

12-1-2013

An Antidote to Efforts by Drug Manufacturers to Delay the Entry of Generic Competition via Sham Petitioning

Ana Jemec Friedman

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Recommended Citation

Ana J. Friedman, *An Antidote to Efforts by Drug Manufacturers to Delay the Entry of Generic Competition via Sham Petitioning*, 92 N.C. L. REV. 277 (2013).

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An Antidote to Efforts by Drug Manufacturers to Delay the Entry of Generic Competition via Sham Petitioning*

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INTRODUCTION

In 2011 alone, United States consumers saved almost \$200 billion simply by using the generic equivalents of brand-name medications.¹ While the general public views this level of access to generic pharmaceuticals as a positive, brand-name drug manufacturers see the \$200 billion figure as representing profits lost to generic competitors. In fact, “[b]rand-name drug companies lose an estimated half of their UNITED STATES sales during the first six months of

1. Ed Silverman, *Generics Saved Consumers How Much Money?*, PHARMALOT (Aug. 2, 2012, 10:46 AM), <http://www.pharmalot.com/2012/08/generics-saved-consumers-how-much-money/>.

generic production alone.”² Unsurprisingly, several of these brand-name manufacturers have used various tactics, including sham Food and Drug Administration (“FDA”) citizen petitions, to forestall the entry of cost-saving generic pharmaceuticals into the market, effectively extending the brand-name manufacturers’ monopolies beyond their pharmaceuticals’ patent terms.

However, generic pharmaceuticals have not always been as readily available as they are today. Before the enactment of the Hatch-Waxman Act in 1984,³ only thirty-five percent of the top-selling brand-name pharmaceuticals with expired patent terms had generic counterparts.⁴ The Hatch-Waxman Act removed several of the obstacles to generic manufacturers by permitting them to submit a shortened application called the Abbreviated New Drug Application (“ANDA”) and by allowing them to rely on the brand-name manufacturer’s clinical trials rather than duplicating the efforts themselves.⁵ As a result of the Act, virtually all top-selling pharmaceuticals whose patent terms have expired currently face generic competition,⁶ and almost seventy-five percent of all prescriptions are for generic equivalents of brand-name pharmaceuticals.⁷

Despite the success of the Hatch-Waxman Act, consumers and generic manufacturers have raised several antitrust challenges alleging that brand-name manufacturers have manipulated the FDA regulatory processes in an effort to extend their monopolies beyond

2. Christine S. Paine, Comment, *Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering*, 33 SETON HALL L. REV. 479, 479 (2003).

3. Drug Price Competition and Patent Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of 15 U.S.C.; 21 U.S.C.; 28 U.S.C.; 35 U.S.C.).

4. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37 (1998), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf> (noting that the figure excludes antibiotics and drugs approved before 1962).

5. See *infra* Part I.A.

6. CONG. BUDGET OFFICE, *supra* note 4, at 37 (“Before the Act (in 1983), only 35 percent of the top-selling drugs no longer under patent had generic copies available. Today, nearly all do.”).

7. See OFFICE OF SCI. & DATA POLICY, U.S. DEP’T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 2 (2010) [hereinafter OFFICE OF SCI. & DATA POLICY], available at <http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf> (“The rate of generic prescribing for all prescriptions reached almost 75 percent in 2009.”).

the expiration of their pharmaceuticals' patent terms.⁸ One tactic used by some brand-name manufacturers involves filing baseless citizen petitions with the FDA. The ability to file citizen petitions with the FDA originates in the First Amendment, which protects "the right . . . to petition the Government."⁹ In light of this constitutional mandate, the Administrative Procedure Act ("APA")¹⁰ provides individuals a forum for exercising this First Amendment right in the context of administrative agencies.¹¹ As applied to the FDA under the Hatch-Waxman Act, the APA petition process permits the public to request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action."¹² Thus, any party—including a brand-name manufacturer—may submit a petition to the FDA regarding the approval or denial of an ANDA.¹³ In some situations, such petitions may result in the FDA delaying ANDA approval beyond the brand-name pharmaceutical's patent term expiration.¹⁴ These delays can restrict competition and cost consumers millions.¹⁵ However, because this right is constitutionally protected, parties filing citizen petitions have enjoyed broad protection from antitrust liability under the *Noerr-Pennington* doctrine, which "limit[s] the enforcement of antitrust laws against certain private acts that urge government action."¹⁶

In an effort to curb delays due to citizen petitions, Congress passed the Food and Drug Administration Amendments Act of 2007

8. See Seth C. Silber, Jonathan Lutinski & Rachel Taylon, *Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?*, ANTITRUST HEALTH CARE CHRON., Jan. 2012, at 26, 26–27, available at <http://www.wsgr.com/PDFSearch/silber0112.pdf>.

9. U.S. CONST. amend. I ("Congress shall make no law . . . abridging . . . the right of the people . . . to petition the Government for a redress of grievances.").

10. Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.).

11. See DONALD D. BARRY & HOWARD R. WHITCOMB, THE LEGAL FOUNDATIONS OF PUBLIC ADMINISTRATION 32 (3d ed. 2005).

12. 21 C.F.R. § 10.30(b) (2012).

13. See *id.*

14. See *infra* Part III.A.

15. See, e.g., Second Amended Consolidated Class Complaint and Jury Demand for End Payors at 3, *In re Wellbutrin XL Antitrust Litig.*, No. 2:08-cv-2433, 2012 U.S. Dist. LEXIS 66312 (E.D. Pa. Jan. 7, 2011) (stating that the brand-name manufacturer's petition delayed approval of the generic manufacturer's ANDA by four months, which allegedly cost consumers approximately \$150 million).

16. FED. TRADE COMM'N, ENFORCEMENT PERSPECTIVES ON THE *NOERR-PENNINGTON* DOCTRINE: AN FTC STAFF REPORT 1 (2006), available at <http://www.ftc.gov/reports/P013518enfperspectNoerr-Penningtondoctrine.pdf>; see *infra* notes 103–14 and accompanying text.

(“FDAAA”).¹⁷ This Act stipulates that the FDA can delay the approval of a pending ANDA only if such a delay is “necessary to protect the public health.”¹⁸

This Comment argues that in light of the broad protection of the *Noerr-Pennington* doctrine, the FDAAA fails to adequately address the concern that brand-name manufacturers may abuse the petition process to achieve anticompetitive results. However, scholars have identified several factors that have led courts to deny defendants’ motions to dismiss and motions for summary judgment regarding antitrust claims brought by consumers and generic manufacturers, thus potentially leading to judgments against brand-name manufacturers abusing the petition process.¹⁹ These factors can be used to design a regulatory approach that balances the competing goals of discouraging parties from abusing the citizen petition process to achieve anticompetitive ends and encouraging parties to submit petitions to raise concerns regarding the potential safety of a pending ANDA.

This Comment proceeds in four parts. Part I provides an overview of the regulatory landscape from before the enactment of the Hatch-Waxman Act in 1984 through the enactment of the FDAAA in 2007. This Part details the citizen petition process and outlines the basis for concerns regarding abuse of this process to achieve anticompetitive ends. Part II discusses the origins of the *Noerr-Pennington* doctrine and its impact on antitrust liability. Next, Part III examines how courts have applied this doctrine in several antitrust cases where the plaintiff alleged that the defendant brand-name manufacturer filed baseless citizen petitions to delay the entry of generic competition into the market. Part III also includes an analysis of the factors that courts have used to deny the defendant drug manufacturers’ motions for summary judgment or motions to dismiss. These factors include (1) suspect petition filing dates; (2) concurrent petition denial and ANDA approval; (3) FDA regulations and practices; and (4) the language of the FDA’s rejection letter. Finally, Part IV concludes by discussing the inadequacy of the changes to the regulatory landscape resulting from the FDAAA and by proposing alternative regulatory schemes that address outstanding concerns regarding anticompetitive abuse of the citizen petition process. These alternative schemes include (1) limiting the timeframe

17. Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified in scattered sections of 21 U.S.C.).

18. 21 U.S.C. § 355(q)(1)(A)(ii) (2012).

19. See *infra* notes 193–94 and accompanying text.

during which parties with a commercial interest in the ANDA can submit a petition that has the power to delay its approval; (2) creating an irrebuttable presumption that when parties request relief that is contrary to current FDA regulations and practices, the relief requested does not have public health implications (and thus, under the FDAAA, cannot serve as a basis for delaying approval of the ANDA); and (3) reducing the protection of the *Noerr-Pennington* doctrine by allowing the FDA to make a determination of baselessness that can shift the burden of proof to the defendant in any resulting court proceeding.

I. OVERVIEW OF THE LEGISLATIVE LANDSCAPE

Brand-name manufacturers with patent protection over their innovator pharmaceuticals generally charge a significant premium over the market price within their market niche.²⁰ Even after a brand-name pharmaceutical's patent term expires and generic equivalents of that pharmaceutical can legally enter the market, the brand-name manufacturers generally choose to maintain premium prices rather than drop their prices to compete with those of their generic competitors, thus creating a "two-tiered market, in which price-sensitive consumers switch to the cheaper generics while brand loyalists stick with the higher-priced branded drugs."²¹ In this two-tiered market, generic pharmaceuticals—which are comparable to their brand-name counterparts "in dosage form, strength, route of administration, quality, performance characteristics and intended use"²²—cost an average of eighty to eighty-five percent less than the brand-name counterparts.²³ However, prior to the enactment of the Hatch-Waxman Act in 1984, consumers had little access to these

20. Christopher J. Kochevar, Note, *Reforming Judicial Review of Bioequivalence Determinations*, 87 N.Y.U. L. REV. 2040, 2041 (2012).

21. John A. Rizzo & Richard Zeckhauser, *Generic Script Share and the Price of Brand-Name Drugs: The Role of Consumer Choice*, 9 INT'L J. HEALTH CARE FIN. ECON. 291, 292 (2009), available at http://www.hks.harvard.edu/fs/rzeckhau/generic_script.pdf. Indeed, "within six months of patent loss, more than 80% of a brand's prescription volume is replaced by generics." Kate Rodgers, *Generic Drugs Are Cheaper, but Not Always Best Choice*, FOX BUS. (Apr. 21, 2011), <http://www.foxbusiness.com/personal-finance/2011/04/20/brand-vs-generic-drugs/>.

22. *Abbreviated New Drug Application (ANDA): Generics*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/> (last updated July 17, 2013).

23. *Facts About Generic Drugs*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm> (last updated July 17, 2013).

cheaper generic pharmaceuticals because the regulatory landscape presented their manufacturers with several obstacles to market entry.

One obstacle faced by generic pharmaceutical manufacturers was that after the Federal Circuit's holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²⁴ generic producers were prohibited from conducting any testing or clinical trials required for FDA approval until the corresponding brand-name drug's patent-term expired.²⁵ This decision resulted in a lag of approximately two years between the brand-name pharmaceutical's patent term expiration and the introduction of a generic equivalent.²⁶

Further, every manufacturer—brand-name and generic—seeking to introduce a new pharmaceutical into the market was required to file a New Drug Application (“NDA”) before the pharmaceutical was eligible for FDA approval.²⁷ This application process mandated that all manufacturers prove the safety and effectiveness of their pharmaceuticals using data from pre-clinical animal trials and human clinical trials.²⁸ Thus, even if the brand-name manufacturer had already completed the necessary trials to prove safety and effectiveness and obtained FDA approval, a manufacturer seeking approval for the generic equivalent would have to complete its own trials to essentially re-prove safety and effectiveness. This process of completing the necessary trials, submitting the NDA application, and obtaining FDA approval was time-consuming and expensive, often requiring up to a decade or longer to complete.²⁹ Thus, “[t]he time and expense associated with gaining FDA approval provided little incentive for a generic drug producer, who had to ‘re-prove’ what the brand-name drug companies had already established, to enter the market.”³⁰ Due to these two obstacles, until the mid-1980s, only

24. 733 F.2d 858 (Fed. Cir. 1984).

25. See, e.g., Paul Wiegel, *Was the FDA Exemption to Patent Infringement*, 35 U.S.C. § 271(e)(1), *Intended to Exempt a Pharmaceutical Manufacturer's Activities in the Development of New Drugs?*, 2007 B.C. INTELL. PROP. & TECH. F., no. 5, at 1, available at <http://bciprf.org/wp-content/uploads/2011/07/21-WAS-THE-FDA-EXEMPTION-TO-PATENT-INFRINGEMENT.pdf> (“It was hoped that the [Hatch-Waxman Act] would get generic drugs to the market around two years earlier than under the prior system.”).

26. *Roche Prods.*, 733 F.2d at 864.

27. *New Drug Application*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last updated Feb. 21, 2013) (providing an overview of the NDA requirement).

28. *Id.*

29. See *Roche Prods.*, 733 F.2d at 864 (noting that it can take “on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements”).

30. Stacey B. Lee, *Is a Cure on the Way?—The Bad Medicine of Generics*, *Citizen Petitions*, and Noerr-Pennington Immunity, 20 KAN. J.L. & PUB. POL’Y 98, 102 (2010).

thirty-five percent of the top-selling brand-name pharmaceuticals whose patent terms had expired had generic counterparts.³¹

A. *The Hatch-Waxman Act*

In 1984, in an effort to increase consumer access to cheaper generic pharmaceuticals, Congress passed the Hatch-Waxman Act.³² This Act removes some of the obstacles to manufacturers of generic pharmaceuticals. First, the Hatch-Waxman Act permits generic manufacturers to begin testing and creating generic versions of an approved brand-name pharmaceutical at any point prior to its patent expiration, which removes the two-year lag between the brand-name pharmaceutical's patent term expiration and the introduction of a generic equivalent.³³ Second, the Act authorizes manufacturers to seek FDA approval for generic pharmaceuticals through an accelerated process using an ANDA.³⁴ This process eliminates the need for generic manufacturers to perform costly and duplicative trials "by allowing the manufacturer to rely on the safety and efficacy data provided in the NDA for the drug's branded counterpart."³⁵ However, in lieu of completing these duplicative preclinical and clinical trials, generic manufacturers must show that their pharmaceutical is therapeutically equivalent to its brand-name counterpart by proving that the two products are "bioequivalent."³⁶ Essentially, "[t]he generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug."³⁷ The cost of bioequivalence studies is a fraction of the cost of large clinical trials required for a successful brand-name NDA, thus enabling generic manufacturers to sell their pharmaceuticals at much lower prices than their brand-name

31. CONG. BUDGET OFFICE, *supra* note 4, at 27.

32. Drug Price Competition and Patent Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of 15 U.S.C.; 21 U.S.C.; 28 U.S.C.; 35 U.S.C.).

33. See WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., IB10105, THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS 2 (2004); Tamsen Valoir & Linda J. Paradiso, *Patent Strategy for Medical Products*, INTELL. PROP. & TECH. L.J., Sept. 2011, at 8, 9 (noting that Hatch-Waxman "allow[s] bioequivalence testing to be performed *prior* to patent expiration" so that "the FDA can now approve generic drug applications immediately on patent expiration").

34. *Abbreviated New Drug Application (ANDA): Generics*, *supra* note 22.

35. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 682 (2d Cir. 2009).

36. *Abbreviated New Drug Application (ANDA): Generics*, *supra* note 22.

37. *Id.*

equivalents.³⁸ Generally, the ANDA approval process, including bioequivalence testing, takes approximately three to five years.³⁹

Since the introduction of the Hatch-Waxman Act, virtually all top-selling drugs whose patent terms have expired face generic competition—compared to only thirty-five percent before its enactment.⁴⁰ Also, almost seventy-five percent of all prescriptions are for generic pharmaceuticals,⁴¹ and in 2010 alone, the use of generics saved consumers \$158 billion.⁴² Further, the increased availability of generic pharmaceuticals has reduced Medicare's annual prescription cost by approximately \$33 billion.⁴³

Despite the overwhelming increase in the availability of cheaper generic pharmaceuticals resulting from the enactment of the Hatch-Waxman Act, several antitrust challenges have been raised regarding the efforts of brand-name manufacturers to extend their monopolies beyond the expiration of their patent terms by manipulating the FDA regulatory processes.⁴⁴ First, generic manufacturers allege that brand-name manufacturers have sought "frivolous drug patents" on "additional features of the drug products or purified forms of the drugs."⁴⁵ These changes in formulation, which generally yield only "minor or no substantive therapeutic improvements," often have the effect of shifting the market to the new formulation, thus destroying

38. Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & LAW 275, 277–78 (1995).

39. Laura Giles, Note, *Promoting Generic Drug Availability: Reforming the Hatch-Waxman Act to Prevent Unnecessary Delays to Consumers*, 75 ST. JOHN'S L. REV. 357, 363 (2001) (specifying that the process may take longer where there are legal challenges). If the ANDA is submitted for the generic equivalent of a brand-name pharmaceutical without any patent protection or with an expired patent term, then ANDA approval is immediately effective. See SCHACHT & THOMAS, *supra* note 33, at 2. If, however, the ANDA is submitted when the brand-name pharmaceutical's patent term is still effective or when the brand-name pharmaceutical's patent is being challenged, then ANDA approval will be tentative until either the brand-name pharmaceutical's patent expires or the brand-name pharmaceutical's patent is deemed invalid. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 189–90 (1999).

40. CONG. BUDGET OFFICE, *supra* note 4, at 37.

41. See OFFICE OF SCI. & DATA POLICY, *supra* note 7, at 2 ("The rate of generic prescribing for all prescriptions reached almost 75 percent in 2009.").

42. *Facts about Generic Drugs*, *supra* note 23.

43. CONG. BUDGET OFFICE, EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING, at vii (2010), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf> ("CBO estimates that dispensing generic drugs rather than their brand-name counterparts reduced total prescription drug costs in 2007 by about \$33 billion.").

44. See Silber et al., *supra* note 8, at 26–27.

45. See Paine, *supra* note 2, at 479–81.

the market for generic equivalents of the original formulation.⁴⁶ Another tactic involves labeling changes, including changes in the brand-name pharmaceutical's "use code," which, due to equivalence requirements for generic pharmaceuticals, may delay the entry of the generic to the market.⁴⁷ A third alleged exploitation involves improperly listing invalid patents in the Orange Book and then listing additional patents in the Orange Book subsequent to a generic applicant's ANDA filing.⁴⁸ This tactic may enable the brand-name manufacturer to benefit from additional thirty-month stays under the relevant provisions, thus delaying the entry of the generic to the market.⁴⁹ Further, some brand-name manufacturers have made payments to manufacturers of generic equivalents or entered into licensing agreements with the generic manufacturers to postpone the introduction of approved generic equivalents to the market.⁵⁰ However, in *Federal Trade Commission v. Actavis*,⁵¹ the Supreme Court held that such pay-for-delay agreements can have anticompetitive effects and are not immune to antitrust attacks.⁵² This Comment focuses on a final tactic used by some brand-name manufacturers to extend the exclusivity of their pharmaceuticals beyond the expiration of their patent terms. This tactic involves the brand-name manufacturer filing a baseless citizen petition with the FDA in an effort to delay the FDA's approval of an ANDA for a pharmaceutical's generic equivalent.⁵³

46. Silber et al., *supra* note 8, at 27.

47. *See id.* (citing *Novo Nordisk v. Caraco Pharm. Labs.*, 601 F.3d 1359 (Fed. Cir. 2010) (contending that the brand-name manufacturer manipulated its patent use code in an effort to preempt anticipated generic entry)).

48. FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 39–52 (July 2002) [hereinafter *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION*], available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. The Orange Book "identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act." *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm> (last updated Oct. 31, 2013).

49. *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION*, *supra* note 48, at 40.

50. *See id.* at 25–37.

51. 133 S. Ct. 2223 (2013).

52. *Id.* at 2237 (noting that the Court declined to hold that "reverse payment settlement arrangements are presumptively unlawful").

53. *See infra* Part III.A.

B. *The FDA Citizen Petition Process*

The First Amendment guarantees the right “to petition the Government for a redress of grievances.”⁵⁴ In the context of administrative agencies, the APA provides individuals with a mechanism for taking advantage of this First Amendment right to petition.⁵⁵ Specifically, the APA gives citizens the ability to petition any administrative agency for the issuance, amendment, or repeal of a rule.⁵⁶

As applied to the FDA under the Hatch-Waxman Act, the APA petition process permits the public to request that the FDA “issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action.”⁵⁷ Thus, any member of the public, including a brand-name or generic pharmaceutical manufacturer, may submit a citizen’s petition to the FDA regarding the approval or denial of an ANDA.⁵⁸ For example, a party could petition the FDA during its consideration of an ANDA to request additional testing in order to assure safety or bioequivalence to the generic pharmaceutical’s brand-name counterpart.⁵⁹ Prior to the enactment of the FDAAA in 2007,⁶⁰ the FDA was required to reply to every citizen petition concerning an ANDA for a generic pharmaceutical by denying the petition, approving it, or tentatively

54. U.S. CONST. amend. I (“Congress shall make no law . . . abridging . . . the right of the people . . . to petition the Government for a redress of grievances.”). The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of the United States’ republican form of government. *See, e.g.,* *United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass’n*, 389 U.S. 217, 222 (1967) (stating that the right to “petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights”).

55. *See* BARRY & WHITCOMB, *supra* note 11, at 32 (stating that the APA created “‘a bill of rights for the hundreds of thousands of Americans whose affairs are controlled or regulated in one way or another by agencies of the Federal Government’” (quoting 92 CONG. REC. 2149 (1946) (statement of Sen. McCarran) *reprinted in* ADMINISTRATIVE PROCEDURE ACT, 79TH CONG., LEGISLATIVE HISTORY, 1944-1946, at 298 (1946))). The purpose of the APA was to “provide for public participation in the rule making process.” U.S. DEP’T OF JUSTICE, ATTORNEY GENERAL’S MANUAL ON THE ADMINISTRATIVE PROCEDURES ACT 9 (1947), *available at* <http://www.law.fsu.edu/library/admin/1947i.html>.

56. *See* 5 U.S.C. § 553(e) (2012) (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”). Because the APA’s mandate does not define the specific procedures agencies must follow, “each federal agency has a different process for petitions.” *How to File a Petition for Rulemaking*, CTR. FOR EFFECTIVE GOV’T, <http://www.foreffectivegov.org/node/4061> (last visited Nov. 7, 2013); *see* 21 C.F.R. § 10.25(a) (2013) (describing the process for petitioning the FDA).

57. 21 C.F.R. § 10.25(a).

58. *See id.* § 10.30(a).

59. *See* Giles, *supra* note 39, at 369.

60. *See infra* Part I.C (discussing the citizen petition provisions of the FDAAA).

responding to it before the FDA could approve that ANDA.⁶¹ In other words, “[i]f the FDA denies the [brand-name manufacturer’s] petition, or does not respond in a timely manner, the [manufacturer] can file a lawsuit for both preliminary and permanent injunctive relief against the Agency.”⁶² Furthermore, because citizen petitions are frequently submitted by brand-name manufacturers on the eve of their pharmaceuticals’ patent term expirations—and thus, the eve of the potential ANDA approval date for their generic equivalents—and because reviewing and responding to each citizen petition can take up to six months or even longer, the consequence of this mandatory response by the FDA was often a delay in the generic’s ANDA approval.⁶³ Such a delay effectively extended the brand-name manufacturer’s monopoly beyond the pharmaceutical’s patent term.

As the number of ANDAs climbed following Congress’s enactment of the Hatch-Waxman Act, the number of citizen petitions filed regarding ANDAs also increased, and in 2008, the FDA had a backlog of over 1,000 citizen petitions to review.⁶⁴ As noted by former FDA Chief Counsel Sheldon Bradshaw, a significant portion of the petitions filed were

designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before.⁶⁵

The FDA had little trouble rejecting these petitions:

61. See 21 C.F.R. § 10.30(e); Giles, *supra* note 39, at 369.

62. Lee, *supra* note 30, at 111 (citing Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & LAW 275, 282 (1995)).

63. See *The Generic Drug Maze: Speeding Access To Affordable Life-Saving Drugs Before the Spec. Comm. On Aging*, 109th Cong. 6 (2006) [hereinafter *Buehler Statement*] (statement of Gary Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration); Giles, *supra* note 39, at 369.

64. Lee, *supra* note 30, at 111–12 (citing *Buehler Statement*, *supra* note 63, at 5); Martin Sipkoff, *FDA Approach to Citizen Petitions May be a Mixed Blessing*, MANAGED CARE (Feb. 2008), <http://www.managedcaremag.com/archives/0802/0802.medmgmt.html> (noting that the ANDA backlog doubled between 2006 and 2008).

65. Complaint at 10, *Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Astellas Pharma US, Inc.*, No. 1:11-cv-11870 (D. Mass. Oct. 21, 2011) (citing Sheldon Bradshaw, former FDA Chief Counsel, Speech at the Generic Pharmaceutical Association Annual Policy Conference (Sept. 19, 2005)), available at <http://www.wexlerwallace.com/wp-content/uploads/2012/02/Class-Action-Complaint-00218050.pdf>.

[B]etween 2003 and 2006, the FDA ruled on twenty-one citizen petitions. The Agency determined that all but one of the petitions lacked merit. Moreover, ten of those filings were identified as “eleventh hour petitions”—submitted within six months of the anticipated entry date of the generic drug. None of the “eleventh-hour petitions” raised a meritorious health or safety concern. Between 2001 and 2005, the FDA dismissed seventy-six percent of the petitions it reviewed for lack of merit.⁶⁶

Although the FDA rejects most of these petitions, the rejection may nevertheless occur after the brand-name pharmaceutical’s patent term has expired, thus extending that pharmaceutical’s exclusivity.⁶⁷ Such a delay is most likely to occur where a petition is filed in the “eleventh hour.” However, because the citizen petition process is grounded in First Amendment rights, brand-name manufacturers can file these “eleventh hour” citizen petitions with “virtual impunity” against antitrust liability due to the broad protections provided by the *Noerr-Pennington* doctrine.⁶⁸

C. *The Food and Drug Administration Amendments Act of 2007*

The FDA dismissed over three quarters of all citizen petitions filed during the five-year period between 2001 and 2005 on the basis that the petitions lacked merit.⁶⁹ Further, former FDA Chief Counsel Sheldon Bradshaw noted that a significant portion of the petitions filed had been last minute petitions designed as an attempt to delay ANDA approval rather than timely petitions designed to raise legitimate concerns regarding the “legality or scientific soundness” of approving an ANDA.⁷⁰ Due to concerns over brand-name manufacturers abusing the citizen petition process and other provisions of the Hatch-Waxman Act, Congress passed the FDAAA.⁷¹

Among other things, the FDAAA adds section 505(q) to the Federal Food, Drug, and Cosmetic Act (“FDCA”), which stipulates that, for all citizen petitions submitted on or after September 27, 2007,

[t]he Secretary shall not delay approval of a pending [ANDA] application . . . because of any request to take any form of

66. Lee, *supra* note 30, at 112 (citations omitted).

67. See Giles, *supra* note 39, at 369.

68. Lee, *supra* note 30, at 109; see also *infra* Part II.

69. Lee, *supra* note 30, at 112 (citing *Buehler Statement*, *supra* note 63, at 4–6).

70. See *supra* note 65 and accompanying text.

71. See *supra* note 17 and accompanying text.

action relating to the application . . . unless . . . the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.⁷²

To determine whether a delay is necessary to protect the public health, the FDA considers the following:

If the application were approved before the Agency completed the substantive review of the issues in the petition and, after further review, the Agency concluded that the petitioner's arguments against approval were meritorious, could the presence on the market of drug products that did not meet the requirements for approval negatively affect the public health?⁷³

One example identified by the FDA as potentially implicating public health concerns is "whether a proposed generic drug product is bioequivalent to the reference listed drug."⁷⁴ When a decision is made that a delay is necessary to protect the public health, the FDA must provide the applicant notification of this determination of delay within thirty days of the decision, along with a description of any clarifications or additional data that the applicant should submit to allow prompt review of the ANDA.⁷⁵ Moreover, the FDAAA authorizes the FDA to summarily deny any citizen petition whose primary purpose is "delaying the approval of an application" and which "does not on its face raise valid scientific or regulatory issues."⁷⁶ Under the original FDAAA provisions, the FDA was required to take final action on a petition within 180 days of the petition filing date.⁷⁷ This 180-day timeframe has since been reduced to a non-extendable 150 days by the FDA Safety and Innovation Act.⁷⁸ Taken together, these provisions reflect an effort by Congress to minimize the occurrence of delays in ANDA approval due to sham citizen petitions, and when such delays are deemed necessary to

72. Federal Food, Drug, and Cosmetic Act § 505(q), 21 U.S.C. § 355(q)(1)(A) (2012).

73. CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., OMB CONTROL NO. 0910-0679, GUIDANCE FOR INDUSTRY: CITIZEN PETITIONS AND PETITIONS FOR STAY OF ACTION SUBJECT TO SECTION 505(q) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 8 (2011), *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079353.pdf>.

74. *Id.*

75. 21 U.S.C. § 355(q)(1)(B).

76. *Id.* § 355(q)(1)(E).

77. *Id.* § 355(q)(1)(F).

78. Pub. L. No. 112-144, § 1135, 126 Stat. 993, 1123 (2012) (codified as amended at 21 U.S.C. § 355(q)).

“protect the public health,” to implement a system where such delays are resolved as efficiently as possible.⁷⁹

Included in the FDAAA is the requirement that the FDA submit an annual report to Congress.⁸⁰ The report must include

(A) the number of applications that were approved during the preceding 12-month period; (B) the number of such applications whose effective dates were delayed by petitions . . . during such period; (C) the number of days by which such applications were so delayed; and (D) the number of such petitions that were submitted during such period.⁸¹

The 2010 report submitted by the FDA indicated that, during the period between October 1, 2009, and September 30, 2010, a total of twenty citizen petitions were filed, and only one ANDA approval was delayed for a period of nine days because of a citizen petition.⁸² The FDA stated that its

decision to delay the approval of one pending ANDA by nine days was based on the agency’s assessment that further review of the issues raised in the [citizen] petition was required to fully assess the petitioners’ arguments against approval. FDA was concerned that if it approved the ANDA before resolving the issues raised in the petition and later concluded that one or more of the arguments against approval were meritorious, then the presence on the market of drug products that did not meet the requirements for approval could negatively affect the public health. Thus, FDA decided to delay approval of the product at issue for an additional nine days to complete its analysis of the petition.⁸³

Ultimately, the FDA determined that further delaying the approval of the pending ANDA was unnecessary to protect the public health, and the agency approved it.⁸⁴

79. See *supra* notes 72–77 and accompanying text.

80. 21 U.S.C. § 355(q)(3).

81. *Id.*

82. FOOD & DRUG ADMIN., THIRD ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2010, at 3 (June 23, 2011) [hereinafter 2010 FDA REPORT], available at <http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/FDAAImplementationChart/UCM348662.pdf>.

83. *Id.*

84. *Id.*

Notably, in its 2010 report, the FDA indicated that the data on implementing section 505(q) between 2008 and 2010 were insufficient to determine whether section 505(q) was achieving its intended effect.⁸⁵ The FDA noted that since the enactment of section 505(q), it has received “serial” citizen petitions, often from the same petitioner regarding the same specific drug or class of drugs, and that “[r]esponding to such serial petitions requires the use of substantial FDA resources, on a repeated basis, over a protracted period of time.”⁸⁶ The FDA concluded its report by stating that “the agency is concerned that section 505(q) may not be discouraging the submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products.”⁸⁷

The FDA’s 2011 report echoes similar sentiments.⁸⁸ During the period between October 1, 2010, and September 30, 2011, a total of twenty citizen petitions were filed—the same number as in 2010—and only one ANDA approval was delayed due to a citizen petition, but this time, the delay was seventy-eight days.⁸⁹ The seventy-eight-day delay was due to the FDA’s concern that

if it approved the ANDA before resolving the issues raised in the petitions and later concluded that one or more of the arguments against approval were meritorious, then the presence on the market of drug products that did not meet the requirements for approval could negatively affect the public health.⁹⁰

At the end of its review, the FDA again determined that further delaying the approval of the pending ANDA was unnecessary to protect the public health, and the agency approved the pending ANDA.⁹¹ As in the 2010 report, the FDA noted that “serial” petitions burden FDA resources and concluded that “the agency is concerned

85. *Id.* at 4.

86. *Id.* at 5.

87. *Id.*

88. FOOD & DRUG ADMIN., FOURTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2011, at 6 (Dec. 14, 2012) [hereinafter 2011 FDA REPORT], available at <http://www.hpm.com/pdf/blog/FDA%20FY2011%20505q%20CP%20Report.pdf>.

89. *Id.* at 3–4.

90. *Id.* at 3.

91. *Id.* (“This delay had no impact on the marketing of the product because, as a result of a court’s patent decision, the holder of the ANDA is enjoined from marketing the product for several years.”).

that section 505(q) may not be discouraging the submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products.”⁹² The FDA added that over the four-year period during which the Agency has been reviewing 505(q) citizen petitions, approximately five percent of the petitions received delayed ANDA approval.⁹³ Further, the FDA criticized the FDAAA provisions, stating that “[t]hough many 505(q) petitions do not necessarily raise issues that are important to the public health, the statute requires FDA to prioritize these petitions over other matters . . . that do raise important health concerns.”⁹⁴ Consequently, the FDA stated that it “remains concerned about the resources required to respond to 505(q) petitions within the statutory deadline at the expense of completing the other work of the agency.”⁹⁵

As the nine-day delay to ANDA approval in the 2010 report and the seventy-eight-day delay in the 2011 report indicate, under the provisions of the 2007 FDAAA, brand-name manufacturers may still have the ability to delay ANDA approval for their generic competitors even if the issues in their citizen petitions do not implicate public health concerns. This delay would occur for at least the duration of time it takes the FDA to make a determination of whether a petition has the potential to implicate public health concerns. Notably, a delay of generic entry to the market for a period as short as nine days could be costly to consumers. For example, in *In re Wellbutrin XL Antitrust Litigation*,⁹⁶ the delayed entry of the generic to the market allegedly cost consumers \$37 million per month, the equivalent of over \$11 million for a nine-day period.⁹⁷

Further, the FDA’s discussion of “serial” petitioning raises an additional concern regarding cost. According to the FDA, “serial” petitioning substantially burdens the Agency’s resources, including

92. *Id.* at 6.

93. *Id.* at 5.

94. *Id.* at 6.

95. *Id.*

96. No. 2:08-cv-2433, 2012 U.S. Dist. LEXIS 66312 (E.D. Pa. May 11, 2012).

97. Second Amended Consolidated Class Complaint and Jury Demand for End Payors at 3, *In re Wellbutrin XL*, 2012 U.S. Dist. LEXIS 66312. Another example of the costs associated with delays occurred with the brand-name pharmaceutical Ditropan XL. Kohl, Leahy Introduce Bill to Stop Frivolous Citizen Petitions, Speed Generic Drug Approval, U.S. SENATE SPECIAL COMM. ON AGING: PRESS ROOM (Sept. 28, 2006), <http://www.aging.senate.gov/record.cfm?id=268246>. The patent owners submitted a citizen petition to the FDA one month before the generic equivalent, Oxybutynin, was expected to be approved for sale. *Id.* The FDA reviewed the petition for over a year while Ditropan XL generated “more than \$1.8 million in sales, daily.” *Id.*

financial resources.⁹⁸ The Agency is financed primarily through user fees, including fees paid by pharmaceutical manufacturers seeking approval of their products, and increases in the FDA budget lead to higher user fees.⁹⁹ Presumably, pharmaceutical manufacturers would pass any fee increases to consumers via increased prices.

II. ANTITRUST LIABILITY AND THE *NOERR-PENNINGTON* DOCTRINE

The purpose of the Sherman Antitrust Act¹⁰⁰ is “[t]o protect the consumers by preventing arrangements designed, or which tend, to advance the cost of goods to the consumer.”¹⁰¹ Based on its purpose, the Act would seem to prohibit brand-name manufacturers from extending their monopolies beyond the expiration of their pharmaceuticals’ patent terms by filing citizen petitions that lack merit, thus delaying the entry of cheaper generic equivalents to the market.¹⁰² However, because the right to petition the federal government is constitutionally protected,¹⁰³ brand-name manufacturers have enjoyed broad protection against liability arising from such seemingly anticompetitive citizen petitions.¹⁰⁴

In *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*,¹⁰⁵ the Supreme Court considered whether lobbying the legislature “to seek passage or defeat of legislation” could subject an

98. 2011 FDA REPORT, *supra* note 88, at 6; 2010 FDA REPORT, *supra* note 82, at 5.

99. See John LaMattina, *Is the FDA Being Compromised by Pharma Payments?*, FORBES (Aug. 7, 2013, 8:48 AM), <http://www.forbes.com/sites/johnlamattina/2013/08/07/is-the-fda-being-compromised-by-pharma-payments/>; Joseph M. Mercola, *FDA Wants More Money, Claims They Are a “Bargain”*, MERCOLA.COM (May 1, 2013), <http://articles.mercola.com/sites/articles/archive/2013/05/01/fda-budget-increase.aspx>.

100. Sherman Antitrust Act, ch. 647, §§ 1–8, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1–7 (1982)).

101. Will Entrekin, *Why the DoJ Lawsuit is Good for eBooks*, HUFFINGTON POST (Apr. 12, 2012) (quoting Senator John Sherman), http://www.huffingtonpost.com/will-entrekin/doj-lawsuit-good-for-ebooks_b_1422380.html.

102. See, e.g., *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) (“The purpose of the Act is not to protect businesses from the working of the market; it is to protect the public from the failure of the market. The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.”); *D.R. Wilder Mfg. Co. v. Corn Prods. Ref. Co.*, 236 U.S. 165, 173–74 (1915) (“[T]he Anti-Trust Act was intended in the most comprehensive way to provide against combinations or conspiracies in restraint of trade or commerce, the monopolization of trade or commerce or attempts to monopolize the same.”).

103. U.S. CONST. amend. I (preserving “the right of the people . . . to petition the Government for a redress of grievances”); see *supra* Part I.B.

104. Lee, *supra* note 30, at 109.

105. 365 U.S. 127 (1961).

individual or group of people to antitrust liability.¹⁰⁶ The Court held that antitrust liability under the Sherman Act cannot be premised on “mere solicitation of governmental action with respect to the passage and enforcement of laws,” even if such activities are deceptive in nature.¹⁰⁷ This decision was followed by *United Mine Workers of America v. Pennington*,¹⁰⁸ where the Supreme Court expanded the *Noerr* holding beyond the legislative branch by excluding “[j]oint efforts to influence public officials” from antitrust liability even if such efforts are “intended to eliminate competition.”¹⁰⁹ Finally, in *California Motor Transport Co. v. Trucking Unlimited*,¹¹⁰ the Supreme Court further defined the breadth of this doctrine by stating that the constitutional right to petition extends to “all departments of the Government,” including the legislative branch, the executive branch, and the judiciary.¹¹¹ As such, the Court held that parties exercising this right were immune from antitrust liability.¹¹² This trilogy of cases established the *Noerr-Pennington* doctrine, which “limit[s] the enforcement of the antitrust laws against certain private acts that urge government action.”¹¹³ Through this doctrine, brand-name manufacturers petitioning the FDA regarding ANDAs have received broad protection from antitrust liability.¹¹⁴ However, the protection offered by the *Noerr-Pennington* doctrine is not absolute.

In *Noerr*, the Supreme Court first discussed potential limitations to the protection afforded by the *Noerr-Pennington* doctrine. There, the Court noted that “there may be situations in which a publicity campaign, ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be

106. *Id.* at 135. The Court stated that “[t]he right of petition is one of the freedoms protected by the Bill of Rights.” *Id.* at 138.

107. *Id.* at 138, 145; *see also* *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999) (stating that a party exercising its First Amendment right to “petition[] the government for redress generally is immune from antitrust liability”).

108. 381 U.S. 657 (1965).

109. *Id.* at 670.

110. 404 U.S. 508 (1972).

111. *Id.* at 510.

112. *Id.* at 510–11 (“We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests *vis-à-vis* their competitors.”).

113. FED. TRADE COMM’N, *supra* note 16, at 1.

114. *See, e.g.,* *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999) (acknowledging the “broad immunity” provided by the *Noerr-Pennington* doctrine).

justified.”¹¹⁵ The Supreme Court reiterated this sham exception in *California Motor Transport Co.* and extended its application beyond the lobbying context by stating that “[m]isrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process.”¹¹⁶ Subsequently, in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*,¹¹⁷ the Supreme Court laid out the two-pronged test used to determine whether a party’s conduct falls within the sham exception, thus excluding that party from *Noerr-Pennington* immunity.¹¹⁸ The case discussed the sham exception only in the context of litigation, but the same test applies to petitions submitted to administrative agencies.¹¹⁹

The first prong of this sham exception test is the objective prong. Under this prong, plaintiffs arguing that a defendant’s conduct falls within the sham exception must show that the petition was

objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits. If an objective [party] could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail.¹²⁰

This showing of a realistic expectation of success on the merits has been referred to as “probable cause.”¹²¹

If the first prong is satisfied, analysis moves to the second prong, an examination of “the litigant’s subjective motivation.”¹²² Under the second prong, the issue is whether the conduct in question “conceals

115. *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

116. *Cal. Motor Transp. Co.*, 404 U.S. at 513.

117. 508 U.S. 49 (1993).

118. *Id.* at 60–61.

119. *See In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (applying the two prongs of the *Prof'l Real Estate Investors* test to a citizen petition filed with the FDA); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999) (applying the two prongs of the test to petitions to the International Trade Commission and the Department of Commerce); *see also In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 309 (E.D. Pa. 2011) (applying the two prongs of the test to citizen petitions filed with the FDA).

120. *Prof'l Real Estate Investors*, 508 U.S. at 60; *see also Cheminor*, 168 F.3d at 122–23 (discussing whether a petitioner could “realistically expect” to succeed on the merits of a petition).

121. *See, e.g., Prof'l Real Estate Investors*, 508 U.S. at 62 (“The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation.”).

122. *Id.* at 60.

‘an attempt to interfere directly with the business relationships of a competitor.’ ”¹²³ To prevail, plaintiffs must show that “the subjective intent of the petitioning party was to inhibit competition, rather than to petition the Government for redress.”¹²⁴

Though this sham exception to the *Noerr-Pennington* doctrine applies to alleged anticompetitive activity directed at any of the three branches of government, courts have refused to apply it uniformly.¹²⁵ For example, in the context of citizen petitions to the FDA, the District Court for the Central District of California reasoned, “[T]o the extent a citizen petition urges the FDA to exercise administrative discretion, the process more closely resembles traditional legislative or executive lobbying. In this context, courts must exercise great caution, if not abstain from interfering with the process entirely.”¹²⁶ Thus, despite the sham exception, the *Noerr-Pennington* doctrine is still “[o]ne of the most significant hurdles for [antitrust] plaintiffs” alleging that a brand-name manufacturer has used the citizen petition process to “unlawfully monopolize the market for a particular drug.”¹²⁷ A further challenge to antitrust plaintiffs is that, if a petition contains multiple claims, courts have held that “conduct is not a sham if ‘at least one claim in the [petition] has objective merit.’ ”¹²⁸

123. *Id.* at 60–61 (quoting *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)).

124. *In re Flonase*, 795 F. Supp. 2d at 311 (citing *Profl Real Estate Investors*, 508 U.S. at 60–61).

125. *Compare* *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, No. 5:03-00887-MRP, 2009 U.S. Dist. LEXIS 132345, at *55–56 (C.D. Cal. Feb. 17, 2009) (granting the brand-name manufacturer’s motion to dismiss), and *M. Sean Royall & Joshua Lipton, The Complexities of Litigating Generic Drug Exclusion Claims in the Antitrust Class Action Context*, 24 ANTITRUST 22, 23 (2010) (“[B]ecause a citizen petition can be more akin to legislative or executive lobbying than to an adjudicatory process, such petitions are arguably entitled to even broader *Noerr-Pennington* doctrine immunity than applies to court proceedings.”), with *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 686 (2d Cir. 2009) (overturning dismissal and acknowledging sufficiency of the plaintiff’s allegations to demonstrate defendant’s FDA petition was a sham), and *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1062 (9th Cir. 1998) (noting that “the exact scope of the sham exception to the *Noerr-Pennington* doctrine has not always been clear in the administrative context” but finding it applicable to “a sufficiently circumscribed form of administrative authority” that is not “essentially political”).

126. *Aventis Pharma S.A.*, 2009 U.S. Dist. LEXIS 132345, at *40.

127. Silber et al., *supra* note 8, at 30.

128. *In re Flonase*, 795 F. Supp. 2d at 312 (quoting *Dentsply Int’l, Inc. v. New Tech. Co.*, No. 06-272, 1996 U.S. Dist. LEXIS 19846, at *9 (D. Del. Dec. 19, 1996)).

III. THE *NOERR-PENNINGTON* DOCTRINE APPLIEDA. *Case Law*

Although the citizen petition process has raised concerns regarding potential anticompetitive abuse of the petition process by brand-name pharmaceutical manufacturers, “[t]he FTC has not brought any enforcement action premised on frivolous or untimely citizen petitions.”¹²⁹ However, several courts have applied the *Noerr-Pennington* doctrine to address allegations of defendant brand-name manufacturers abusing the citizen petition process by filing sham petitions to achieve anticompetitive ends.¹³⁰

1. *In re DDAVP Direct Purchaser Antitrust Litigation*

In *In re DDAVP Direct Purchaser Antitrust Litigation*,¹³¹ the Second Circuit held that the plaintiffs’ allegations were sufficient to plausibly demonstrate that the defendants’ petitions could be sham petitions and thus denied the defendant brand-name manufacturer’s motion to dismiss.¹³² In that case, Barr Laboratories, Inc. (“Barr”) had filed an ANDA for a generic version of desmopressin (“DDAVP”).¹³³ After Barr filed the ANDA, Ferring Pharmaceuticals (“Ferring”), the owner of the DDAVP patent, filed a citizen petition urging the FDA to require Barr to conduct and submit additional tests in order for Barr to establish the bioequivalence of its generic to DDAVP.¹³⁴ The FDA rejected Ferring’s petition, stating that Ferring

129. Laura S. Shores, *Pharmaceutical Patent Life Extension Strategies: Are REMS Programs Next?*, ANTITRUST HEALTH CARE CHRON., Mar. 2012, at 19, 22, available at http://www.pepperlaw.com/publications_article.aspx?ArticleKey=2335#20.

130. See discussion *infra* Part III.A.1–4.

131. 585 F.3d 677 (2d Cir. 2009).

132. *Id.* at 695.

133. *Id.* at 682. DDAVP is used to treat “the symptoms of a certain type of diabetes insipidus,” “bed-wetting,” and “excessive thirst and the passage of an abnormally large amount of urine that may occur after a head injury or after certain types of surgery.” NAT’L INSTS. OF HEALTH, *Desmopressin Oral*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a608010.html> (last reviewed Sept. 1, 2010).

134. *In re DDAVP*, 585 F.3d at 685. This petition was filed over a year before the DDAVP patent was ruled invalid. *Id.* at 687. The District Court for the Southern District of New York held that the patent was “unenforceable due to inequitable conduct before the PTO by Ferring and its agents.” *Id.* at 683; see *Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 U.S. Dist. LEXIS 3597, at *29 (S.D.N.Y. Feb. 7, 2005), *aff’d*, 437 F.3d 1181 (Fed. Cir. 2006).

offered “ ‘no convincing evidence’ ” and that its arguments lacked “ ‘any basis’ ” of support.¹³⁵

Subsequently, direct purchasers of DDAVP filed complaints against both Ferring, the patent owner, and Aventis Pharmaceuticals (“Aventis”), the DDAVP marketer and NDA-holder, alleging that they “abused the patent system to unlawfully maintain a monopoly over [a drug]” through anticompetitive acts, including “ ‘filing a sham citizen petition to further delay FDA final approval of Barr’s ANDA.’ ”¹³⁶ The plaintiffs further alleged that these anticompetitive acts by the defendants delayed the entry of lower-priced generic pharmaceuticals, thus forcing them to pay “supra-competitive prices.”¹³⁷ The district court dismissed the plaintiffs’ sham citizen petition claim, noting that the defendants had not acted in subjective bad faith.¹³⁸ Specifically, the district court found that the citizen petition was “First Amendment protected activity even though delay of Barr’s access to the market was foreseeable.”¹³⁹

On appeal, the Second Circuit emphasized the sham exception to the broad protection afforded by the *Noerr-Pennington* doctrine, stating that “[w]hen petitioning activity ‘ostensibly directed toward influencing governmental action[] is a sham . . . to cover what is . . . nothing more than an attempt to interfere directly with the business relationships of a competitor[, then] the application of the Sherman Act would be justified.’ ”¹⁴⁰ The Second Circuit found that the defendants’ petition fell within the sham exception to the *Noerr-Pennington* doctrine and reversed the district court’s dismissal of the plaintiffs’ sham citizen petition claim.¹⁴¹ In reaching this holding, the Second Circuit focused on the language used by the FDA in its rejection letter to Ferring, which stated that Ferring’s petition “had no convincing evidence” and lacked “any basis” for its arguments.¹⁴² The court further relied on the district court’s statement that Ferring’s citizen petition was a tactic “ ‘motivated by a desire to keep

135. *In re DDAVP*, 585 F.3d at 694 (quoting Complaint at 115, *In re DDAVP*, 585 F.3d 677 (No. 06-5535-CV)).

136. *Id.* at 682–83 (quoting Complaint at 115, *In re DDAVP*, 585 F.3d 677 (No. 06-5535-CV)).

137. *Id.* at 685, 688.

138. *In re DDAVP Direct Purchaser Antitrust Litig.*, No. 05 Cv. 2237, 2006 U.S. Dist. LEXIS 96201, at *22 (S.D.N.Y. Nov. 2, 2006).

139. *Id.* at *23.

140. *In re DDAVP*, 585 F.3d at 686 (quoting *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)).

141. *Id.* at 695.

142. *Id.* at 694 (citation omitted).

out competition for as long as possible after the expiration of the patent.’ ”¹⁴³ Also, during the initial litigation, the Southern District of New York had deemed Ferring’s DDAVP patent invalid “due to inequitable conduct before the PTO by Ferring and its agents.”¹⁴⁴ Although Ferring’s petition was submitted well before the DDAVP patent was held unenforceable (rather than on the eve of the patent term’s expiration), the Second Circuit reasoned that the DDAVP patent “became unenforceable almost five months before the FDA rejected the citizen petition. During that time, the defendants were free to ‘supplement, amend, or withdraw’ the petition, which at that point they knew to be based upon an unenforceable patent[,]” but they failed to do so.¹⁴⁵ Finally, the fact that the FDA ultimately approved the generic pharmaceutical on the same day that it rejected Ferring’s citizen petition supported the plaintiffs’ allegations that the petition delayed the entry of the generic to the market.¹⁴⁶ These factors led the court to find that the plaintiffs’ allegations were sufficient to plausibly demonstrate that Ferring’s petitions were a sham.¹⁴⁷ Ultimately, the parties entered a settlement agreement requiring Ferring and Aventis to pay \$20.25 million to the plaintiff class.¹⁴⁸

143. *Id.* (quoting *Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 U.S. Dist. LEXIS 3597, at *17 (S.D.N.Y. Feb. 7, 2005), *aff’d*, 437 F.3d 1181 (Fed. Cir. 2006)).

144. *Id.* at 683; see *Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 U.S. Dist. LEXIS 3597, at *10 (S.D.N.Y. Feb. 7, 2005), *aff’d*, 437 F.3d 1181 (Fed. Cir. 2006).

145. *In re DDAVP*, 585 F.3d at 687 (citations omitted) (quoting 21 C.F.R. § 10.30(g) (2009)).

146. *Id.* at 694.

147. *Id.* at 695.

148. Health Care and Pharm. Comm., A.B.A. Antitrust Section, *Ferring and Aventis Agree to \$20.25 M Settlement with Class of DDAVP Direct Purchasers*, RECENT DEVELOPMENTS, Sept. 2011, at 3, available at http://www.americanbar.org/content/dam/aba/publications/antitrust_law/at301000_recentdev_201109.authcheckdam.pdf. This settlement agreement covered all of the claims in the case:

(1) “[p]rocurring the 398 patent by committing fraud and/or engaging in inequitable conduct before the PTO,” (2) “[i]mproperly listing the fraudulently obtained 398 patent in the [FDA’s] Orange Book,” thereby enabling patent infringement claims against potential competitors, (3) prosecuting sham infringement litigation against generic competitors, and (4) “filing a sham citizen petition to further delay FDA final approval of Barr’s ANDA.”

In re DDAVP, 585 F.3d at 683 (alterations in original) (quoting Complaint at 144, *In re DDAVP*, 585 F.3d 677 (No. 06-5535-CV)).

2. *Louisiana Wholesale Drug Co. v Sanofi-Aventis*

*Louisiana Wholesale Drug Co. v Sanofi-Aventis*¹⁴⁹ is another case in which a court found that the defendant's citizen petition could potentially fall within the sham exception of the *Noerr-Pennington* doctrine and therefore denied the defendant's motion to dismiss.¹⁵⁰ There, Louisiana Wholesale Drug Company ("Louisiana Wholesale") filed a complaint against Aventis alleging that Aventis unlawfully delayed the entry of generic competitors of Arava to the market by filing a sham citizen petition.¹⁵¹ On the end date of Arava's patent term—and thus, the end of its exclusivity—five generic manufacturers submitted ANDAs for generic versions of two of the three available strengths of Arava (the 10mg and 20mg strengths, but not the 100mg strength).¹⁵² Aventis then filed a citizen petition with the FDA on the day before generic approval for 10mg and 20mg leflunomide (generic Arava), requesting that the FDA approve the ANDAs only if they (1) contained bioequivalence studies confirming that five 20mg tablets of the generic are bioequivalent to one 100mg Arava tablet or (2) sought approval for a 100mg dose of the generic.¹⁵³

After a delay of over five months, the FDA finally approved the ANDAs for the generic manufacturers on the same day that it denied Aventis's citizen petition, stating that Aventis's citizen petition "seem[ed] to be based on a false premise" that a generic manufacturer recommending the 100mg dose on its label has to either produce its own 100mg tablet or recommend using five 20mg tablets.¹⁵⁴ The FDA noted that a generic manufacturer could in fact recommend a dosage on its label—in this case, 100mg—that differs from the standard doses the manufacturer actually manufactures.¹⁵⁵ Moreover, no regulations require generic applicants to seek approval for all strengths of a brand-name pharmaceutical.¹⁵⁶

149. No. 07-CIV-7343, 2009 U.S. Dist. LEXIS 77206 (S.D.N.Y. Aug. 28, 2009).

150. *Id.* at *3–4.

151. *Id.* at *3. Arava is used to treat rheumatoid arthritis. NAT'L INSTS. OF HEALTH, *Leflunomide*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a600032.html> (last reviewed Mar. 16, 2011).

152. *La. Wholesale Drug Co.*, 2009 U.S. Dist. LEXIS 77206, at *4–5; *La. Wholesale Drug Co. v. Sanofi-Aventis*, 2008 U.S. Dist. LEXIS 81328, at *3 (S.D.N.Y. Oct. 14, 2008).

153. *La. Wholesale Drug Co.*, 2009 U.S. Dist. LEXIS 77206, at *6. In support of its petition, Aventis noted that a previous patent licensee for Arava had submitted a request to the FDA "to permit five 20 mg tablets to serve as an alternative to the 100 mg tablet loading dose without a showing of bioequivalence." *Id.* at *6–7. The FDA had rejected that request. *Id.*

154. *Id.* at *7 (internal quotation marks omitted).

155. *Id.* at *8.

156. *Id.*

After the FDA's rejection of Aventis's citizen petition, Louisiana Wholesale filed suit alleging that (1) the citizen petition was both objectively and subjectively baseless, thus falling within the sham exception of the *Noerr-Pennington* doctrine, and that (2) as a result of the petition, generic competition to Avara was delayed.¹⁵⁷ The district court agreed and denied Aventis's motion for summary judgment.¹⁵⁸ The court focused on the fact that, as a sophisticated manufacturer, Aventis was familiar with FDA regulations and would not reasonably have believed that its citizen petition was viable.¹⁵⁹ Also, the court noted that Aventis had previously listed pharmaceutical strengths that the company itself did not manufacture on generic and brand-name labels.¹⁶⁰ The case ultimately proceeded to a jury trial, and the jury unanimously found for Aventis, concluding that Louisiana Wholesale had failed to prove that Aventis's citizen petition was "objectively baseless."¹⁶¹ Although the district court denied Louisiana Wholesale's motion for judgment as a matter of law or new trial because Louisiana Wholesale failed to show either that there was a complete lack of evidence supporting the jury's verdict or that there was an " 'overwhelming amount of evidence in [its] favor,' " the case still illustrates how courts are turning an increasingly skeptical eye towards brand-name manufacturers' citizen petitions.¹⁶²

157. *Id.* at *8–9.

158. *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343, 2008 U.S. Dist. LEXIS 81328, at *2–3 (S.D.N.Y. Oct. 14, 2008).

159. *Id.* at *12–13 ("No reasonable pharmaceutical manufacturer could have expected Aventis's Citizen Petition to succeed on the merits because Aventis ignored the law by requesting relief that was contrary to existing law and precedent. As I held previously, ignoring the law, filing administrative or legal actions that do not request reasonable extensions or development of the law and mischaracterization of the relevant issues or legal standards exemplify objectively baseless actions.").

160. *Id.* at *15–16 ("But Defendants knew that drug manufacturers were permitted under FDA regulations to cross-reference other drugs and dosages because they themselves did so in two instances." (citing Def. Ex. 73, FDA Denial of Petition)).

161. *La. Wholesale Drug Co.*, 2009 U.S. Dist. LEXIS 77206, at *9. In reaching this conclusion, the jury relied on Aventis's evidence that (1) the FDA had not yet addressed the loading dose issue raised in this case; (2) the defendant drug manufacturers had approached this loading dose inconsistently, thus indicating that the issue is unsettled; and (3) "in reviewing the ANDAs for generic leflunomide, the FDA took action consistent with some of the views espoused by Aventis in the Citizen Petition." *Id.* at *17–22.

162. *See id.* at *22 (quoting *Galdieri-Ambrosini v. Nat'l Realty & Dev. Corp.*, 136 F.3d 276, 289 (2d Cir. 1998)).

3. *In re Flonase Antitrust Litigation*

A third case where a court initially denied the defendant's motion for summary judgment is *In re Flonase Antitrust Litigation*.¹⁶³ There, Roxane Laboratories ("Roxane"), the manufacturer of the generic version of Flonase, along with direct and indirect purchasers of Flonase, filed lawsuits against Glaxo-Smith Klein PLC ("GSK"), the manufacturer of Flonase, alleging that GSK filed a series of sham petitions to the FDA in an attempt to delay the entry of generic Flonase to the market.¹⁶⁴ The FDA had approved Roxane's ANDA and rejected all of GSK's petitions on the same day, stating in its rejection letter that "GSK [is] not . . . permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved."¹⁶⁵ After this rejection, GSK filed a lawsuit in the District of Maryland for a temporary restraining order and a preliminary injunction seeking to enjoin Roxane from selling generic Flonase and attempting to reverse the FDA's denial of its citizen petition.¹⁶⁶ The District Court for the District of Maryland initially granted the restraining order but subsequently denied GSK's motion for a preliminary injunction.¹⁶⁷

In each of the three resulting Flonase antitrust lawsuits against GSK filed in the Eastern District of Pennsylvania by direct purchasers of Flonase, indirect purchasers of Flonase, and Roxane, GSK moved for summary judgment, claiming immunity from antitrust liability

163. 815 F. Supp. 2d 867 (E.D. Pa. 2011).

164. *Id.* at 871–72. GSK's exclusivity over Flonase was set to expire on April 14, 2004. *See Silber et al., supra* note 8, at 33. Roxane had submitted its ANDA in October of 2002. *Id.* "During the period between May 2004 through June 2005, GSK made a series of petitions to the FDA regarding the FDA's approval of the ANDAs for Flonase." *Id.* The FDA did not reject GSK's petitions and approve the ANDA until February of 2006, almost two years after the end of Flonase's exclusivity. *Id.* Flonase is used to treat "sneezing and stuffy, runny, or itchy nose" associated with "seasonal (occurs only at certain times of year), and perennial (occurs all year round) allergic rhinitis and perennial nonallergic rhinitis." NAT'L INSTS. OF HEALTH, *Fluticasone Nasal Spray*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a695002.html> (last reviewed Sept. 1, 2010).

165. Letter from Randall W. Lutter, Acting Assoc. Comm'r for Policy and Planning, Food and Drug Admin., to Frederick H. Branding, McGuireWoods, LLP, et al. 24 (Feb. 22, 2006), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2004-P-0152-0005>.

166. *See* Complaint at 30–31, *Glaxo Grp. Ltd. v. Leavitt*, No. AMD-06cv469, 2006 U.S. Dist. LEXIS 10938 (D. Md. Feb. 23, 2006), ECF No. 1.

167. *See* Temporary Restraining Order at 1–2, *Glaxo Grp. Ltd.*, 2006 U.S. Dist. LEXIS 10938 (No. AMD-06cv469); Order at 1, *Glaxo Grp. Ltd.*, 2006 U.S. Dist. LEXIS 10938 (No. AMD-06cv469).

under the *Noerr-Pennington* doctrine.¹⁶⁸ GSK conceded that the plaintiffs had provided enough evidence to satisfy the subjective prong of the sham exception to the *Noerr-Pennington* doctrine.¹⁶⁹ Thus, the only issue was whether GSK's conduct was "objectively baseless" because its petition had no realistic expectation of success.¹⁷⁰ The District Court for the Eastern District of Pennsylvania held that for each of GSK's six citizen petitions there was a genuine issue of material fact regarding whether GSK's conduct was "objectively baseless" and thus denied GSK's motion for summary judgment.¹⁷¹

GSK had first requested that the FDA refrain from approving Roxane's ANDA until after the agency issued final guidance on nasal aerosols and nasal sprays, which was still in draft form at the time of GSK's petition.¹⁷² The FDA rejected this request, stating that although it is "desirable" to issue final guidance prior to ANDA approval, doing so "is not always possible."¹⁷³ The District Court for the Eastern District of Pennsylvania noted that because the FDA is not obligated to issue guidance, and because ANDA applicants are not required to use such guidance, this request was contrary to the agency's regulations and practices and could therefore be found objectively baseless.¹⁷⁴ GSK also requested that the FDA require ANDAs to include data from certain studies that are not required by law.¹⁷⁵ Because such data is not required by law, the court reasoned that the petition could also be a sham.¹⁷⁶ The court further found that genuine issues of fact remained regarding GSK's final four petitions.¹⁷⁷ Because genuine issues of fact remained with regard to

168. *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 302 (E.D. Pa. 2008).

169. *Id.* at 311.

170. *Id.*

171. *Id.* at 317.

172. *Id.* at 305. The FDA had issued a draft guidance regarding this issue in 1999, which it later amended in 2003, but the guidance was never finalized. *Id.* at 304-05.

173. *Id.* at 305.

174. *Id.* at 312. This request was contrary to FDA regulations and practices. *Id.*

175. *Id.* at 313.

176. *Id.*

177. *Id.* at 317. The court also considered GSK's lawsuit seeking a temporary restraining order and preliminary injunction. GSK argued that because the court initially granted the temporary restraining order before denying GSK's motion for preliminary injunction, its petitions were not objectively baseless (the reasoning being that the court would not have initially granted the temporary restraining order if it believed that GSK had no realistic expectation of success on the merits of the case). *Id.* at 316. However, the court rejected this argument, stating that a temporary restraining order grant does not itself establish an objective basis for petitioning activity. *Id.* at 316-17. Instead, the court

whether GSK acted objectively baseless by filing all six petitions, the court denied GSK's motion for summary judgment.¹⁷⁸ In January 2013, the parties reached a settlement agreement of \$150 million for direct purchasers and \$35 million for indirect purchasers, which was approved by the District Court for the Eastern District of Pennsylvania in June 2013.¹⁷⁹

4. *In re Wellbutrin XL Antitrust Litigation*

There are also examples of cases where the defendant brand-name manufacturer was successful in seeking protection under the *Noerr-Pennington* doctrine and the manufacturer's motion to dismiss or motion for summary judgment was granted.¹⁸⁰ In *In re Wellbutrin XL Antitrust Litigation*,¹⁸¹ Wellbutrin XL purchasers filed a suit against Biovail, Wellbutrin XL's manufacturer, for "illegally conspiring to prevent generic versions of Wellbutrin XL from entering the American market by filing sham patent infringement lawsuits and a citizen petition with the [FDA], and entering into agreements with generic companies to settle the lawsuits."¹⁸² One of

stated that the ultimate denial of GSK's preliminary injunction motion provides evidence that that lawsuit itself was objectively baseless. *Id.* at 316–17.

178. *Id.* at 317.

179. *In re Flonase Antitrust Litig.*, No. 08-cv-3149, 2013 U.S. Dist. LEXIS 83976, at *2–3 (E.D. Pa. June 14, 2013) (approving the settlement agreement for direct purchasers); *Med. Mut. of Ohio v. Smithkline Beecham Corp.*, Nos. 08-3301 and 12-4212, 2013 U.S. Dist. LEXIS 85926, at *44 (E.D. Pa. June 19, 2013) (approving the settlement agreement for indirect purchasers).

180. *See, e.g., Aventis Pharma, S.A. v. Amphastar Pharmaceuticals*, No. 5:03-00887-MRP, 2009 U.S. Dist. LEXIS 132345, at *9 (C.D. Cal. Feb. 17, 2009) (granting Aventis's motion to dismiss).

181. No. 08-2431, 2012 U.S. Dist. LEXIS 66312 (E.D. Pa. May 11, 2012) (granting partial summary judgment).

182. *Id.* at *4. Specifically,

[t]he Citizen Petition requested that the FDA require any ANDA for a generic version of Wellbutrin XL to satisfy the following four criteria:

(1) All bioequivalence trials should calculate and evaluate parameters based on concentrations of the parent drug and active metabolites; . . .

(2) Any generic formulation should be shown to be bioequivalent to Wellbutrin XL, sustained release and immediate release bupropion; . . .

(3) The bioequivalence studies should be conducted at steady-state evaluating the performance of the dosage form based on AUC, Cmax, Cmin; . . . and

the plaintiffs' allegations was that Biovail filed a baseless FDA citizen petition.¹⁸³ Approximately one year after Biovail's petition was filed, the FDA granted it in part and denied it in part, stating that brand-name manufacturers have no "right to be free of generic competition" after their patents expire or are held unenforceable and that "Biovail [should] not be permitted to shield its market share."¹⁸⁴ The plaintiffs alleged that Biovail's petition delayed approval of the generic manufacturer's ANDA by four months, which allegedly cost consumers approximately \$150 million.¹⁸⁵

However, the court noted that Biovail's citizen petition did include some successful arguments and held that the plaintiffs failed to meet the threshold requirement of presenting evidence that "the unsuccessful and arguably sham requests in the Citizen Petition actually delayed FDA approval of the generic ANDAs any further than the delay caused by the successful requests."¹⁸⁶ Thus, the plaintiffs did not allege an antitrust injury, which is a necessary element of every antitrust claim.¹⁸⁷ Despite this missing element, the

(4) Data using the FDA's approach for evaluating the effect of alcohol on the performance of the controlled-release dosage form should be required to ensure the absence of "dose dumping."

Id. at *62–63. Wellbutrin XL is used to treat depression and seasonal affective disorder and is also used "to help people stop smoking." NAT'L INSTS. OF HEALTH, *Bupropion*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a695033.html> (last revised Sept. 15, 2013).

183. *In re Wellbutrin XL*, 2012 U.S. Dist. LEXIS 66312, at *4.

184. Letter from Randall W. Lutter, Acting Assoc. Comm'r for Policy and Planning, Food and Drug Admin., to John B. Dubeck, Keller and Heckman LLP at 16 (Dec. 14, 2006), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0366-0004>.

185. Second Amended Consolidated Class Action Complaint and Jury Demand for End Payors at 3, *In re Wellbutrin XL*, 2012 U.S. Dist. LEXIS 66312. Biovail made the following arguments in favor of its motion for summary judgment as to the Citizen Petition: (1) Because the petition was granted in part,

the entire petition is immunized from antitrust liability under the Noerr-Pennington doctrine; (2) Second, that any competitive harm is immune from antitrust liability because it resulted from government decision; (3) Third, that even if the entire petition is not immunized, the unsuccessful requests were not objectively baseless; and (4) Finally, that even if the unsuccessful requests were objectively baseless, the plaintiffs have not shown that they caused any delay.

In re Wellbutrin XL, 2012 U.S. Dist. LEXIS 66312, at *71.

186. *In re Wellbutrin XL*, 2012 U.S. Dist. LEXIS 66312, at *83. The court raised the question of whether a mixed petition (a petition where some, but not all, of the claims were successful) should be immune; however, it did not answer this question because the Plaintiffs did not meet the threshold requirement of showing that the Citizen Petition further delayed the ANDA approval. *Id.*

187. See *infra* note 202 and accompanying text.

court still addressed Biovail's citizen petition. The court noted that the FDA was already aware of one of the issues raised in the defendant's citizen petition—the issue of dose dumping—but that the FDA had not issued any requirements regarding this concern.¹⁸⁸ The court found that

the FDA's awareness about the dangers of dose dumping . . . do[es] not mean that those two requests were not "reasonably calculated to elicit a favorable outcome." The outcomes were not yet set in stone, and even if they were, 21 C.F.R. § 10.30 permits citizen petitions to amend or revoke regulations. To characterize these granted requests as sham requests and eliminate *Noerr-Pennington* immunity merely because the FDA was already aware of the concerns brought up therein would unreasonably curtail the First Amendment right to petition the government and influence policy.¹⁸⁹

Biovail's petition also included an argument requesting that the FDA require generic manufacturers to measure levels of certain metabolites, but this request was contrary to an FDA guidance document.¹⁹⁰ The court reasoned that Biovail's petition failed to provide factual or legal support for deviating from FDA guidance, and thus, Biovail could not "realistically expect success on the merits of the metabolites evaluation request."¹⁹¹ Nevertheless, the court ultimately granted summary judgment as to the citizen petition because the plaintiffs failed to raise a genuine issue of material fact as to the causal connection between the unsuccessful petitions and the alleged antitrust injury.¹⁹²

188. *In re Wellbutrin XL*, 2012 U.S. Dist. LEXIS 66312, at *69.

189. *Id.* at *79 (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993)). The court reasoned that the inquiry for the sham exception to the *Noerr-Pennington* doctrine is forward looking and that here, the Plaintiffs were asking the court

to strip citizen petition requests that were granted by the FDA from *Noerr-Pennington* immunity merely because the FDA was already aware of the concerns discussed therein. But to do so would discourage companies from attempting to shape the development of and contribute to the discourse surrounding FDA policies once the FDA becomes aware of an issue.

Id. at *77. This statement recognizes the policy of encouraging parties to submit petitions in an effort to further help ensure safety.

190. *Id.* at *88–93.

191. *Id.* at *93.

192. *Id.* at *115–16.

B. Factors Supporting Possible Finding of Sham Petition

Based on this case law, scholars have identified several factors leading courts to find that a genuine issue of material fact remains regarding whether a citizen petition falls under the sham exception of the *Noerr-Pennington* doctrine (thus allowing a plaintiff's antitrust claim based on an alleged sham citizen petition to survive a motion for summary judgment or motion to dismiss).¹⁹³ These factors include: (1) whether the citizen petition was filed on the eve of the brand-name pharmaceutical's patent term expiration; (2) whether the FDA approved the generic's ANDA on the same date it rejected the corresponding citizen petition; (3) whether the relief requested contradicts the FDA's regulations and practices; and (4) whether the tone of the FDA's rejection letter suggests that the petition was objectively baseless.¹⁹⁴

"Suspect timing," or whether the citizen petition was filed on the eve of the brand-name pharmaceutical's patent term expiration, and thus, the eve of potential generic ANDA approval, is a significant factor courts have considered as tending to support a finding of baselessness.¹⁹⁵ In *In re Flonase Antitrust Litigation*, where the court denied the defendant's motion to dismiss, Roxane alleged that "just days after the expiration of the statutory exclusivity period for GSK's Flonase, and on the eve of what could have been the FDA's approval of Roxane Laboratories' ANDA, GSK filed the first in a series of objectively baseless citizen petitions."¹⁹⁶ These petitions were submitted nearly two years after Roxane had filed its ANDA application with the FDA.¹⁹⁷ Similarly, in *Louisiana Wholesale Drug Co.*, another case where the court denied the defendant's motion to dismiss, the court noted that Aventis filed its citizen petition "one year after the generic manufacturers submitted their ANDAs for FDA approval when no new health and safety information on the loading dose or leflunomide in general and no new FDA regulations on labeling had occurred."¹⁹⁸ In comparison, in *In re Wellbutrin XL Antitrust Litigation*, rather than being filed on the eve of the brand-

193. See Silber et al., *supra* note 8, at 36–39.

194. *Id.*

195. *Id.* at 36–37. While this factor would seem to more appropriately apply to the subjective prong of the *Noerr-Pennington* sham exception test, courts have also applied it to the objective prong. *Id.* at 37.

196. Complaint of Roxane Laboratories, Inc. at 7, *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011) (No. 09-cv-1638).

197. *In re Flonase*, 795 F. Supp. 2d at 304–05.

198. *La. Wholesale Drug Co. v. Sanofi-Aventis*, 2008 U.S. Dist. LEXIS 3611, at *14–17 (S.D.N.Y. 2008).

name drug's patent expiration, the defendant's citizen petition was filed several months prior to the expiration of the Wellbutrin XL patent.¹⁹⁹ There, the court granted the defendant's motion to dismiss.²⁰⁰

A second factor considered by courts is the timing of the FDA's approval of an ANDA compared to the rejection date of the citizen petition concerning that ANDA. Courts have generally considered the FDA's concurrent rejection of the brand-name manufacturer's citizen petition and approval of the generic manufacturer's ANDA to indicate that the citizen petition actually caused delay to generic entry, thus supporting the existence of an antitrust injury.²⁰¹ This conclusion is significant because proving antitrust injury, which can be difficult in this context, is a requirement for a successful antitrust challenge.²⁰² The difficulty of proving an antitrust injury—showing that a baseless citizen petition was the cause of any delay in FDA approval of the related ANDA—arises in the context of citizen petitions because “[d]isaggregating antitrust injury can be difficult in any case, but even more so where the conduct was the subject of a multifaceted, confidential regulatory review process.”²⁰³ However, when a brand-name manufacturer submits multiple citizen petitions, some of which are successful, concurrent citizen petition rejection and ANDA approval may not provide evidence of an antitrust injury.²⁰⁴ As some scholars have noted, “[w]here some aspects of the petition were allegedly groundless and others were not, it can be a challenge to ascribe any delay to the allegedly ‘sham’ component of a broader petition. . . . Such difficulties are amplified by the courts’ reluctance to delve into the decision making processes of expert agencies.”²⁰⁵

Another factor that courts consider when examining whether the defendant's citizen petition may fall under the sham exception is the FDA's regulations and practices. In some cases, brand-name manufacturers, whom courts typically classify as “sophisticated

199. See *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2012 U.S. Dist. LEXIS 66312, at *19–21 (E.D. Pa. May 11, 2012).

200. *Id.* at *116.

201. See Silber et al., *supra* note 8, at 39.

202. *In re Wellbutrin XL*, 2012 U.S. Dist. LEXIS 66312, at *52 (“The elements of an antitrust claim are (1) a violation of the antitrust laws; (2) individual injury resulting from that violation; and (3) measurable damages.”).

203. Royall & Lipton, *supra* note 125, at 24 (citing M. Sean Royall, *Disaggregation of Antitrust Damages*, 65 ANTITRUST L.J. 311 (1997)).

204. See, e.g., *In re Wellbutrin*, 2012 U.S. Dist. LEXIS 66312.

205. Royall & Lipton, *supra* note 125, at 24 (citing *Mt. Hood Stages v. Greyhound Corp.*, 616 F.2d 394, 398–400 (9th Cir. 1980); *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, No. 03-00887, slip op. at 4 (C.D. Cal. May 15, 2009)).

parties,” have requested relief that is contrary to current FDA regulations and practices. For example, in *Louisiana Wholesale Drug Co.*, Aventis sought to require generic manufacturers to produce 100mg tablets in order to succeed with ANDAs.²⁰⁶ At trial, Louisiana Wholesale offered evidence that the relief requested in Aventis’s citizen petition was contrary to FDA regulations and practices.²⁰⁷ The court supported its conclusion that Aventis’s petition was subjectively baseless by noting that, on its own product labels, Aventis had previously cross-referenced pharmaceuticals that it did not actually manufacture.²⁰⁸ Under this factor, courts have “an expectation that [the manufacturers of brand-name pharmaceuticals] have knowledge of FDA practices and procedures,” thus tending to show subjective baselessness on the part of the manufacturers.²⁰⁹

In examining the objective baselessness prong of the sham exception to the *Noerr-Pennington* doctrine, courts have frequently emphasized the wording of the FDA’s rejection of the defendant’s citizen petition.²¹⁰ For example, in *In re DDAVP Direct Purchaser Antitrust Litigation*, the court emphasized the language of the FDA rejection letter, which stated that the petition “had no convincing evidence.”²¹¹ Also, in *Louisiana Wholesale Drug Co.*, the court noted the FDA’s statement that Aventis’s petition “seem[ed] to be based on a false premise,”²¹² and in *In re Wellbutrin XL Antitrust Litigation*, the FDA response to the citizen petition provided that “Biovail [should] not be permitted to shield its market share.”²¹³ Similarly, in regard to *In re Flonase Antitrust Litigation*, the FDA stated that “[t]he policies behind Hatch-Waxman dictate that GSK [should] not be permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved.”²¹⁴ In contrast, if the FDA’s rejection letter indicated that the petition contained arguments that were considered legitimate by the FDA,

206. *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-CIV-7343, 2009 U.S. Dist. LEXIS 77206, at *5 (S.D.N.Y. 2009).

207. *Id.* at *9.

208. *Id.* at *8.

209. Silber et al., *supra* note 8, at 38.

210. *Id.* at 38–39.

211. *In re DDAVP*, 585 F.3d 677, 694 (2d Cir. 2009) (citing Complaint at 115, *La. Wholesale Drug Co.*, 2009 U.S. Dist. LEXIS 77206 (No. 07-CIV-7343)).

212. *La. Wholesale Drug Co.*, 2009 U.S. Dist. LEXIS 77206, at *7 (internal quotations omitted).

213. Letter from Randall W. Lutter, *supra* note 184, at 16.

214. Letter from Randall W. Lutter, *supra* note 165, at 24.

such language would likely provide evidence pointing away from objective baselessness.²¹⁵

IV. AMENDMENTS TO THE HATCH-WAXMAN ACT—DID THEY DO ENOUGH?

As the FDA has acknowledged, the 2007 FDAAA has not been entirely successful in “discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products.”²¹⁶ Consequently, several commentators have recommended various approaches to address the concerns raised by abuse of the citizen petition process.

Some scholars have argued that only parties with a “non-commercial interest” in a generic pharmaceutical seeking FDA approval should be permitted to file citizen petitions relating to that generic drug’s ANDA.²¹⁷ Such a requirement would prevent brand-name manufacturers from abusing the citizen petition process in an effort to extend their monopoly beyond their pharmaceutical’s patent term. However, such a requirement would also prevent these same manufacturers, who arguably have the greatest depth of knowledge about a particular pharmaceutical, from raising any valid concerns regarding the bioequivalence and safety of a proposed generic equivalent.²¹⁸

Further, scholars have urged the FDA to “exercis[e] its discretion to refer unsuccessful citizen petitions to the FTC or Department of Justice.”²¹⁹ Such actions by the FDA would theoretically discourage the abuse of the citizen petition process.²²⁰ Another proposed measure for penalizing parties engaging in sham petitioning was set forth in the Citizen Petition Fairness and Accuracy Act of 2006, a bill which would have enabled the Department of

215. Silber et al., *supra* note 8, at 38–39.

216. 2010 FDA REPORT, *supra* note 82, at 5.

217. See, e.g., Giles, *supra* note 39, at 375 (“Pioneer drug companies should be prevented from filing Citizen Petitions relating to the approval of an ANDA. These petitions should be reserved for those who have a noncommercial interest in the drug.”).

218. Cf. *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 139 (1961) (“Indeed, it is quite probably people with just such a hope of personal advantage who provide much of the information upon which governments must act. A construction of the Sherman Act that would disqualify people from taking a public position on matters in which they are financially interested would thus deprive the government of a valuable source of information and, at the same time, deprive the people of their right to petition in the very instances in which that right may be of the most importance to them.”).

219. Lee, *supra* note 30, at 125.

220. See *id.* (“Abusing government processes will continue so long as there is no penalty for engaging in this type of conduct.”).

Health and Human Services to sanction parties abusing the citizen petition process with fines of up to \$1 million and either suspension or revocation of the violator's right to file citizen petitions in the future.²²¹ This proposed legislation was never enacted.²²² However, referring unsuccessful citizen petitions to the FTC or Department of Justice or imposing the sanctions described in the Citizen Petition Fairness and Accuracy Act of 2006 could have a chilling effect on the citizen petition process by discouraging parties from voicing their concerns for fear of the repercussions that may result if their petitions are denied. Because the parties most frequently accused of filing sham citizen petitions—namely, manufacturers of brand-name pharmaceuticals whose patent term is nearing its expiration date—are the very parties who arguably have the most intimate knowledge regarding a particular pharmaceutical, any legislation aimed at addressing sham citizen petitioning should encourage these parties to raise valid concerns regarding the safety of a proposed generic equivalent rather than risk a chilling effect on the citizen petition process.

A better approach would be to use the factors that courts have relied on when denying defendant brand-name manufacturers' motions to dismiss to formulate a solution to the sham petitioning problem. As discussed in Part III.B, the factors considered by courts include (1) suspect timing, (2) concurrent petition denial and ANDA approval, (3) FDA regulations and practices, and (4) the language of the FDA's rejection letter.²²³

A. *Suspect Timing*

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

The FDA could make an additional regulatory improvement by imposing a time frame for citizen petition submissions. Similar to the predefined comment period for citizens to respond to a proposed FDA rule, citizens should be given a defined forty-

221. Citizen Petition Fairness and Accuracy Act of 2006, S. 3981, 109th Cong. (2006).

222. The proposed bill was read twice and then referred to the Committee on Health, Education, Labor, and Pensions without taking a Roll Call vote. Citizen Petition Fairness and Accuracy Act of 2006, S. 3981, 109th Cong., <http://beta.congress.gov/bill/109th/senate-bill/3981> (last visited Nov. 7, 2013). The bill was reintroduced in 2007 but was again referred to a committee and ultimately died. Citizen Petition Fairness and Accuracy Act of 2007, S. 25, 110th Cong., <http://www.govtrack.us/congress/bills/110/s25> (last visited Nov. 7, 2013).

223. See *supra* Part III.B.

five day comment period to raise health and safety concerns in response to ANDA applications. This would avoid eleventh-hour petitions and enable the FDA to rule in time for an approved generic to go to market without an unjust delay. These regulatory reforms would decrease the incentives for brand-name companies to submit sham petitions and help to safeguard the citizen petition process.²²⁴

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

Instead, the scope of this recommendation should be narrowed to brand-name manufacturers with a commercial interest in the generic pharmaceutical's entry to the market. Those who manufacture the brand-name pharmaceutical whose patent term is nearing expiration should be required to submit their citizen petitions a reasonable amount of time, perhaps 150 days, before their patent's expiration date in order for the FDA to consider their petitions in the ANDA approval process. Because the FDA must respond to citizen petitions within 150 days of their submission,²²⁵ this approach would enable the FDA to resolve all citizen petitions submitted by brand-name manufacturers with a commercial interest prior to the expiration of the brand-name pharmaceutical's patent term. Further, under this approach, the FDA should still have the ability to consider petitions submitted by brand-name manufacturers with a commercial interest after the proposed 150-day deadline, but the Agency should no longer be required to respond to such petitions within 150 days of their submission.²²⁶ Moreover, when considering late petitions by brand-name manufacturers, the FDA should be prohibited from making a decision to delay ANDA approval unless it determines, prior to the brand-name pharmaceutical's patent term expiration, that the concerns raised in the petition have public health implications.

224. Lee, *supra* note 30, at 126.

225. 21 U.S.C. § 355(q)(1)(F) (2012).

226. Relaxing the requirement that the FDA respond to *all* petitions within 150 days helps address the FDA's concern that "[t]hrough many 505(q) petitions do not necessarily raise issues that are important to the public health, the statute requires FDA to prioritize these petitions above other matters . . . that do raise important health concerns." 2011 FDA REPORT, *supra* note 88, at 6.

Under this Comment's approach, the "nine-day delay" scenario discussed in the FDA's 2010 report²²⁷ and the "seventy-eight-day delay" scenario discussed in the FDA's 2011 report²²⁸ would no longer be possible. The approach narrowly addresses the concern of brand-name manufacturers using sham citizen petitions to achieve anticompetitive ends, while preserving the full extent of other parties' constitutional right to petition the government. Parties without a financial interest in the approval of the generic ANDA would still be able to submit petitions up until the ANDA's approval, thus maximizing the benefit to the public health that can be achieved from the citizen petition process.

B. Concurrent Petition Denial and ANDA Approval

Under the approach detailed above, the second factor, concurrent petition denial and ANDA approval, becomes irrelevant. Brand-name manufacturers with a commercial interest in a generic pharmaceutical's entry to the market would generally be prohibited from submitting citizen petitions within 150 days of the end of the brand-name pharmaceutical's patent term, thus enabling the FDA to respond to their petitions prior to patent term expiration. The only situation in which a brand-name manufacturer would be able to submit a citizen petition that delays ANDA approval is if the FDA were to determine, prior to the brand-name pharmaceutical's patent term expiration, that the petition implicates public health concerns.

C. FDA Regulations and Practices

The third factor, considering FDA regulations and practices to determine whether the petition is objectively baseless, should be addressed by creating an irrebuttable presumption that when a party requests relief that is contrary to current FDA regulations and practices, the requested relief does not have public health implications. As a result of this irrebuttable presumption, under section 505(q), the FDA would be prohibited from delaying approval of an ANDA based on such a petition.²²⁹

For example, Aventis, the defendant brand-name manufacturer in *Louisiana Wholesale Drug Co.*, sought to require generic manufacturers to produce 100mg tablets before receiving ANDA

227. 2010 FDA REPORT, *supra* note 82, at 3.

228. 2011 FDA REPORT, *supra* note 88, at 3.

229. See *supra* notes 72–73 and accompanying text.

approval.²³⁰ This request was contrary to FDA regulations and practices,²³¹ and therefore, under this Comment's proposed statutory scheme, the FDA would be required to presume that Aventis's request does not have public health implications. Thus, the FDA would be unable to delay the approval of an ANDA based on this request.

D. The Language of the FDA's Rejection Letter

Finally, courts have used the fourth factor, the language of the FDA's rejection letter, as evidence of objective baselessness.²³² Some commentators have recommended granting the FDA the express authority to identify certain petitions as "objectively baseless" and making such a determination final and appealable only in court.²³³ Thus, for petitions classified by the FDA as "objectively baseless," if the petitioner elects not to appeal the FDA's determination, the objective prong of the sham exception would be deemed satisfied, and only the subjective prong would be at issue in court.²³⁴ However, this approach may discourage parties from voicing their concerns to the FDA through citizen petitions for fear of losing one prong of *Noerr-Pennington* protection in any subsequent court proceedings if the FDA finds their petitions to be "objectively baseless."

Rather than making this determination final, such a determination of objective baselessness by the FDA should instead shift the burden of proof in any resulting court proceedings. Therefore, instead of the plaintiff carrying the burden of proving that the defendant's petition was objectively baseless, the defendant would have the burden of proving that its petition was not objectively baseless.²³⁵ This approach, along with the other recommendations discussed in this Section, would balance the competing goals of discouraging parties from abusing the citizen petition process to

230. See *supra* notes 152–53 and accompanying text.

231. See *supra* notes 154–62 and accompanying text.

232. See *supra* notes 210–15 and accompanying text.

233. Lee, *supra* note 30, at 125.

234. *Id.*

235. The court in *In re Wellbutrin XL Antitrust Litigation* discussed the standard of proof for objective baselessness in a *Noerr-Pennington* case. *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2012 U.S. Dist. LEXIS 66312, at *16–19 (E.D. Pa. May 11, 2012). The court noted that there is disagreement among the courts as to whether preponderance of the evidence or clear and convincing evidence is the appropriate standard of proof. *Id.* Because the cases addressing sham petitioning by brand-name drug manufacturers are generally civil cases, the burden of proof for establishing that a petition is not objectively baseless under this proposed scheme should be preponderance of the evidence.

achieve anticompetitive ends and encouraging parties to submit petitions raising concerns about the potential safety of a pending ANDA.

CONCLUSION

With generic pharmaceuticals costing an average of eighty to eighty-five percent less than their brand-name counterparts,²³⁶ access to generic pharmaceuticals can significantly benefit American consumers. However, entry of a generic pharmaceutical into the market can also have a detrimental impact on the brand-name manufacturer's profitability.²³⁷ As described in this Comment, some brand-name manufacturers have attempted to extend their pharmaceuticals' exclusivity through various tactics, including filing sham citizen petitions with the FDA in an effort to delay the FDA's approval of generic equivalents.

Because the ability to file citizen petitions with the FDA originates in the First Amendment, parties filing such petitions enjoy broad protection from antitrust liability. Further, Congress's attempt to curb abuse of the petition process through the FDAAA has not been entirely successful in eliminating sham petitions. This Comment proposes an alternative regulatory approach that addresses outstanding concerns of anticompetitive abuse of the citizen petition process. This approach balances two competing goals by discouraging parties from abusing the petition process while also encouraging parties to submit petitions raising concerns regarding the potential safety of generic pharmaceuticals awaiting FDA approval.

ANA JEMEC FRIEDMAN**

236. *Facts about Generic Drugs*, *supra* note 23.

237. *See supra* note 2 and accompanying text.

** The author would like to thank her husband, Doug, for his endless support throughout the writing process. Thank you also to the *North Carolina Law Review* board and staff members, especially Anna Tison, for their tireless efforts in the editing and publication of this Comment.