit against Apotex, a suit which involved a dispute over methods of administering the very tizanidine capsules which were the subject of Apotex's ANDA. *Id.* With Acorda's patent-infringement suit no longer hindering Apotex's ANDA, Acorda's citizen petition challenging Apotex's claims of bioequivalence in its ANDA created one last hurdle for Apotex to overcome in its quest to have its generic approved by the FDA. *Id.*

facturer Acorda, alleging that Acorda had violated Section Two of the Sherman Act by filing a sham citizen petition as a way to limit competition in the market for its tizanidine capsules.⁴⁹ On February 3, 2012, while Apotex's antitrust suit was still pending in district court, the FDA approved Apotex's ANDA and denied Acorda's citizen petition.⁵⁰ Apotex amended its pleadings in the antitrust action, relying heavily on the near-simultaneity of the FDA's decisions, arguing that one could infer from the sequence of events that but-for Acorda's citizen suit, the ANDA might have been approved sooner, meaning that the citizen suit delayed approval of the ANDA.⁵¹

The district court noted, however, that although the FDA's near-simultaneous approval of the generic application and its denial of the brand-name manufacturer's citizen petition was indeed evidence in favor of the plaintiff's claim, it was insufficient on its own to state a claim for a violation of the Sherman Act.⁵² The district court observed that, because Congress had expressly ordered the FDA not to allow citizen petitions to delay ANDA reviews, it was unlikely that the citizen petition Acorda filed actually delayed Apotex's ANDA.⁵³ The United States District Court for the Southern District of New York subsequently granted the brand-name manufacturer's motion to dismiss with respect to the Sherman Act claim.⁵⁴

II. PHARMACEUTICAL DRUG ANTITRUST LITIGATION IN THE SECOND CIRCUIT

The pharmaceutical industry is particularly ripe for antitrust claims and counterclaims given the statutorily created monopolies that brand-name drug companies enjoy by virtue of their exclusivity periods.⁵⁵ In May 2016, in *Apotex Inc. v. Acorda Therapeutics, Inc.*, the United States Court of Appeals for the Second Circuit refused to extend antitrust liability to Acorda, a brand-name drug manufacturer that had allegedly filed a citizen petition to delay approval of Apotex's competing generic.⁵⁶ Section A of this Part dis-

⁴⁹ *Id.* at 55, 58; Complaint, *Apotex Inc v. Acorda Therapeutics, Inc.*, No. 11-cv-08803 (S.D.N.Y. Oct. 23, 2014). Apotex also alleged in a separate claim that Acorda's representations on its label for Zanaflex Capsules constituted false advertising in violation of the Lanham Act, but the district court granted summary judgment in favor of defendant Acorda. *Apotex*, 823 F.3d at 55, 58.

⁵⁰ *Apotex*, 823 F.3d at 58.

⁵¹ *Id.*; Amended Complaint at 6–9, *Apotex*, No. 11-cv-08803.

⁵² *Apotex*, 823 F.3d at 58; *Apotex*, No. 11-cv-08803, slip. op. at 8.

⁵³ *Apotex*, 823 F.3d at 58; *Apotex*, No. 11-cv-08803, slip. op. at 6–7; see 21 U.S.C. § 355(q) (2012) (providing that “the Secretary shall not delay approval” of an ANDA unless a citizen petition is filed and the Secretary of Health and Human Services determines that “delay is necessary to protect the public health”).

⁵⁴ *Apotex*, No. 11-cv-08803, slip. op. at 8, 14.

⁵⁵ See Lipstein et al., *supra* note 5, at 15 (explaining that the tension between brand-name and generic manufacturers has led to a litany of antitrust litigation).

⁵⁶ 823 F.3d 51, 62 (2d Cir. 2016).

cusses prior Second Circuit precedent applying antitrust principles to citizen petitions, and the FDA's recent interpretative guidance ("Guidance for Industry").⁵⁷ Section B discusses the Second Circuit's evaluation of the FDA Guidance for Industry and the reasoning in *Apotex* behind its holding that the evidence at bar was insufficient to state a claim for an antitrust violation under Section Two of the Sherman Act.⁵⁸

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

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

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

In November 2014, after *In re DDAVP*, the FDA released Guidance for Industry, a document that the Second Circuit deemed persuasive in reaching its decisions in *Apotex*.⁶³ The FDA Guidance for Industry outlines the FDA's interpretation of Section 355(q) of the FDCA with respect to citizen

⁵⁷ See *infra* 59–67 and accompanying text.

⁵⁸ See *infra* 68–73 and accompanying text.

⁵⁹ See *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694–95 (2d Cir. 2009) (noting that although sham litigation and sham administrative petitions are not identical, a petition that is both objectively and subjectively a sham can serve as the basis for antitrust liability).

⁶⁰ See *id.* at 687 (noting that the defendant's intent and the legitimacy of the defendant's citizen petition were called into question by the fact that the defendant refused to withdraw or amend their petition for five months after they lost their patent challenge, which had been the basis of their petition).

⁶¹ *Id.* at 682–83.

⁶² *Id.* at 695.

⁶³ *Apotex*, 823 F.3d at 59–60; see GUIDANCE FOR INDUSTRY, *supra* note 8, at 14 (explaining that because the FDA's response to a filed citizen suit is considered final agency action, it is subject to immediate judicial review which means that the affected ANDA applicant would lose any notice of an opportunity for hearing and subsequent process that they would otherwise be guaranteed at the agency level).

petitions and, in particular, how citizen petitions related to a pending ANDA are to be evaluated.⁶⁴ Guidance for Industry states that, with respect to the timing of an ANDA review and a citizen petition, the FDA's priority is to protect the procedural rights of ANDA applicants to challenge adverse agency decisions with respect to their application, including notice of an opportunity for a hearing.⁶⁵ Because a ruling on a citizen petition is considered final agency action reviewable only by the courts, a FDA ruling on a citizen petition before a FDA decision on whether to grant an ANDA would leave the ANDA applicant unable to challenge the FDA's finding at the agency level.⁶⁶ Thus, according to Guidance for Industry, the FDA prefers to wait to decide on a citizen petition until after it renders a decision on the ANDA application at issue.⁶⁷

B. *The Second Circuit's Reasoning in Apotex*

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

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

In light of the Guidance, the Second Circuit held that the FDA's actions with respect to approving the ANDA application and ruling on the

⁶⁴ 21 U.S.C. § 355(q) (2012); GUIDANCE FOR INDUSTRY, *supra* note 8, at 1.

⁶⁵ GUIDANCE FOR INDUSTRY, *supra* note 8, at 13–14.

⁶⁶ *Id.*

⁶⁷ *See id.* (noting that responding to a citizen petition could well interfere with both the application review process, as well as the applicant's procedural rights to challenge agency determinations).

⁶⁸ 823 F.3d at 62.

⁶⁹ *Id.*

⁷⁰ *Id.* at 59; *see also* Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60–61 (1993) (holding that for a lawsuit to be considered a sham capable of violating antitrust law, it must be (1) objectively baseless such that no reasonable person would expect to win on the merits, and (2) be a subjective attempt by the filing party to directly interfere with a competitor's business).

⁷¹ *Apotex*, 823 F.3d at 59.

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

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

Despite the factual similarity to its own precedent, the U.S. Court of Appeals for the Second Circuit in 2016, in *Apotex Inc. v. Acorda Therapeutics, Inc.*, dismissed a generic drug manufacturer's claim that a brand-name drug manufacturer violated U.S. antitrust law by filing a sham citizen suit to delay the FDA's approval of the generic.⁷⁵ In so deciding, the Second Circuit effectively raised the burden of proof for showing a particular citizen suit is a sham by reducing the presumptive weight it had previously afforded to the timing of the FDA's decisions.⁷⁶ After *Apotex*, the significance of the timing of the FDA's review of an ANDA and its disposition of a related citizen suit has been downgraded from sufficient to state a claim of sham litigation to merely relevant in that assessment.⁷⁷ Despite the fact that the Second Circuit had held that the petitioners in 2009 in *In re DDAVP Direct*

⁷² *Id.* at 60. If the FDA, after its review of an IND or ANDA, determines that the application cannot be approved in its current state because it is deficient in some manner, applicants are entitled to notice of an opportunity for a hearing on the matter so that they may challenge the FDA's determination. *Id.*

⁷³ *Id.* at 60–61.

⁷⁴ *Id.* at 62.

⁷⁵ Compare *Apotex Inc. v. Acorda Therapeutics*, 823 F.3d 51, 61–62 (2d Cir. 2016) (distinguishing prior precedent in light of the FDA's newly published administrative guidance), with *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 685–86 (2d Cir. 2009) (holding that the plaintiff purchasers had sufficiently stated a claim for sham litigation).

⁷⁶ Compare *Apotex*, 823 F.3d at 61 (noting that *Apotex* had pled no other facts aside from the timing of the FDA's actions to prove that Acorda's citizen suit was both objectively and subjectively a sham), with *In re DDAVP*, 585 F.3d at 694 (holding that plaintiffs had stated a claim for sham litigation and noting that even though the FDA ultimately rejected the citizen petition, the possibility that the petition delayed generic competition was more probable since the FDA rejected the petition and approved the generic on the same day). As *Apotex* failed to present other facts from which the court could plausibly infer that the brand-name manufacturer's citizen suit was a sham, the Second Circuit determined that the timing argument was insufficient alone to overturn the district court's ruling in favor of the brand-name manufacturer. *Apotex*, 823 F.3d at 61.

⁷⁷ *Apotex*, 823 F.3d at 60–61.

Purchaser Antitrust Litigation had stated a claim for sham litigation based purely on the timing of the FDA's actions, the Second Circuit in *Apotex* suggested that such evidence is not enough and that plaintiffs must plead additional facts that the petition is baseless in order to survive a motion to dismiss.⁷⁸

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

Generics are not only much cheaper than brand-name drugs, but each generic that enters the market puts additional downward pressure on the price of the incumbent brand-name drug.⁸⁴ The Second Circuit's ruling that

⁷⁸ *Id.* at 61. *But see In re DDAVP*, 585 F.3d at 694 (noting that the likelihood that a sham petition actually delayed generic competition is heightened when the FDA approves the generic drug on the same day that it rejected the citizen petition).

⁷⁹ *See generally* GUIDANCE FOR INDUSTRY, *supra* note 7 (stating in the header of each page that the document "Contains Nonbinding Recommendations").

⁸⁰ *The Antitrust Laws*, *supra* note 35 (explaining that the Sherman Act was designed to be a "comprehensive charter of economic liberty" with the goal of protecting unrestrained competition); *see also Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, *supra* note 3 (noting that the Hatch-Waxman Act was intended to maintain existing incentives for brand-name drug manufacturers to innovate while allowing consumers to be able to purchase cheaper generic versions of brand-name drugs after patent and marketing exclusivity expiration in a more expedient fashion). The formal name for the Hatch-Waxman Act, "Drug Price Competition and Patent Term Restoration Act of 1984" clearly expresses that at least one goal in creating an easier, shorter process for generic approval was to increase competition for high-priced brand-name drugs. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

⁸¹ *The Antitrust Laws*, *supra* note 35.

⁸² *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, *supra* note 3.

⁸³ *Id.*; *The Antitrust Laws*, *supra* note 35.

⁸⁴ *Generic Competition and Drug Prices*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> [<https://perma.cc/Z42Q-NRMR>]. In a study covering 1999 through 2004, researchers found that although the first generic was priced only slightly below the brand-name price, the second generic to enter the market had a dramatic impact, with a price that was fifty-two percent of the price of the brand-name drug. *Id.*; *see Apotex*, 823 F.3d at 55 (stating that generic entry may be motivated by developing a drug with fewer

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

CONCLUSION

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

The Second Circuit's ruling creates a perverse incentive that may induce other brand-name drug companies seeking to extend the life of their monopolies to file their own citizen suits with the sole purpose of undermining their generic competitors. In such circumstances, the public will be

side effects, as both Apotex and Acorda sought to develop a capsule form of tizanidine to reduce the drowsiness associated with their tablets).

⁸⁵ See Lipstein et al., *supra* note 5, at 15 (observing that the natural tension between brand-name and generic manufacturers that Hatch-Waxman Act created has led to an explosion of patent infringement cases and antitrust counterclaims).

⁸⁶ See Carrier & Wander, *supra* note 7, at 256, 259 (hypothesizing that, notwithstanding the fact that most citizen petitions are ultimately denied, a significant number of citizen petitions are brought by brand-name drug companies simply to delay generic competitors).

⁸⁷ See *id.* at 254–55 (noting that Congress passed the Hatch-Waxman Act to increase generic competition).

⁸⁸ See *id.* at 254–56 (noting that the Hatch-Waxman Act has increased generic penetration in brand-name drug markets and has led to a significant decrease in the average price of those drugs).

forced to continue to pay for higher-priced brand-name drugs, as there will be no other choices in the absence of generic competitors.

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

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