

The Antitrust Implications of Filing “Sham” Citizen Petitions with the FDA

MATTHEW AVERY*, WILLIAM NEWSOM**, AND BRIAN HAHN***

The First Amendment protects the right of all citizens to petition the government. The Food and Drug Administration (the “FDA”) has provided a means by which citizens or interested entities can voice their concerns to the FDA by filing a so-called “citizen petition.” However, some brand-name pharmaceutical companies have abused this process by filing baseless petitions with the FDA in an effort to delay generic competition. Such anticompetitive activity is generally protected by the Noerr-Pennington doctrine, which grants antitrust immunity to activity that involves petitioning the government for redress. However, the immunity does not apply to “sham” petitions, the main objective of which is to cause anticompetitive harm through the process, rather than the outcome, of a petition. The citizen petition process has provided a number of examples of likely sham petitions, resulting in delayed generic entry into the market. In some cases, such delay has resulted in billions of dollars in extra profits for brand-name manufacturers submitting “sham” petitions, at the expense of consumers and generic manufacturers.

This Article analyzes recent cases in which plaintiffs allege that the citizen petitions aim to delay generic entry, and suggests precautions that practitioners can take in such lawsuits. It proposes a variety of changes to FDA regulations, as well as additions to judicial doctrines, to curb the problems caused by sham petitions. It also serves as a guide to brand-name manufacturers who wish to avoid liability under the “sham” exception. These proposals may become more relevant as the rate of filing citizen petitions grows and more generic drug applications accrue in the FDA’s backlog.

* Associate at Baker Botts LLP in Palo Alto, California.

** Associate at Pearson, Simon & Warshaw, LLP in San Francisco, California. Mr. Newsom’s firm was counsel to Roxane Pharmaceuticals, Inc. in the *In re Flonase* antitrust litigation.

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FDA has a commonsense policy to allow ordinary citizens or medical experts to submit petitions to the agency about drugs that it is considering approving. This procedure should be used to protect public health—but too often, it is subverted by those who seek only to delay the entry onto the market of generic drugs.

—Senator Edward M. Kennedy¹

INTRODUCTION

The next few years will be uniquely challenging for the pharmaceutical industry. For more than a decade, the number of new drug approvals issued by the Food and Drug Administration (the “FDA” or “Agency”) has steadily declined,² while the cost of research and development continues to rise.³ Compounding this problem is a rapidly approaching “patent cliff.”⁴ Between 2009 and 2014, over forty of the most popular brand-name drugs are scheduled to lose patent protection, including at least nine of the top fifteen best selling drugs in the world.⁵ And generic companies continue to file hundreds of applications each year to market generic versions of brand-name drugs; the FDA approved

1. Press Release, Edward M. Kennedy, Statement of Senator Edward M. Kennedy on the Passage of the Food and Drug Amendments Act of 2007 (Sept. 21, 2009), available at <http://www.help.senate.gov/newsroom/press/release/?id=do4cfc73-1449-4cc8-82do-5de3foed4287>.

2. See Matthew Avery, *Personalized Medicine and Rescuing “Unsafe” Drugs with Pharmacogenomics: A Regulatory Perspective*, 65 FOOD & DRUG L.J. 37, 38 (2010); Matthew Arnold, *FDA BLA Approvals Rose in 2009 While NMEs Stumbled*, MED. MARKETING & MEDIA (Dec. 31, 2009), <http://www.mmm-online.com/fda-bla-approvals-rose-in-2009-while-nmes-stumbled/article/160496>. In 1996, the FDA approved fifty-three new drugs, but in 2011, the FDA only approved thirty new drugs. See Anna Edney, *Drug Approvals Hit a Seven-Year High in 2011 on Improved Data*, BLOOMBERG (Jan. 5, 2012), <http://www.bloomberg.com/news/2012-01-05/drug-approvals-in-u-s-reached-a-seven-year-high-in-2011-on-improved-data.html>.

3. See BURRILL & CO., BIOTECH 2008 LIFE SCIENCES: A 20/20 VISION TO 2020 43 (2008); *Pills Get Smart: Potential Encapsulated*, THE ECONOMIST, Jan. 2010, at 78. Over the same period, research and development spending by pharmaceutical manufacturers has increased 187%, from \$16.9 billion to \$67.4 billion. See PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY PROFILE 2011.

4. Christopher K. Hepp, *Big Pharma Gearing up to Face the Patent Cliff*, PHILA. INQUIRER (Nov. 12, 2010), available at <http://www.philly.com/inquirer/business/107412428.html>; see *More Than 1,000 Drug Patents Expiring During the Next Two Years*, MED. DEVICE & DIAGNOSTIC INDUS. (Dec. 3, 2010), www.mddionline.com/blog/devicetalk/more-1000-drug-patents-expiring-during-next-two-years-pharmalive-special-report.

5. See Kathy Method, *Going, Going, Gone*, MODERN MED. (Aug. 10, 2009), <http://drugtopics.modernmedicine.com/news/going-going-gone> (listing brand-name drugs expiring between 2009 and 2012); Tom Randall, *Drugmakers Poised to Report Biggest Drop Since 2006 on Record Patent Loss*, BLOOMBERG (Apr. 15, 2011), <http://www.bloomberg.com/news/2011-04-15/drugmakers-poised-to-report-biggest-drop-since-2006-on-record-patent-loss.html>. Between 2007 and 2010, more than seventy drugs were scheduled to go off patent. See David Collis & Troy Smith, *Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co. and Pfizer Inc.*, HARVARD BUS. SCH., Nov. 2007, at 5. One group reported that nine of the top ten biggest drugs in the world will lose patent protection by 2014. See Hepp, *supra* note 4.

476 such applications in 2012.⁶ In 2013 and beyond, \$125 billion in brand-name drug sales may become exposed to generic competition.⁷

Once a pharmaceutical product loses patent protection, competitors almost always introduce generic versions of the drug as quickly as possible.⁸ Generic drugs can capture eighty to ninety percent of the market within months of entering the marketplace.⁹ In response to this intense generic competition, patent holders have used a variety of controversial means to effectively extend their patent-granted monopoly.¹⁰ While it is important that pharmaceutical pioneers have financial incentives to continue developing life-saving drugs,¹¹ indefinite monopoly profits come at the expense of consumers. Thus, actions by patent holders that seek to extend market exclusivity should be closely examined for impropriety.

One example of such impropriety arises when pharmaceutical patent holders file citizen petitions with the FDA to delay approval of generic versions of the pioneer's drug.¹² The citizen petition process was designed

6. Sohini Das, *Gujarat Pharma Firms Lag Behind Industry Majors in USFDA Approvals*, BUS. STANDARD (Jan. 31, 2013), http://www.business-standard.com/article/companies/gujarat-pharma-firms-lag-behind-industry-majors-in-usfa-approvals-113013100009_1.html (reporting 476 total applications approved in 2012, an increase from 431 in 2011).

7. See Lynne Taylor, *Indian Drug Majors: "20%+ Growth in 2013, Driven by Exports"*, PHARMATIMES (Feb. 5, 2013), http://www.pharmatimes.com/Article/13-02-05/Indian_drug_majors_20_growth_in_2013_driven_by_exports.aspx (predicting that "[t]he U.S. generic market . . . could grow at an annual average rate of around 8%–9% in the medium term, due to patent expiries—set to be worth around \$125 billion during 2013–15").

8. See CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 37 n.2 (July 1998) (reporting that ninety-five percent of off-patent drugs had generic equivalents in 1994).

9. For example, the generic form of Prozac (fluoxetine) claimed approximately 65% of the market within a month of generic entry, 80% by the end of the first generic competitor's 180-day exclusivity period, and leveled out at almost 90% after a year of generic competition. See Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFFAIRS 210, 214 (2004).

10. Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of "Authorized Generics"*, 62 FOOD & DRUG L.J. 739, 742 (2007) ("Recently, under the rubric of 'Lifecycle Management,' consultants and pharmaceutical executives have been encouraging various actions to squeeze the most profitability from existing drugs. Certain of these actions have been criticized as unethical, anticompetitive or even fraudulent."); Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 179–83 (2008).

11. Carmelo Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 195 (2005) (reporting a positive correlation between profits and research spending). Note that the standard patent term is twenty years from the date when the patent application was filed. 35 U.S.C. § 154(a)(2) (2011). But because of the lengthy regulatory process, the average pioneer drug enjoys only eleven to twelve years of patent protection after FDA approval. See *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 151–52 (1st Sess. 2007) (statement of Billy Tauzin, President & CEO, PhRMA).

12. See *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 211–12 (E.D. Pa. 2012). A citizen petition is a petition that any person may submit to the FDA to request the FDA Commissioner to "issue, amend, or revoke" a regulation or order, or to request the Commissioner to "take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30 (2013).

to enable an individual to voice concerns about the safety or efficacy of a drug or medical device. In practice, however, it has become another tool for pioneers to improperly thwart generic competition.¹³ Rather than voicing legitimate concerns about unsafe drugs, pioneers have used the process to forestall FDA approval of generic challengers.

For example, GlaxoSmithKline allegedly used the citizen petition process to delay FDA approval of a generic version of its blockbuster drug Flonase (fluticasone propionate nasal spray) by raising safety questions about *its own drug*.¹⁴ Although generic competitors had developed a nasal-spray delivery mechanism identical to the original Flonase package, GlaxoSmithKline altered the specifications of its own delivery system and then petitioned the FDA to withhold generic approval until the generic challengers could meet the more exacting standards that GlaxoSmithKline had just devised.¹⁵ A generic challenger and two classes of purchasers of Flonase filed an antitrust suit against GlaxoSmithKline, asserting that the company improperly used the citizen petition process to delay generic entry.¹⁶

However, proving that a citizen petition violates antitrust laws is no easy task. As a general rule, efforts by individuals or groups to petition the government are immune from antitrust liability under the *Noerr-Pennington* doctrine—such petitions are not illegal even if undertaken for anticompetitive purposes.¹⁷ But the *Noerr-Pennington* doctrine does not apply to attempts to influence government action when the conduct is a “mere sham” covering what is actually harassment of a competitor.¹⁸ For a petition to be considered a “sham,” it must be both objectively baseless and improperly motivated.¹⁹ A lawsuit may only be considered a sham if the filer is attempting to use the government process itself—as opposed to the outcome of that process—as an anticompetitive weapon.²⁰ This can be the case with citizen petitions if the petition was intended for anticompetitive purposes and lacked a reasonable scientific basis.²¹ The

13. See *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 305–08 (E.D. Pa. 2011); *Graceway Pharm. L.L.C. v. Sebelius*, 783 F. Supp. 2d 104, 108 (D.D.C. 2011); *Hill Dermaceuticals, Inc. v. U.S. Food & Drug Admin.*, 524 F. Supp. 2d 5, 7 (D.D.C. 2007).

14. *In re Flonase*, 795 F. Supp. 2d at 301–02.

15. See *id.* at 307–08.

16. *Id.* at 301.

17. See *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 139–40 (1961) (“*Noerr*”); *United Mine Workers v. Pennington*, 381 U.S. 657, 678 (1965) (“*Pennington*”).

18. *Noerr*, 365 U.S. at 144.

19. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993).

20. *Id.* at 61; see *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991) (“A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay.”).

21. *Professional Real Estate* initially described the types of activity regarded as a sham as “repetitive lawsuits carrying the hallmark of *insubstantial* claims.” 508 U.S. at 58 (quoting *Otter Tail Power Co. v. United States*, 410 U.S. 366, 380 (1973)) (first emphasis added). This scope of the sham

intended anticompetitive effect of such petitions is to delay generic entry beyond the expiration of a patent, effectively extending the pioneer's patent monopoly while the petition is pending.²²

This Article analyzes how the citizen petition process can be used as an anticompetitive weapon, especially by brand-name drug manufacturers seeking to hinder generic competition. Part I provides a brief overview of the regulatory process for generic drugs, particularly the Hatch-Waxman Act and the Paragraph IV certification process. Part II explains the citizen petition process, including its regulatory background, practical application, and recent developments. Part II also describes, by way of example, various ways in which the citizen petition process can be abused for anticompetitive purposes. Part III reviews the *Noerr-Pennington* doctrine and describes the application of antitrust law to the abuse of the citizen petition process. Part IV reviews recent antitrust cases that challenge the use of citizen petitions by pharmaceutical patent holders. Part V provides strategic considerations for practitioners who are considering using citizen petitions during the Hatch-Waxman process. Finally, Part VI proposes modifying the current regulatory regime to resolve problems with the citizen petition process.²³

exception was later interpreted by *Louisiana Wholesale Drug Co. v. Sanofi-Aventis* to extend to the petition process beyond the litigation context laid out in *Professional Real Estate*. La. Wholesale Drug v. Sanofi-Aventis, No. 07 Civ. 7343(HB), 2009 WL 2708110, at *4 (S.D.N.Y. Aug. 28, 2009) (“In [*Professional Real Estate*], the Supreme Court articulated the two-step inquiry that applies to claims of ‘sham’ petitioning or litigation.”).

22. See, e.g., *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 304 (E.D. Pa. 2011).

23. This Article does not address the following issues: (1) citizen petitions in response to new drug applications (“NDAs”), (2) the antitrust implications of reverse payment settlements or authorized generics, and (3) anti-SLAPP lawsuits in response to antitrust challenges to citizen petitions. For a brief discussion of the use of citizen petitions in response to NDA filings, see *infra* note 62. For a discussion of the antitrust implications of reverse payments, see generally William J. Newsom, *Exceeding the Scope of the Patent: Solving the Reverse Payment Settlement Problem Through Antitrust Enforcement and Regulatory Reform*, 1 HASTINGS SCI. & TECH. L.J. 201 (2009). For a discussion of the antitrust implications of using authorized generics, see generally FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 2011. The Supreme Court recently held that reverse payment settlement agreements may be antitrust violations subject to a “rule of reason” analysis. *FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013). The Court rejected both the traditional scope-of-the-patent test, which made most reverse payment settlement agreements presumptively lawful and the FTC’s proposal to make such settlements presumptively unlawful. *Id.* at 2237. Instead, the Court took the middle ground and held that courts reviewing such agreements should apply the rule-of-reason analysis but left it to the lower courts to figure out what types of settlements would actually be antitrust violations. *Id.* Regarding anti-SLAPP lawsuits in the citizen petition context, a citizen petition is a lawful exercise of public participation in an agency decision, and an antitrust suit to enjoin such a petition could be seen as stifling public participation, and can thus be susceptible to an anti-SLAPP challenge. See, e.g., CAL. CIV. CODE § 425.16 (West 2013) (protecting a person who has engaged in constitutionally protected activity from “SLAPP” lawsuits). See generally *Flatley v. Mauro*, 39 Cal. 4th 299 (2006) (holding that anti-SLAPP protection does not apply to speech and petitioning activity that is illegal as a matter of law and is therefore not constitutionally protected).

I. THE HATCH-WAXMAN ACT AND PARAGRAPH IV CERTIFICATIONS

The marketing of generic drugs is regulated by the Hatch-Waxman Act.²⁴ Under Hatch-Waxman, before a generic drug manufacturer can enter the market, it must seek regulatory approval from the FDA by filing an Abbreviated New Drug Application (“ANDA”).²⁵ A pharmaceutical company must list all patents that claim its brand-name drug in the FDA’s so-called *Orange Book*.²⁶ As part of the ANDA, the generic applicant must make one of the following certifications regarding *each* patent listed in the *Orange Book* that claims the drug it seeks to copy: (I) that the drug is not patented or that patent information has not been filed; (II) that the patent has expired; (III) that the generic drug will not enter the market until the patent expires; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted.²⁷ These are commonly called Paragraph I, II, III, and IV certifications, respectively.

By making a Paragraph IV certification, a generic manufacturer can seek FDA approval to market a generic equivalent of a pioneer’s patented drug before the patent term has expired.²⁸ However, subsection 271(e) of the Patent Act provides that making a Paragraph IV certification alone is an act of patent infringement.²⁹ Consequently, the mere filing of an ANDA with a Paragraph IV certification allows the pioneer to sue the generic

24. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the “Hatch-Waxman Act” or “Hatch-Waxman”) (codified as amended at 21 U.S.C. § 355(j) (2006); 35 U.S.C. §§ 156, 271(e) (2006)).

25. H.R. REP. NO. 98-857(1), at 16 (1984). As can be expected, the number of ANDAs submitted to the FDA has increased and created a backlog of pending ANDAs. See Kurt R. Karst, *OGD Finished 2010 on a High Note—Really High!*, FDA LAW BLOG (Feb. 3, 2011, 2:01 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/ogd-finished-2010-on-a-high-note-really-high.html; Kurt R. Karst, *OGD’s ANDA Backlog and Median ANDA Approval Times are Up—WAY UP!*, FDA LAW BLOG (Feb. 25, 2010, 12:23 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/02/ogds-anda-backlog-and-median-anda-approval-times-are-up-way-up-the-solution-lies-in-resources-says-f.html.

26. See 21 U.S.C. § 355(b)(1) (2011). The *Orange Book* is the common name for the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is published monthly. OFFICE OF GENERIC DRUGS, FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2008) [hereinafter *Orange Book*].

27. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

28. Consequently, patent challenges pursuant to Paragraph IV are a frequently deployed mechanism for the early introduction of generic competition. See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 10* (2002) (reporting challenges involving 130 drugs between 1984 and 2001); *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”*: *Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 113, 117 (1st Sess. 2003) (statement of Timothy Muris, Chairman, FTC) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

29. 35 U.S.C. § 271(e)(2)(A) (2011) (“It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent.”).

challenger for infringing its *Orange Book*-listed patents, which is typically what happens.³⁰

As an incentive for generic manufacturers to risk ANDA litigation, the Hatch-Waxman Act provides a 180-day exclusivity period to the first generic manufacturer to file an ANDA containing a Paragraph IV certification for a particular drug.³¹ The FDA cannot approve later-filed ANDAs for the same drug until 180 days after the first filer begins commercially marketing a generic equivalent of the drug.³² As a result, the first filer's product will be the only generic equivalent on the market during this period. This exclusivity period is very valuable to generic manufacturers,³³ as they can sell their product at a price significantly higher than they could if multiple generics were on the market.³⁴ However, the 180-day exclusivity can also work to the advantage of the pioneer because if the pioneer can delay or prevent approval of the first filer, it delays generic entry entirely.

II. THE USE AND ABUSE OF CITIZEN PETITIONS

The First Amendment of the Constitution guarantees individuals the right to petition the government.³⁵ The right to petition ensures that people may freely complain to the government or seek its assistance.³⁶ Drawing on this right, the Administrative Procedure Act allows any "interested person" to petition federal agencies regarding the adoption,

30. For more discussion of Paragraph IV challenges, see Avery, *supra* note 10, at 175–82. The Hatch-Waxman Act requires all Paragraph IV ANDA applicants to provide notice of the application to the challenged NDA and patent holder, including a detailed factual and legal analysis explaining why the patent is either invalid or not infringed. 21 U.S.C. § 355(j)(2)(B). After receiving such notice, the NDA holder has forty-five days to bring an infringement action against the ANDA applicant. *Id.* If suit is not filed within that time, the ANDA can be approved immediately. *Id.* But if suit is brought during that time, then the FDA is barred from approving the ANDA for thirty months. *Id.* During this thirty-month stay, the FDA can only grant "tentative approval" of the ANDA, such that it can become effective immediately upon expiration of the stay. *Id.* § 355(j)(5)(B)(iv)(II)(dd).

31. Until the 180-day exclusivity period has run, the FDA may not approve any successive ANDA applications on the same patent. *See id.* § 355(j)(5)(B)(iv).

32. *Id.*

33. *See* Leila Abboud, *Drug Makers Use New Tactic to Ding Generics*, WALL ST. J., Jan. 27, 2004, at B1 ("In 2002, when Barr successfully challenged the patent protection on Eli Lilly & Co.'s big antidepressant Prozac, Barr got revenue of about \$368 million from the new drug, or 31% of its total for the year.").

34. For example, when generic Prozac (Fluoxetine) entered the market, the first generic challenger sold it at \$1.91 per capsule, or twelve percent below the cost of brand-name Prozac. Two months after the exclusivity period expired, multiple generics had entered the market and the price of generic Prozac had dropped to \$0.32 per capsule. Benjamin G. Druss et al., *Listening To Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFFAIRS 210, 213–14 (2004).

35. 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.").

36. *See* Robert A. Zauzmer, *The Misapplication of the Noerr-Pennington Doctrine in Non-Antitrust Right to Petition Cases*, 36 STAN. L. REV. 1243, 1244 (1984). One may not automatically escape all punishment if the petitioning comprises illegal acts. *Id.*

alteration, or rejection of the agency's rules.³⁷ Consistent with the Administrative Procedure Act, the FDA has adopted regulations allowing for so-called citizen petitions, which permit individuals to influence the Agency's regulations on health and safety.³⁸ Citizen petitions allow anyone to file a petition with the FDA regarding the Agency's rulemaking activities or, more importantly, its administrative actions.³⁹

Individuals have used the citizen petition process to lobby the FDA on a variety of health and safety issues.⁴⁰ However, brand-name manufacturers have wielded citizen petitions in an attempt to manipulate the FDA's approval of generic drug applications. Some brand-name manufacturers have responded to ANDAs by filing citizen petitions that question the FDA's safety, efficacy, and bioequivalence standards for approving generic drugs.⁴¹ Generic manufacturers sometimes respond with their own citizen petitions, which typically object to the strict requirements proposed by brand-name manufacturers.⁴² These generic companies have also responded with lawsuits alleging that the pioneers violated antitrust and unfair competition laws by filing baseless and frivolous citizen petitions.⁴³ In their defense, brand-name companies have argued that they are merely taking advantage of their constitutional rights, and that the citizen petitions were properly filed according to

37. Administrative Procedure Act, 5 U.S.C. § 553(e) (2012).

38. 21 C.F.R. § 10.30(b) (2013) ("A [citizen] petition (including any attachments) must be submitted in accordance with § 10.20 and in the following form").

39. 21 U.S.C. § 355(q) (2011); 21 C.F.R. §§ 10.20, 10.25, 10.30. As applied to the FDA, the right to petition guarantees citizens the right to ask the agency to "issue, amend, or revoke" a regulation or order. 21 C.F.R. § 10.30(b). Such a petition must be submitted to the FDA before any legal suit can be filed to complain about an action or failure to act. *Id.* § 10.45. Regulations that specifically applied to citizen petitions related to ANDAs were codified by the Food and Drug Administration Amendments Act of 2007. *See* 21 U.S.C. § 355(q); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.). Non-citizens may also file citizen petitions. 21 C.F.R. § 10.30(a).

40. *See Finance Senators Urge FDA To Respond To Its Citizen Petition Process*, VACCINE INJURY HELP CENTER (May 31, 2011), <http://www.vaccineinjuryhelpcenter.com/finance-senators-urge-fda-to-respond-to-its-citizen-petition-process>; *see also* Memorandum from June Gibbs Brown, Dep't of Health & Human Servs., Review of the Food and Drug Administration's Citizen Petition Process, at 1 (July 17, 1998) (reviewing the FDA's effectiveness in handling citizen petitions).

41. *See, e.g., In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011) (addressing a brand-name manufacturer that filed citizen petitions requesting that FDA finalize guidelines and impose more stringent testing standards before approving any ANDAs); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009) (involving a brand-name manufacturer that filed citizen petitions requesting that FDA not approve any ANDA filed for the generic version unless the ANDA had data from certain bioequivalence studies).

42. Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & L. 275, 281 (1996).

43. *See, e.g., In re Flonase*, 795 F. Supp. 2d at 300-01, 309; *La. Wholesale Drug*, 2009 WL 2708110, at *2. In addition to federal statutes, some generic companies have tried to use state unfair competition laws against citizen petition filers. *See, e.g., Am. Home Products Corp. v. Johnson & Johnson*, Nos. 94-1209, 94-1210, 1995 WL 387901 (Fed. Cir. June 29, 1995).

FDA law and regulations.⁴⁴ Understanding the procedure and application of a citizen petition is vital to understanding the struggle between brand-name and generic manufacturers vying for market power.

A. THE CITIZEN PETITION PROCESS

Any person or corporation may submit a citizen petition to the FDA.⁴⁵ A citizen petition may request that the Agency “issue, amend, or revoke” a regulation or order, or that the Agency take or not take a particular action.⁴⁶ The citizen petition must specify the action requested, an explanation of the factual and legal basis for the request, and, if appropriate, a statement regarding the environmental and economic impact of the requested action.⁴⁷ The petition must also include a certification stating that it contains all relevant information, including any that may be unfavorable to the petition.⁴⁸

Upon receipt, the FDA categorizes citizen petitions into those that raise scientific issues and those that raise legal issues.⁴⁹ Petitions raising scientific issues typically focus on the validity of bioequivalence testing methods.⁵⁰ Citizen petitions that focus on legal issues typically raise concerns regarding the ANDA approval process itself, the fundamental requirements for a generic drug, the patent certifications required by an ANDA applicant, and marketing exclusivity issues.⁵¹

The FDA is required to provide a response to a citizen petition within a statutorily specified timeframe—previously 180 days, now 150 days, as of October 2012.⁵² However, this first response need not

44. See, e.g., *La. Wholesale Drug*, 2009 WL 2708110, at *2; *In re Flonase*, 795 F. Supp. 2d at 300–01, 309.

45. 21 C.F.R. § 10.30(a) (2013).

46. *Id.* § 10.30(b); see 21 U.S.C. § 355(q) (2011).

47. 21 C.F.R. § 10.30(b).

48. *Id.*; see 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, 110 (2010) (describing the scope and content of citizen petitions).

49. Molzon, *supra* note 42, at 281.

50. *Id.* According to the FDA, “[a] generic drug is identical—or bioequivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.” *Generic Drugs: Questions and Answers*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last visited Oct. 31, 2013). “A [generic] drug shall be considered to be bioequivalent to a listed drug if—(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses.” 21 U.S.C. § 355(j)(8)(B)(i).

51. Molzon, *supra* note 42, at 281.

52. 21 C.F.R. § 10.30(e)(2) (requiring the FDA to respond within 180 days, except as provided in 21 C.F.R. § 10.30(e)(4)). This, however, was not always the case. See Lee, *supra* note 48, at 110, 112; see *infra* notes 72–73 (listing authority for reducing the time limit to 150 days).

necessarily address the substance of the petition.⁵³ In response, the FDA could (1) deny the petition outright; (2) grant the petition, in whole or in part, and take action as requested; (3) provide a tentative response requesting more information; or (4) modify the suggested action, postpone action, or take other delaying tactics.⁵⁴ If the petition is denied, it is unlikely to receive judicial review because the FDA's refusal to grant the requested relief is within its discretion to choose which issues to pursue.⁵⁵ Federal courts have held that the FDA has broad discretion over both the regulatory process and the scientific methodology the Agency uses for approving generic drugs.⁵⁶

Generally, FDA prioritizes responses to petitions by considering available resources for the category of subject matter, overall work of the agency, and statutory time requirements.⁵⁷ Despite the statutorily imposed 180-day response requirement, the FDA has often failed to meet that deadline.⁵⁸ For example, in 2008 the Agency's average response time was 226 days, with nearly seventeen percent exceeding the 180-day deadline.⁵⁹ These lengthy response times are attributed, in part, to a sharp increase in

53. 21 C.F.R. § 10.30(e)(2). The response will either: approve the petition, deny the petition, or provide a tentative response indicating why the FDA was unable to reach a decision, for example, because of other priorities or need for more information. The tentative response may also indicate a likely final response and when it may furnish a final response.

54. *Id.* § 10.30(e); Frederick K. Grittner, *Citizen Petition*, 3 WEST'S FED. ADMIN. PRAC. § 3833 (2011); Lee, *supra* note 48, at 111.

55. Grittner, *supra* note 54, § 3833; Heckler v. Chaney, 470 U.S. 821, 842 (1985) (suggesting that the FDA's discretion applies to at least legal challenges in petitions because "the [Federal Food, Drug, and Cosmetic Act] is not a mandatory statute that requires the FDA to prosecute all violations of the Act. Thus, the FDA clearly has significant discretion to choose which alleged violations of the Act to prosecute. . . . [T]he basis on which the agency chose to exercise this discretion—that other problems were viewed as more pressing—generally will be enough to pass muster").

56. *See* Schering Corp. v. FDA, 51 F.3d 390, 398 (3d Cir. 1995) ("[21 U.S.C. § 355(j)] vests the FDA with discretion to determine whether *in vitro* or *in vivo* bioequivalence studies, or both, will be required for the approval of generic drugs under the abbreviated application process."), *cert. denied* 116 S. Ct. 274 (1995); Schering Corp. v. Sullivan, 782 F. Supp. 645, 651 (D.D.C. 1992) ("Congress did not intend to restrict the FDA's discretion to determine how the bioequivalence requirement is to be met."), *vacated as moot, sub nom.*, Schering Corp. v. Shalala, 995 F.2d 1103, 1105 (D.C. Cir. 1993); Fisons Corp. v. Shalala, 860 F. Supp. 859, 865 (D.D.C. 1994).

57. *See* 21 C.F.R. § 10.30(e)(1).

58. *Id.* § 10.30(e)(2); Grittner, *supra* note 54, § 3833; *see* Lee, *supra* note 48, at 110; Brown, *supra* note 40, at 3; Karst, *OGD's ANDA Backlog*, *supra* note 25.

59. *See* *FDA Citizen Petition Tracker*, FDA LAW BLOG, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/CPTracker.xls (Oct. 2, 2013) (recording receipt and decision dates that span from 181 to 1555 days for late responses); *see also* Kurt R. Karst, *Introducing the FDC Act § 505(q) Citizen Petition Tracker . . .*, FDA LAW BLOG (Oct. 21, 2008, 11:34 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/10/introducing-the.html. In 2008, the FDA gave late responses (i.e., 181 days or later after receipt of the petition) to eight citizen petitions, with five received that are still pending as of March 2012. *FDA Citizen Petition Tracker*, *supra*. In 2009, three were given late responses, with one received that is still pending. In 2010, two were given late responses, with two received that are still pending. *Id.* In 2011, the FDA received one that was pending past 180 days. *Id.* The 180-day deadline was revised in 2012, so 2012 numbers were omitted to allow for a consistent comparison, though they can be found in the *Citizen Petition Tracker*, *supra*.

the number of petitions filed on the eve of brand-name product patent expiry, combined with the FDA's limited staff.⁶⁰ The FDA's response times are likely to worsen as federal funding declines.⁶¹

B. DELAYING ANDA APPROVAL WITH CITIZEN PETITION

Seeking ANDA approval is a relatively lengthy process. In some cases, pharmaceutical companies have attempted to further lengthen this process by filing citizen petitions that raise frivolous issues regarding the approval of a generic competitor's ANDA.⁶² The FDA's administration of its review process for citizen petitions has been a subject of enduring concern within the Agency.⁶³ Furthermore, as the ANDA backlog continues to grow, delays caused by citizen petitions have become even more problematic. The number of citizen petitions filed annually with the FDA has increased steadily over the years, from ten in 2001 to thirty-three in 2012.⁶⁴

Some brand-name manufacturers have taken advantage of the increasingly inefficient ANDA process in order to delay approval of generic drugs using these "blocking" petitions. Citizen petitions filed to fend off generic competition typically object to bioequivalence standards or a previous approval of an ANDA.⁶⁵ Prior to 2007, the FDA would automatically suspend ANDA approval in response to any citizen petition until the issues presented in the petition were completely

60. Lee, *supra* note 48, at 110; see BROWN, *supra* note 40, at 5–6 (citing policies, procedures, screening and prioritizing system, management, and failure to implement most recommendations as factors contributing to FDA's ineffective citizen petition process in the 1990s).

61. See Dave McCleary, *Budget Reductions & User Fees—ANDA approval times?*, CUSTOPHARM BLOG (Aug. 10, 2011), <http://www.custopharm.com/blog/bid/66365/Budget-reductions-User-Fees-ANDA-approval-times>.

62. Hypothetically, competitors may also use the citizen petition process to delay the approval of a new brand-name drug. Although the Authors do not know of any cases where this has happened, theoretically a competitor could file a citizen petition that raises issues regarding FDA's approval of an NDA. The FDA is required to take final action on any citizen petition relating to new drug applications. 21 U.S.C. §§ 355(b)(2), (q)(1)(F) (2013) (listing rules regarding NDAs). A citizen petition with the primary intent to delay the approval of an NDA may be denied at any point. *Id.* § 355(q)(1)(E) (2011); CTR. FOR DRUG EVALUATION & RESEARCH, FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: CITIZEN PETITIONS AND PETITIONS FOR STAY OF ACTION SUBJECT TO SECTION 505(Q) OF THE FED. FOOD, DRUG, AND COSMETIC ACT 4 (2011) [hereinafter FDA, GUIDANCE ON CITIZEN PETITIONS]; see 21 U.S.C. § 355(b)(2).

63. Lee, *supra* note 48, at 111; see BROWN, *supra* note 40, at i, 3–4.

64. See *FDA Citizen Petition Tracker*, *supra* note 59; Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 269–70 (2012). In addition, the Food and Drug Administration Amendments Act of 2007, discussed below, was unsuccessful in slowing down citizen petitions submitted to the FDA. *Id.* at 252 ("After passage of the legislation, the number of filings per year increased from 27 to 34. Brand petitions against generics increased from 9 to 16 per year.").

65. See Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 680 n.31 (2010).

resolved.⁶⁶ FDA regulations also allow anyone to request that the FDA stay the effective date of any administrative action.⁶⁷ In view of the rampant abuse of these mechanisms, the Agency indicated that many of these citizen petitions were of dubious merit that appeared to be attempts by brand-name manufacturers to manipulate the FDA's processes in order to artificially extend their drugs' market exclusivities past their patent expirations.⁶⁸ For example, from 2003 to 2006, twenty out of twenty-one ANDA-related citizen petitions reviewed by the FDA were found to be without merit.⁶⁹ Many of these meritless petitions were filed by brand-name companies during the six-month period just prior to the launch date of a generic competitor.⁷⁰ As of late 2005, FDA officials acknowledged ongoing abuses of the citizen petition process.⁷¹

In response to these abuses, Congress passed the Food and Drug Administration Amendments Act of 2007 (the "FDAAA"), which added § 505(q) to the Food, Drug, and Cosmetic Act (the "FDCA").⁷² Section 505(q) created a 180-day deadline (now reduced to 150 days under the FDA Safety and Innovation Act of 2012, but hereinafter referred to as the "180-day period") for responding to citizen petitions, which was intended to limit the adverse impact of citizen petitions on ANDA approval.⁷³ The revised FDCA now states that the FDA cannot delay the approval of an ANDA as a result of a citizen petition unless the Agency "determines, upon reviewing the petition, that a delay is necessary to protect the public health."⁷⁴ The revisions also address meritless filings of citizen petitions based on guidelines issued by the FDA.⁷⁵ If the FDA finds that a petition's main objective is to delay approval of an ANDA without raising legitimate scientific or regulatory issues, then the FDA

66. See Lee, *supra* note 48, at 110, 112. That changed with the introduction of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.).

67. 21 C.F.R. § 10.35 (2012).

68. Sheldon Bradshaw, FDA Chief Counsel, Speech Before the Generic Pharmaceutical Association Annual Policy Conference (Sept. 19, 2005) (recording on file with Generic Pharm. Ass'n).

69. Press Release, U.S. Senate Special Comm. on Aging, Kohl, Leahy Introduce Bill to Stop Frivolous Citizen Petitions, Speed Generic Drug Approval (Sept. 28, 2006) (on file with U.S. Senate).

70. See *id.*

71. Letter from Kathleen D. Jaeger, President and CEO, Generic Pharm. Ass'n, to Andrew C. Von Eschenbach, Comm'r, FDA (Dec. 15, 2005) (on file with Generic Pharm. Ass'n) [hereinafter Letter from Jaeger].

72. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.). Section 505(q) was codified as 21 U.S.C. § 355(q) (2011).

73. 21 U.S.C. § 355(q)(1)(F); FDA, GUIDANCE ON CITIZEN PETITIONS, *supra* note 62, at 4; see Lee, *supra* note 48, at 112. The FDA Safety and Innovation Act amendments took effect on October 1, 2012. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 106, 1135, 126 Stat. 993 (2012).

74. 21 U.S.C. § 355(q)(1)(A).

75. *Id.* § 355(q)(1)(E).

may deny the petition at any time.⁷⁶ The FDA is considered to have taken final agency action on a petition if the Agency makes a final decision during the 180-day period or if the 180-day period expires without the FDA having made a final decision.⁷⁷ If a civil action is filed against the FDA regarding any issue raised in the petition before the FDA has made a final decision, then a court can dismiss the action without prejudice for failure to exhaust administrative remedies.⁷⁸ As for ANDA applicants, if a delay beyond the 180-day period is necessary, the FDA must notify the applicant within thirty days of making such a determination.⁷⁹

However, § 505(q) failed to stop abuse of the citizen petition process. In 2008, a bipartisan group of legislators from the House and Senate expressed concerns that the FDA was not implementing the new law aggressively enough.⁸⁰ In 2009, the FDA released a draft guidance for citizen petitions subject to § 505(q).⁸¹ The FDA's interpretation includes verification requirements in final citizen petitions, and discusses how the Agency determines if § 505(q) applies to a particular petition and whether such a petition would delay approval of a pending application.⁸² In 2011, the FDA released a final guidance that was substantially similar except that the final guidance clarified that the Agency would require strict adherence to complete statutory certification and verification statements.⁸³ In spite of such efforts from the legislature and the FDA, the FDA's regulatory procedures continue to be misused, and its failures tolerated.⁸⁴

Although citizen petitions objecting to the FDA's approval of particular ANDAs have been criticized as anticompetitive measures against generics, they may be reasonable and even necessary.⁸⁵ For example, questioning the FDA's safety, efficacy, and bioequivalence

76. *Id.* However, the FDA has never actually used this provision to summarily deny a citizen petition. Kurt R. Karst, *Public Shaming: FDA Edges Closer to Citizen Petition Denial for Intent to Delay Generic Drug Approval, But Prefers to Pass the Buck on Enforcement*, FDA LAW BLOG (Aug. 28, 2013, 7:19 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/08/public-shaming-fda-edges-closer-to-citizen-petition-denial-for-intent-to-delay-generic-drug-approval.html.

77. *Id.* § 355(q)(2)(A).

78. *Id.* § 355(q)(2)(B). A civil action would be filed against the FDA Secretary.

79. *Id.* § 355(q)(1)(B).

80. Press Release, Generic Pharm. Ass'n, GPhA Comments on U.S. Letter Questioning FDA's Implementation of Citizen Petition Reforms (Apr. 11, 2008).

81. See Lee, *supra* note 48, at 113.

82. See, e.g., Kurt R. Karst, *Reports Detail FDA's 505(q) Citizen Petition Response Track Record; Section 505(q) May Have Some Unintended Consequences, FDA Says (Part I)*, FDA LAW BLOG (Jan. 24, 2011, 4:27 AM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/01/reports-detail-fdas-505q-citizen-petition-response-track-record-section-505q-may-have-some-unintended.html; Erin A. Lawrence, *Citizen Petitions Guidance Finalized*, FDA LAWYERS BLOG (June 15, 2011), <http://www.fdalawyersblog.com/2011/06/citizen-petitions-guidance-fin.html>.

83. Lawrence, *supra* note 82.

84. See *infra* Part IV.

85. See Noah, *supra* note 65, at 680.

standards for approving generic drugs can be necessary to mitigate possible tort liability for harm caused by the generics. Some state courts have extended liability to New Drug Application (“NDA”) holders when consumers are harmed by generic copies of their brand-name drugs.⁸⁶ This may happen, for example, when patients take a generic version while relying on an inadequate warning accompanying a brand-name drug.⁸⁷ Alternatively, under a “market share” theory, patients may sue both brand-name and generic manufacturers when they do not know the source of the injury-causing drug.⁸⁸ In this case, courts may be justified in imposing tort liability on the brand-name manufacturer even if it was not the source of the harm.⁸⁹

III. THE *NOERR-PENNINGTON* DOCTRINE

The abusive strategy of filing frivolous citizen petitions in order to delay generic entry is made possible by the *Noerr-Pennington* doctrine.⁹⁰ Although generic manufacturers may file antitrust and unfair competition lawsuits in response to frivolous citizen petitions, *Noerr-Pennington* immunizes brand-name manufacturers from liability for petitioning conduct in most cases, even if anticompetitive in nature.⁹¹

A. *NOERR-PENNINGTON* IMMUNITY

The *Noerr-Pennington* doctrine originated from two Supreme Court cases, *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.* and *United Mine Workers v. Pennington*, and was expanded by a third, *California Motor Transport Co. v. Trucking Unlimited*. In these cases, the Supreme Court held that efforts by individuals or groups to petition the government—even for anticompetitive purposes—are immune from antitrust liability.⁹² *Noerr-Pennington* immunity extends to

86. *Id.*

87. *Id.* at 684–85.

88. *Id.* at 685–86. If a plaintiff cannot identify which particular manufacturers of a product caused plaintiff’s harm, the “market share” theory allows recovery against each manufacturer named by plaintiff in proportion to their market share. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 15 cmt. c (1998).

89. Noah, *supra* note 65, at 686; *see* *Sindell v. Abbott Labs.*, 26 Cal. 3d 588, 610–14 (1980); *Martin v. Abbott Labs.*, 102 Wash. 2d 581, 601–07 (1984).

90. *See* Lee, *supra* note 48, at 99, 116.

91. *Id.* at 109.

92. *See* *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (“Certainly the right to petition extends to all departments of the Government.”); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965) (“Noerr shields from the Sherman Act a concerted effort to influence public officials regardless of intent of purpose. . . . Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition.”); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136–37 (1961) (clarifying that “the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a

attempts to influence legislators, administrative agencies, courts, and foreign governments, even where the attempts to influence are illegal for other reasons—for example, bribing government officials.⁹³ The Court based this immunity on the First Amendment's right to petition, finding that such immunity was necessary to protect a citizen's ability to participate in government.⁹⁴

In *Noerr*, a group of trucking companies and their trade association filed an antitrust lawsuit against major railroads, the presidents of those railroads, and their public relations firm.⁹⁵ The plaintiffs' complaint alleged that the defendants had conspired to restrict trade and monopolize the long-distance freight business in violation of the Sherman Act.⁹⁶ The plaintiffs claimed that the defendants' public relations firm lobbied Congress with the sole purpose of injuring the truckers, harming their reputation, and impeding their ability to compete against railroad companies.⁹⁷

The railroad companies, in their defense, maintained that their motivation was not to destroy the trucking business but rather to inform the public and the legislature of the damage that heavy trucks cause to roads and highways.⁹⁸ They then argued that the Sherman Act was inapplicable to efforts to pass or enforce laws, even when the effect was to restrain trade or cause monopolization.⁹⁹ Ironically, the railroad companies counterclaimed using an almost identical theory as the trucking companies, alleging that the truckers violated the Sherman Act by conspiring to destroy the railroad companies' long-distance freight business with negative publicity and adverse legislation.¹⁰⁰

The trial court and the appellate court both sided with the trucking companies and found that the railroads had violated the Sherman Act.¹⁰¹ The Supreme Court reversed, holding that the Sherman Act did not

restraint or a monopoly" and that the "concept of representation depends upon the ability of the people to make their wishes known to their representatives").

93. See *Noerr*, 365 U.S. at 136; *Pennington*, 381 U.S. at 670.

94. *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 379-80 (1991); see *Noerr*, 365 U.S. at 138-39.

95. *Noerr*, 365 U.S. at 129.

96. *Id.*

97. *Id.* The publicity was made to appear generated as independent views when it was actually prepared by the public relations firm and paid for by the railroads. The railroads had tried to influence legislation and succeeded in persuading the Governor of Pennsylvania to veto a bill that would have allowed truckers to carry heavier loads. The plaintiffs sought treble damages and an injunction to restrain the railroads from releasing disparaging information about the trucking companies and from pressuring the legislature or Governor to further the conspiracy. *Id.* at 130-31.

98. *Id.* at 131.

99. *Id.* at 131-32. Other defenses included the assertions that the activities complained of were protected under the First Amendment and that the trucking companies themselves were barred *in pari delicto*. *Id.* at 132 n.6.

100. *Id.* at 132.

101. *Id.* at 132-35.

make it illegal for entities to collaborate to persuade the government to take action, even when it would result in a restraint of trade or monopoly.¹⁰² Such associations bear, at most, very little resemblance to the kind of combinations normally violative of the Sherman Act, such as price fixing, boycotts, and market divisions.¹⁰³ More importantly, the Court held that when the railroads lobbied the government to pass laws restraining the trucking companies, they were merely exercising their constitutional right to petition the government.¹⁰⁴ Although the Court found no antitrust violation, it noted that antitrust laws may apply in cases where such lobbying was “a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.”¹⁰⁵

In *Pennington*, the United Mine Workers of America, a coal miners’ union, initially filed suit to recover royalty payments from the owners of Phillips Brothers Coal Company, a small coal company.¹⁰⁶ Phillips cross-claimed, alleging that United and large coal operators conspired to monopolize interstate commerce in violation of the Sherman Act.¹⁰⁷ The cross-claim alleged that the union and large coal operators thought that overproduction was a large concern in the coal industry.¹⁰⁸ This allegedly led the union and larger companies to agree on measures to place financial pressure on smaller companies.¹⁰⁹ The union and large companies successfully influenced the Secretary of Labor to establish a higher minimum wage for employees of contractors selling coal, which made it difficult for smaller companies to compete.¹¹⁰

The trial court and court of appeals found in favor of Phillips, ruling that the miners’ union was liable under the Sherman Act.¹¹¹ Again, the Supreme Court reversed and found that *Noerr* shielded United from

102. *Id.* at 135–36, 145. The Court in *Noerr* mentions “two or more persons” associating together, ostensibly violating section 1 of the Sherman Act, which prohibits anticompetitive conspiracies and cartels. Citizen petitions in the patented pharmaceutical context implicate section 2 of the Sherman Act, which prohibits monopolies. *See id.* at 136; *see also* 15 U.S.C. §§ 1, 2 (2004).

103. *Noerr*, 365 U.S. at 136.

104. *Id.* at 135–38.

105. *Id.* at 144 (“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 justified.”). This *dictum* created the foundation for the sham exception to *Noerr-Pennington* immunity. *See* discussion *infra* Part III.B.

106. *United Mine Workers v. Pennington*, 381 U.S. 657, 659 (1965).

107. *Id.*

108. *Id.* at 660.

109. *Id.* They agreed that eliminating smaller companies would solve the problem, allowing larger companies to control the market. Examples include the union abandoning its control over working time of miners, agreeing not to oppose the rapid mechanization of mines (which would reduce mine employment), and increasing wages. *Id.*

110. *Id.*

111. *Id.* at 661.

antitrust liability.¹¹² The Court held that the lower courts did not fully appreciate the scope of *Noerr* in their analyses, and stated that *Noerr* protects concerted efforts to influence public officials regardless of anticompetitive intent.¹¹³

The Court expanded the scope of the immunity created by *Noerr* and *Pennington* in *California Motor Transport Co. v. Trucking Unlimited*.¹¹⁴ In addition to generally immunizing attempts to influence the legislative and executive branches, *California Motor Transport* held that the right to petition likewise immunizes advocacy through channels and procedures of state and federal agencies and courts from antitrust liability.¹¹⁵ The Court also revisited *Noerr*'s dicta concerning sham petitioning,¹¹⁶ which is discussed in Part III.B.

The so-called *Noerr-Pennington* doctrine that arose from this trilogy of cases applies to citizen petitions by brand-name drug manufacturers because the citizen petition process is a lawful, statutorily defined means of petitioning the FDA—a government agency—to take or refrain from taking action. Because of its breadth, this doctrine provides a strong defense against antitrust suits filed by generic manufacturers complaining about alleged misuse of citizen petitions.¹¹⁷ As an immunity based on a First Amendment right,¹¹⁸ the *Noerr-Pennington* doctrine *seems* to protect a wide variety of activities by brand-name companies that could harm generic competitors—for example, filing a citizen petition challenging an ANDA just before the filer is about to launch its generic drug. Nonetheless, one widely recognized exception to this doctrine exists: the “sham” exception.¹¹⁹

B. THE “SHAM” EXCEPTION

Noerr-Pennington immunity does not apply to attempts to influence government action when the conduct is a “mere sham” covering what is actually harassment of a competitor.¹²⁰ The right to petition under the First Amendment may not be used as a pretext for achieving “substantive

112. *Id.* at 669–72.

113. *Id.* at 669–70. Jury instructions in the trial court had allowed a jury to find an illegal conspiracy if there had been an anticompetitive purpose. This is not permitted under *Noerr*. *Id.* at 670.

114. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

115. *Id.* at 510–11 (“Certainly the right to petition extends to all departments of the Government.”).

116. *Id.* at 511 (“We said, however, in *Noerr* that there may be instances where the alleged conspiracy ‘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 justified.’”).

117. *See, e.g., In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009).

118. *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 383 (1991); *see E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 138–39 (1961).

119. *Lee, supra* note 48, at 117.

120. *Noerr*, 365 U.S. at 144; *see Cal. Motor Transp.*, 404 U.S. at 511.

evils” that the legislature has authority to control.¹²¹ When a competitor uses the *process* of petitioning, as opposed to the *outcome*, to cause anticompetitive harm, *Noerr-Pennington* protection does not apply.¹²²

The scope of the sham exception depends on the source, context, and nature of the anticompetitive restraint at issue.¹²³ If the anticompetitive conduct “is the result of valid governmental action,” those urging the action are immune from antitrust liability.¹²⁴ Similarly, successfully influencing legislative and executive action through public or political means is almost never a sham.¹²⁵ However, attempts to influence administrative agencies or the judiciary may be deemed a sham based on an explicit two-part test under the Supreme Court’s decision in *Professional Real Estate Investors v. Columbia Pictures Industries*.¹²⁶

This two-step inquiry is sequential.¹²⁷ For a petition to be considered a sham, it must first be objectively baseless—in other words, no reasonable petitioner could realistically expect success on the merits.¹²⁸ If an objective petitioner “could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under [*Noerr-Pennington*], and an antitrust claim premised on the sham exception must fail.”¹²⁹ Loss on the merits of the underlying petition does not necessarily equate with objective baselessness, though it may be instructive.¹³⁰ Only if the challenged petition is objectively meritless may a court take the second step of examining the petitioner’s subjective,

121. *Cal. Motor Transp.*, 404 U.S. at 515.

122. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993).

123. *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988).

124. *Id.* If anticompetitive restraint comes from private action, liability may ensue unless the restraint is “incidental” to a valid effort to influence governmental action, or it is “genuinely aimed at procuring favorable government action.” *Id.* at 499, 500 n.4.

125. *Id.* at 499–50 (“A publicity campaign directed at the general public, seeking legislation or executive action, enjoys antitrust immunity even when the campaign employs unethical and deceptive methods.”); *see id.* at 502 (“The effort to influence governmental action in this case certainly cannot be characterized as a sham given the *actual adoption* of the 1981 Code.”) (emphasis added); *see Lee, supra* note 48, at 118. *Contra Noerr*, 365 U.S. at 144 (“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.”).

126. *Prof'l Real Estate*, 508 U.S. at 60.

127. *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2009 WL 2708110, at *4 (S.D.N.Y. Aug. 28, 2009).

128. *Prof'l Real Estate*, 508 U.S. at 60. The *Professional Real Estate* exception to *Noerr-Pennington* for sham litigations was extended to sham petitions in *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, 2009 WL 2708110, at *4 (stating that the two-step inquiry applies to claims of sham litigation and petitioning). *See infra* Part IV.A. Although the following discussion refers to sham petitions, it is equally applicable to sham lawsuits.

129. *Prof'l Real Estate*, 508 U.S. at 60.

130. *Id.* at 60 n.5 (noting that courts “must ‘resist the understandable temptation to engage in *post hoc* reasoning by concluding’ that an ultimately unsuccessful ‘action must have been unreasonable or without foundation’”).

anticompetitive motivation—whether the lawsuit conceals “an attempt to interfere directly with the business relationships of a competitor” by using the governmental process (i.e., the meritless petition itself) rather than the outcome of that process.¹³¹

Although *Noerr-Pennington* immunity normally applies to citizen petitions filed with the FDA, the sham exception comes into play only if the citizen petition in question is objectively baseless, possibly because it relies on clearly faulty science or a false legal doctrine, or seeks relief that is unavailable. If true, a court must also find a subjective intent to cause anticompetitive harm, such as delaying generic entry, not through the outcome of the citizen petition, but through the citizen petition process itself. Several recent court decisions have highlighted this issue, and in doing so have also raised questions about the extent of the sham exception.

IV. ANTITRUST CHALLENGES TO CITIZEN PETITIONS FILED WITH THE FDA

If an allegedly anticompetitive citizen petition succeeds in achieving the requested relief, it is by definition a reasonable effort to petition for redress and thus not a sham.¹³² But the reverse is not necessarily true, and courts must avoid letting hindsight bias lead them to the conclusion that a losing action was baseless. Parties may have reasonable grounds for submitting citizen petitions but still lose on the merits.¹³³ *Professional Real Estate* and *Noerr-Pennington* thus seem to provide an avenue for delaying citizen petitions without fear of antitrust liability. If a brand-name manufacturer submits a well-supported, though likely-to-fail petition, *Noerr-Pennington* immunity applies and an antitrust countersuit is not likely to succeed. This suggests that even a weak citizen petition with no reasonable expectation of success on the merits is likely to satisfy the threshold inquiry under *Professional Real Estate*. In order to avoid the sham exception to *Noerr-Pennington* immunity, petitioners merely need to demonstrate a reasonable legal or scientific basis for the relief requested.

The sham exception, however, is far from infallible. It has produced confusing standards of “objective baselessness” and raised doubt about a jury’s ability to examine data that support legitimate health and safety concerns.¹³⁴ Recent cases demonstrate the varying levels of success that

131. *Id.* at 60–61 (quoting *Noerr*, 365 U.S. at 144). “Of course, even a plaintiff who defeats the defendant’s claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham must still prove a substantive antitrust violation. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.” *Id.* at 61.

132. *Id.* at 60 n.5. *But see* Carrier, *supra* note 64, at 266–68 (discussing mixed decisions that are “essential denials,” despite providing some relief).

133. *Prof'l Real Estate*, 508 U.S. at 60 n.5.

134. *See* Lee, *supra* note 48, at 124; *see also* *Prof'l Real Estate*, 508 U.S. at 66–67.

brand-name manufacturers have had defending against antitrust claims by generic manufacturers.¹³⁵

A. THE MURKY DEFINITION OF OBJECTIVE BASELESSNESS APPLIED—
LOUISIANA WHOLESALE DRUG CO. V. SANOFI-AVENTIS

Louisiana Wholesale Drug Co. v. Sanofi-Aventis illustrates the limitations of sham petition claims.¹³⁶ This case also interpreted the *Professional Real Estate* sham exception to apply to petitioning, at least in some jurisdictions.¹³⁷ In 1998, Sanofi-Aventis acquired the exclusive right to market its anti-rheumatic therapy drug Arava (leflunomide) in ten-, twenty- and one-hundred-milligram doses for five and a half years.¹³⁸ In 2004, six generic manufacturers filed ANDAs with the FDA seeking to market ten- and twenty-milligram dosages of generic leflunomide.¹³⁹ One year after Aventis's period of exclusivity ended, and one year into FDA review of the ANDA submissions, Aventis filed a citizen petition requesting that the FDA require the ANDA applicants to perform additional bioequivalence testing.¹⁴⁰ The petition further requested that the FDA withhold final approval of any ANDA that did not seek approval of a 100-milligram tablet that is bioequivalent to Arava or did not establish the bioequivalence of five twenty-milligram generic tablets to one 100-milligram Arava tablet.¹⁴¹

In 2005, the FDA denied Aventis's petition and approved the ANDAs on the same day,¹⁴² but Aventis had already succeeded in keeping its generic competitors off the market for an extra six months.¹⁴³ In subsequent litigation, a class of wholesale drug distributors accused Aventis of improperly seeking to delay generic entry and violating the

135. See *supra* note 23 (discussing reverse payment settlements or authorized generics).

136. Lee, *supra* note 48, at 124.

137. See *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 309–10, 310 n.11 (E.D. Pa. 2011) (“Although *PRE* only discussed the sham exception in the context of litigation, the test also generally applies to petitions to administrative agencies.” The Third Circuit has “consistently and without reservation applied the objective prong to comparable administrative agency petitions.”); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2009 WL 2708110, at *4 (S.D.N.Y. Aug. 28, 2009) (stating that the two-step inquiry applies to claims of sham litigation *and* petitioning).

138. *La. Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-7343, 2008 WL 4580016, at *1 (S.D.N.Y. Oct. 14, 2008) (summary judgment).

139. *Id.*

140. *Id.* at *1–2; see Kurt R. Karst, *Recent Rulings Once Again Shine the Light on Sham Citizen Petition Antitrust Issues*, FDA LAW BLOG (Feb. 9, 2010), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2010/02/recent-rulings-once-again-shine-the-light-on-sham-citizen-petition-antitrust-issues-.html.

141. *La. Wholesale Drug*, 2008 WL 4580016, at *2.

142. See *id.* at *2; *La. Wholesale Drug Co.*, 2009 WL 2708110, at *2 (motion to dismiss).

143. The FDA must and did resolve Aventis's citizen petitions within six months (i.e., 180 days) of filing. See 21 C.F.R. § 10.30(e)(2) (2013).

antitrust laws by filing a sham citizen petition for anticompetitive purposes.¹⁴⁴ Aventis invoked the *Noerr-Pennington* doctrine in its defense.¹⁴⁵

The court described the sham exception test as a “two-step inquiry that applies to claims of ‘sham’ petitioning or litigation.”¹⁴⁶ Under the objective prong of the *Professional Real Estate* test, the sham petition must pursue “claims so baseless that no reasonable [person] could realistically expect to secure favorable relief.”¹⁴⁷ In the context of filing citizen petitions with the FDA, the court stated that the relevant inquiry was “whether a reasonable pharmaceutical manufacturer could have realistically expected the FDA to grant [the] relief sought by Sanofi-Aventis in the citizen petition.”¹⁴⁸ If not, the petition would be objectively baseless and would fail the first prong of the *Noerr-Pennington* test.¹⁴⁹

After trial, the jury found in favor of Aventis, and plaintiffs moved for judgment as a matter of law, which the court denied, holding that a reasonable jury could conclude that Aventis’s citizen petition was not objectively baseless.¹⁵⁰ The evidence available “tended to show that the issue raised by the Citizen Petition was sufficiently novel and unsettled to allow an objectively reasonable drug company to ‘perceive[] some likelihood’ that the FDA would grant the relief requested.”¹⁵¹ This case illustrates the vague “objective baselessness” standard, which has been inconsistently applied in sham citizen petition cases.¹⁵²

144. *La. Wholesale Drug Co.*, 2009 WL 2708110, at *1–2.

145. *Id.* at *2.

146. *Id.* at *4 (emphasis added).

147. *Id.*; see *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 (1993).

148. *La. Wholesale Drug*, 2009 WL 2708110, at *4.

149. See *id.*

150. *Id.* at *7.

151. *Id.* at *4 (quoting *Prof'l Real Estate*, 508 U.S. at 62).

152. Although beyond the scope of this Article, Justice Thomas, in his opinion in *Professional Real Estate*, likened the standard to probable cause in the civil context. See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 (1993). Justices Souter, Stevens, and O'Connor concurred in the judgment but noted that the Court erred by referring to “probable cause” and by drawing a sharp line where none was needed, as “objectively reasonable lawsuits may still break the law.” *Id.* at 66–67, 75. Different courts have subsequently interpreted the standard to be applied differently. Compare *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1341–42 (S.D. Fla. 2004) (reasoning that whether defendant’s sham suits were filed without probable cause does not matter because the Court found as a matter of law that defendant had a legal basis for filing each suit, and *Noerr-Pennington* immunity remained intact), with *Mitsubishi Heavy Indus., Ltd. v. Gen. Elec. Co.*, 720 F. Supp. 2d 1061, 1066 (W.D. Ark. 2010) (accepting the notion of probable cause “in explaining the objective element of sham litigation”). Another issue that is beyond the scope of this Article is whether the correct standard of evidence to be applied is that of a preponderance of evidence or whether a clear and convincing standard has been created, possibly haphazardly, by importing the standard for patent invalidity into the sham litigation question. See *In re Wellbutrin XL Antitrust Litig.*, Nos. 08-2431 (direct), 08-2433 (indirect), 2012 WL 1657734, at *4–5, *5 n.7 (E.D. Pa. May 11, 2012).

B. SHAM PETITIONS AND THE REASONABLE LITIGANT—*IN RE FLONASE ANTITRUST LITIGATION*

A second important case, recently settled before trial, concerns citizen petitions that GlaxoSmithKline allegedly used to extend its monopoly on Flonase, a nasal spray containing fluticasone propionate. Flonase is used to treat allergic and non-allergic rhinitis (hay fever) and was one of GlaxoSmithKline's most successful blockbuster drugs.¹⁵³ At its height, GlaxoSmithKline reported sales of Flonase in excess of one billion dollars per year.¹⁵⁴ As the patents covering Flonase neared expiration, GlaxoSmithKline sought to prevent or delay FDA approval of a generic Flonase. One stratagem allegedly used by GlaxoSmithKline to delay approval of the pending ANDAs for generic Flonase was to file citizen petitions raising concerns about the safety and efficacy of the proposed generic.¹⁵⁵

Between 2004 and 2005, GlaxoSmithKline filed six different citizen petitions with the FDA covering a variety of requests.¹⁵⁶ In particular, GlaxoSmithKline petitioned the FDA to deny approval of any Flonase generics until certain standards were established, despite a lack of any research supporting the need for such standards, and the fact that FDA approval was granted to Flonase without them.¹⁵⁷ Further, performing the exact same tests that GlaxoSmithKline used for Flonase approval was virtually impossible for a generic manufacturer because GlaxoSmithKline's testing methodologies are proprietary.¹⁵⁸ Generic challengers alleged that their ANDAs for making generic Flonase were delayed nearly two years by GlaxoSmithKline's numerous citizen petitions while the FDA reviewed and responded to each one.¹⁵⁹

Finally in February 2006, more than two years after GlaxoSmithKline's patent on Flonase expired, the FDA denied all of the citizen petitions and

153. See *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 301 (E.D. Pa. 2011).

154. *Am. Sales Co. v. SmithKline Beecham Corp.*, 274 F.R.D. 127, 130, 131 (E.D. Pa. 2010).

155. See *In re Flonase*, 795 F. Supp. 2d at 304.

156. *Id.* at 305–07. GlaxoSmithKline's citizen petitions requested that the FDA: (1) “refrain from approving ANDAs prior to issuing final guidance,” (2) “require ANDAs to include data from [both allergic and non-allergic rhinitis studies],” (3) “require pharmacokinetic data to be collected over the entire dosage interval of *in vivo* tests,” (4) “reconsider its *in vitro* tests for plume geometry and container shelf life,” (5) “reconsider its endorsement of the geometric mean ratio method,” and (6) “tighten specifications for [droplet size distribution and spray pattern].” *Id.* (emphasis added and omitted).

157. *Id.* at 305–08; Complaint at 9, ¶ 45, *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011) (No. 09-1638).

158. *In re Flonase*, 795 F. Supp. 2d at 308.

159. Complaint at 12, ¶ 59, *In re Flonase*, 795 F. Supp. 2d 300 (No. 09-1638) (alleging Roxane was unable to sell generic Flonase in the U.S. until Mar. 3, 2006, about twenty-two months after GlaxoSmithKline's market exclusivity expired). At the time, the FDA's policy was to respond to all citizen petitions concerning a pending ANDA prior to granting approval. *In re Flonase*, 795 F. Supp. 2d at 303 n.6. See 21 U.S.C. § 355(q)(1)(A) (2013); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.).

approved the first-filed ANDA from Roxane Laboratories on the same day.¹⁶⁰ The following day, GlaxoSmithKline filed suit against the FDA requesting a temporary restraining order barring the ANDA's approval.¹⁶¹ The court granted the order but denied the motion for a preliminary injunction, and GlaxoSmithKline was forced to pay a multi-million dollar bond to cover Roxane's lost sales.¹⁶²

Roxane and two classes of purchasers of Flonase brought suit alleging that GlaxoSmithKline violated antitrust laws by filing citizen petitions and a lawsuit for the sole purpose of delaying market entry of generic Flonase.¹⁶³ After extensive motion practice and discovery, GlaxoSmithKline moved for summary judgment under theories that the plaintiffs could not show causation and that their actions were protected by the *Noerr-Pennington* doctrine.¹⁶⁴ The court denied both motions for summary judgment, noting that genuine issues of material fact remained as to whether GlaxoSmithKline's conduct fell under the sham exception to *Noerr-Pennington* immunity.¹⁶⁵

The court referred to *Professional Real Estate*'s two-step test and reemphasized that although the Court in *Professional Real Estate* only discussed the sham exception in deciding cases of "sham" litigation, the test also generally applies to petitions.¹⁶⁶ GlaxoSmithKline conceded that it had an anticompetitive motivation for filing the citizen petitions, satisfying the second step of the test.¹⁶⁷ Consequently, the plaintiffs' only burden was to show that GlaxoSmithKline's petitions were objectively baseless.¹⁶⁸

160. *In re Flonase*, 795 F. Supp. 2d at 308.

161. *Id.* GlaxoSmithKline alleged that the approval was "arbitrary and capricious, an abuse of discretion, and in violation of the law." *Id.*

162. *Id.*; *Glaxo Group Ltd. v. Leavitt*, 481 F. Supp. 2d 434, 435 (D. Md. 2007).

163. *In re Flonase*, 795 F. Supp. 2d at 301–02, 309; Complaint at 14, *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (No. 09-1638) (alleging unlawful maintenance of monopolization under section 2 of the Sherman Act).

164. *In re Flonase*, 795 F. Supp. 2d at 302.

165. *Id.* at 309.

166. *Id.* at 309–10. *See id.* at 310 n.11; *supra* note 137. The *Professional Real Estate* standard is often applied under a clear and convincing evidence standard. Such a standard would require specific facts showing genuine issues for trial, rather than unsupported assertions. *800 Adept, Inc. v. Murex Secs., Ltd.*, 539 F.3d 1354, 1370 (Fed. Cir. 2008). This standard arose in the context of patent litigation but may be applicable in non-patent cases as well, as in *In re Flonase*. *See* 795 F. Supp. 2d at 301 (alleging antitrust violations). *But see id.* at 311 n.12 (leaving open "what proper standard is in the context of a sham petition claim" since either preponderance or clear and convincing evidence was sufficient for summary judgment).

167. *In re Flonase*, 795 F. Supp. 2d at 311.

168. *Id.* at 311–12. Courts have sometimes referred to a showing of a realistic expectation of success on the merits as a showing of "probable cause." But this characterization ultimately raises the same question as the traditional inquiry—"whether any 'reasonable litigant could realistically expect success on the merits' of the petition." *Id.* at 311. There is still a question, not addressed in this article, as to whether a single sham citizen petition can constitute an antitrust violation. In *In re Flonase*, the court held that "conduct is not a sham if 'at least one claim in the [petition] has objective merit.'" *Id.* at

The court found genuine issues of fact as to whether GlaxoSmithKline's citizen petitions were objectively baseless.¹⁶⁹ The court also found the lawsuit requesting the temporary restraining order to be "objectively baseless."¹⁷⁰ That the temporary restraining order was granted only indicated that there was *some* likelihood that GlaxoSmithKline's suit would succeed on the merits.¹⁷¹ This did not mean that GlaxoSmithKline would *likely* succeed on the merits or even that it had a *realistic* chance of success on the merits.¹⁷² However, even though GlaxoSmithKline lost the motion for summary judgment, it still succeeded in delaying entry of generic Flonase for nearly two years through its filing of citizen petitions.¹⁷³

C. PARTIAL SUCCESS AND CAUSATION—*IN RE WELLBUTRIN XL ANTITRUST LITIGATION*

In *In re Wellbutrin XL Antitrust Litigation*, purchasers of Wellbutrin XL brought an antitrust case against Biovail and GlaxoSmithKline, the producers and distributors of the once-a-day antidepressant, alleging that they illegally conspired to prevent generic versions from entering the market.¹⁷⁴ The complaint argued that defendants schemed to delay generic entry of extended-release bupropion hydrochloride into the market by, among other things, filing an allegedly baseless citizen petition with the FDA.¹⁷⁵ The plaintiffs claimed that this scheme delayed the entry of cheaper alternatives to Wellbutrin XL from November 2005

312 (citing *Dentsply Int'l, Inc. v. New Tech. Co.*, No. 06-0272, 1996 U.S. Dist. Lexis 19846 (D. Del. Dec. 19, 1996)). The courts in *Wellbutrin SR* and *Wellbutrin XL* also found that a single objectively baseless petition or lawsuit can constitute a sham under *Professional Real Estate*. See *In re Wellbutrin SR Antitrust Litig.*, 749 F. Supp. 2d 260, 263–64 (E.D. Pa. 2010); see also *In re Wellbutrin XL Antitrust Litig.*, Nos. 08-2431, 08-2433, 2012 WL 1657734 (E.D. Pa. May 11, 2012).

169. *In re Flonase*, 795 F. Supp. 2d at 317. See *id.* at 312–16 (addressing each petition and why plaintiffs' evidence raise genuine issues of fact).

170. *Id.* at 317.

171. *Id.* at 316.

172. *Id.* at 317. Also, GlaxoSmithKline's motion for a preliminary injunction failed because the judge who denied it "simply . . . [didn't] see any likelihood that [GlaxoSmithKline was] going to prevail." *Id.*

173. See *id.* at 305, 308 (describing how GlaxoSmithKline's first citizen petition was on May 19, 2004, and the FDA denied the citizen petitions and approved Roxane's ANDA on Feb. 22, 2006.; the temporary restraining order was granted on Feb. 24, 2006, but GlaxoSmithKline's motion for a preliminary injunction was denied on Mar. 7, 2006); Complaint at 9, ¶ 45, *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011) (No. 09-1638).

174. *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 131 (E.D. Pa. Aug. 15, 2011); *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2012 WL 1657734, at *1 (E.D. Pa. May 11, 2012). Direct purchasers include Meijer, Inc. and Rochester Drug Co-Operative, Inc. Memorandum for Direct Purchasers' Consolidated, in opposition to motions to dismiss, *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2012 WL 1657734, at n.3. Indirect purchasers include employee welfare benefit plans and Aetna Health of California. *In re Wellbutrin XL*, 2011 WL 3563835, at *1.

175. See *In re Wellbutrin XL*, 2012 WL 1657734, at *1. The plaintiffs also alleged that Biovail and GlaxoSmithKline further schemed to keep generic Wellbutrin XL off the market by filing multiple sham patent infringement lawsuits and then entering into settlements with the generic companies. *Id.*

to December 2006 for the 300-milligram generic and to May 2008 for the 150-milligram generic.¹⁷⁶ The delayed generic entry allowed Biovail and GlaxoSmithKline to generate more than one-billion dollars in additional revenue in 2006 alone.¹⁷⁷

Biovail and GlaxoSmithKline moved for summary judgment under the *Noerr-Pennington* doctrine.¹⁷⁸ The court granted the motion, finding that the plaintiffs failed to demonstrate the existence of a conspiracy.¹⁷⁹ The evidence suggested that the two companies independently considered the filing of a citizen petition.¹⁸⁰ While GlaxoSmithKline decided not to file a petition, Biovail filed one on December 20, 2005 to request that the generic version of Wellbutrin XL satisfy four criteria.¹⁸¹ The petition was granted only with respect to two criteria.¹⁸² Thus, it would seem that GlaxoSmithKline and Biovail had immunity, as a successful petition is deemed reasonable per se under *Professional Real Estate*. However, the court did not decide whether the two rejected criteria were shams, or whether petitions with a mix of sham and non-sham requests may be considered objectively baseless as a whole.¹⁸³

Regardless, the plaintiffs failed to offer any evidence to suggest that the FDA would have approved the ANDAs for generic Wellbutrin XL any earlier if the petition had been limited to only the two successful criteria.¹⁸⁴ Thus, the court found that the plaintiffs failed to show evidence from which a jury could reasonably infer that Biovail and GlaxoSmithKline conspired to delay generic entry by filing the allegedly sham citizen petition.¹⁸⁵

D. A LACK OF CONVINCING EVIDENCE AS SHAM—*IN RE DDAVP DIRECT PURCHASER ANTITRUST LITIGATION*

The *In re DDAVP* litigation illustrates the application of the pleading standard to alleging civil claims relating to sham litigation and sham citizen petitions.¹⁸⁶ In 1991, Ferring B.V. and Ferring Pharmaceuticals acquired a patent covering the tablet form of DDAVP (desmopressin acetate), an

176. *In re Wellbutrin XL*, 282 F.R.D. at 132.

177. Lee, *supra* note 48, at 114; see *Biovail Provides 2006 Guidance*, BUS. WIRE (Mar. 23, 2006, 7:30 AM), <http://www.businesswire.com/news/home/20060323005215/en/Biovail-2006-Guidance>.

178. *In re Wellbutrin XL*, 2012 WL 1657734, at *1.

179. *Id.* at *34–35. Notably, the court regarded one of the alleged sham lawsuits as a “close question,” which does not fit the profile of objectively baseless litigation. *Id.* at *20.

180. *Id.* at *39.

181. *Id.*

182. *Id.* at *21–24.

183. *Id.* at *28.

184. *Id.* at *34.

185. *Id.* at *35.

186. See generally *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (setting the standard for pleading facts in a civil claim to be one that is “plausible on its face”).

antidiuretic prescription medication.¹⁸⁷ Aventis Pharmaceuticals had an exclusive license from Ferring to market and sell these tablets under the DDAVP name.¹⁸⁸ In 2002, Barr Laboratories filed an ANDA with a paragraph IV certification, seeking to market a generic version of DDAVP.¹⁸⁹ Ferring brought suit for infringement but the district court found Ferring's patent unenforceable because of inequitable conduct before the Patent and Trademark Office.¹⁹⁰ In February 2006, the Federal Circuit concluded that Ferring "deliberately concealed" that several scientists who submitted declarations in support of Ferring's patent application had either been employed or received research funds from Ferring.¹⁹¹

Two months later, direct purchasers of DDAVP filed an antitrust lawsuit against Ferring and Aventis.¹⁹² The plaintiffs alleged that Ferring and Aventis had, among other things, filed a sham citizen petition for the purpose of delaying the FDA's final approval of Barr's ANDA.¹⁹³ The defendants jointly moved to dismiss the complaint, arguing that the plaintiffs lacked standing to assert the antitrust violations.¹⁹⁴ Aventis separately argued that the plaintiffs had not sufficiently alleged misconduct.¹⁹⁵

The district court granted both motions and dismissed the suit for failure to plead fraud with sufficient particularity.¹⁹⁶ The district court also rejected the claim regarding the citizen petition because the defendants had not acted in bad faith and the plaintiffs could not plausibly show the existence of a sham.¹⁹⁷

The Second Circuit vacated the summary judgment, applying a low standard on scienter at the pleading stage and allowing "fairly tenuous inferences" because such issues are appropriately resolved by triers of fact.¹⁹⁸ In particular, the Second Circuit disagreed with the district court

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

188. *Id.* The FDA also approved an NDA for Aventis for the tablets. *Id.*

189. *Id.*

190. *Id.* at 683.

191. *Id.*

192. *Id.*

193. *Id.* The plaintiffs also alleged that the defendants (1) obtained the patent through fraud and/or inequitable conduct, (2) improperly listed the patent in the *Orange Book*, and (3) prosecuted sham infringement litigation against generic competitors. *Id.*

194. *Id.*

195. *Id.* at 683–84.

196. *Id.* at 684.

197. *Id.* at 684, 694.

198. *Id.* at 693, 695. The court also found adequate allegation with regard to the plaintiff's sham litigation claim. *Id.* at 694. Based on the defendants' inequitable conduct of not disclosing material information to the Patent and Trademark Office, and the notion that the high materiality of the omission could overcome the relatively weak evidentiary support for intent, plaintiffs' allegations passed muster. *See id.* at 693–94.

that the citizen petition was protected by the First Amendment and that the plaintiffs could not plausibly show the requisite objective and subjective baselessness for a sham.¹⁹⁹ The FDA found neither “convincing evidence” nor basis for the arguments contained in the citizen petition.²⁰⁰ In addition, the district court previously suggested that the petition might have been an anticompetitive litigation tactic designed to keep generic competition from entering the market as long as possible after the patent expired.²⁰¹ Thus, the court found that the plaintiffs could plausibly show the petition to have been a sham and that summary judgment was therefore improper.²⁰²

This case sheds light on the types of evidence required to assert a claim of sham petition against a brand-name manufacturer. Even where citizen petitions and litigation are both involved, an antitrust case relying on the sham exception can be pleaded, at least sufficiently to survive a motion to dismiss.

V. STRATEGIC CONSIDERATIONS FOR PRACTITIONERS

As Part IV indicated, brand-name and generic manufacturers can file citizen petitions in order to protect their profits. Lawyers played a central role in representing their client companies in ways that aligned their interests with the relevant legal standard: the two-part sham exception test. The following sections discuss strategic considerations and precautions for lawyers on both sides of an antitrust suit challenging an alleged sham petition.

A. SOUND SCIENTIFIC BASIS

It is extremely difficult for an antitrust plaintiff to prove liability when a citizen petition has a sound scientific basis, even if it is far-fetched. By contrast, courts are likely to find that citizen petitions with no discernible sound scientific basis, or that employ clearly faulty science or logic, have no “reasonable likelihood of success.” Thus, petitioners can bolster their defense against possible antitrust claims by ensuring that their petitions have a sound scientific basis.

The FDA’s submission rules for citizen petitions require the petition to include a statement of grounds upon which the action relies.²⁰³ Citizen

199. *Id.* at 694.

200. *Id.*

201. *Id.*

202. *See id.* at 695. *See* *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” (citations omitted)).

203. 21 C.F.R. § 10.30(b) (2013).

petitions are categorized by the FDA into two groups: those that raise scientific issues and those that raise solely legal or procedural issues.²⁰⁴ If the FDA finds that a submission's primary objective is to delay approval of an ANDA without raising legitimate scientific or regulatory issues, then the FDA may deny the petition at any time.²⁰⁵ It thus behooves an entity submitting a petition on a scientific basis (as opposed to purely legal) to include sound scientific backing and ample evidentiary support. Even if the subjective purpose behind a citizen petition is to delay approval of an ANDA and to extend the petitioner's period of market exclusivity, a sound scientific basis can defeat a sham suit if the requested relief—even if far-fetched—is not “objectively baseless.”²⁰⁶

The chances for a petition without sound scientific and evidentiary support to be found objectively baseless is significantly higher than one that employs even far-fetched but well-argued and mainstream scientific theories.²⁰⁷ Generic manufacturers affected by a citizen petition will almost certainly argue there is no scientific or medical basis for a brand-name manufacturer to request a certain action from the generic.²⁰⁸ They will also likely offer evidence that the relief requested in the citizen petition is contrary to FDA statutes, regulations, and practices.²⁰⁹ Extensive evidence and a sound and logical scientific basis for the petition can defeat such arguments.

For example, if in *In re Flonase Antitrust Litigation* GlaxoSmithKline had included in its citizen petitions data showing that its original delivery mechanism, with less concise spray pattern and droplet size distribution, were significantly less effective or even dangerous compared to their newer spray bottle (thus denigrating their own original product and justifying a new, more stringent standard), it would be difficult to argue that their citizen petitions were objectively baseless such that a petitioner could not reasonably expect success on the merits.²¹⁰ Without such data, GlaxoSmithKline's citizen petitions essentially argued that Flonase was

204. Molzon, *supra* note 42, at 281. Lee, *supra* note 48, at 110.

205. 21 U.S.C. § 355(q)(1)(E) (2011). But as mentioned previously, the FDA has never actually used this provision to summarily deny a petition. See Karst, *supra* note 76.

206. See *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 315 n.16 (E.D. Pa. 2011) (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)) (noting that a citizen petition to the FDA requires more than any arguable scientific basis and that “the objective prong requires . . . a realistic chance of ‘elicit[ing] a favorable outcome’”).

207. See *Prof'l Real Estate*, 508 U.S. at 60–61.

208. See, e.g., *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2009 WL 2708110, at *7 (S.D.N.Y. Aug. 28, 2009) (plaintiff arguing that defendants knew that there was no difference from a safety or efficacy standpoint between brand-name and generic doses and consequently there was no scientific or medical basis for defendants to request that generic manufacturers seek approval).

209. See, e.g., *id.* at *2 (plaintiff offering evidence and argument at trial that defendant's citizen petition lacked scientific or medical basis and that the relief requested was against FDA regulations).

210. Of course, this would effectively require GlaxoSmithKline to admit that its earlier product was unsafe or ineffective.

safe when released but that the FDA should require greater measures of safety for generics. Even if a citizen petition is unlikely to succeed, a well-reasoned scientific argument with data to support it will turn the issue into a legitimate battle of the experts and will make antitrust suits less likely to succeed.

Brand-name manufacturers should be familiar with such tactics, as they can also use a lack of sound scientific basis to oppose ANDAs. Under the rules for ANDA approval, the application must contain, *inter alia*, information showing that the new drug's conditions of use have been previously approved for another drug and that the active ingredient of the new drug is the same as that of the approved drug.²¹¹ The lack of a sound scientific basis in an ANDA may be raised in a citizen petition itself or in subsequent litigation.²¹² Brand-name manufacturers may also employ other means to attack ANDAs, such as asking the FDA to require other types of statistical analysis and to not approve ANDAs until the FDA finalizes its guidance documents for establishing bioequivalence.²¹³ In short, for a citizen petition to be successful, the filer should ensure that the petition contains a sound scientific basis and determine whether the ANDA itself may lack enough scientific backing to pass as a new, bioequivalent generic drug.

B. SUBJECTIVE INTENT

The second prong of the “sham” inquiry tests the subjective intent of the citizen petition filer.²¹⁴ While a company is not likely to admit to having an anticompetitive intent, discovery provides a glimpse into the company's internal discussions and deliberations. With internal memoranda, emails, presentations, and other documents, one can paint a picture of a corporation's intent or purpose behind filing a citizen petition. For instance, in *In re Flonase Antitrust Litigation*, defendant GlaxoSmithKline requested through a citizen petition that the FDA tighten specifications for droplet size distribution and spray pattern for generic manufacturers of Flonase nasal-spray device.²¹⁵ Plaintiff Roxane's expert testimony asserted that the FDA's existing specifications sufficiently ensured public safety and that the FDA could address any concerns with post-marketing supplements.²¹⁶ In fact, Flonase's own specifications had been tightened through post-market supplements after

211. 21 U.S.C. § 355(j)(2)(A) (2011).

212. *See, e.g., In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 305 (E.D. Pa. 2011).

213. *See, e.g., id.* at 305-07 (detailing brand-name defendant's citizen petitions discussing statistical methods and draft guidance documents).

214. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993).

215. *In re Flonase*, 795 F. Supp. 2d at 315.

216. *Id.* at 316.

its NDA.²¹⁷ Discovery of notes from one of GlaxoSmithKline's strategy meetings revealed that GlaxoSmithKline explicitly recognized this fact and anticipated it to apply to generic companies.²¹⁸

As with many antitrust cases, internal email control and education about practical application of the antitrust laws are crucial to avoiding antitrust liability. Plaintiff's lawyers have won many a case or earned a larger settlement simply because a defendant's internal emails and memoranda overtly stated that it was doing something for anticompetitive purposes.²¹⁹

On the other hand, GlaxoSmithKline was able to point to an internal Roxane email admitting that GlaxoSmithKline's arguments in one of its petitions were strong and scientifically based.²²⁰ Even though the question in *In re Flonase* was whether GlaxoSmithKline's citizen petitions had an objective basis rather than subjective desire to exclude generics from the market, the court conceded that an email may constitute evidence that Roxane believed that the petition raised strong arguments.²²¹ Although Roxane's interpretation of the citizen petitions was not at issue, such an email likely would have been persuasive at trial.²²²

Internal communications are a primary source for determining subjective intent in antitrust cases.²²³ Absent emails, memoranda, presentations, and other sources exhibiting anticompetitive purpose behind—or a disbelief in the merits of—citizen petitions, antitrust plaintiffs would face a difficult task of proving subjective intent.

217. *Id.*

218. *Id.* (quoting the defendant's notes to state: "Given that the FDA has worked with us for 3 years to address [spray pattern and droplet size distribution], it is likely that the [FDA] will give a generic company some leeway in addressing any similar criteria issues").

219. See, e.g., Eric Lai, *Microsoft Settles Embarrassing Antitrust Suit in Iowa*, PCWORLD (Feb. 15, 2007, 10:16 AM), http://www.peworld.idg.com.au/article/4418/microsoft_settles_embarrassing_antitrust_suit_iowa (indicating the internal emails and documents suggested not only anticompetitive practices by the defendant company but embarrassing subjective mindset of its employees); Dylan McGrath, *Update: NY Files Antitrust Suit Against Intel*, EE TIMES (Nov. 4, 2009, 5:00 PM), http://www.eetimes.com/documents.asp?doc_id=1172172 (reporting the emails to defendant from other companies in the industry showed the defendant's intent to commit anticompetitive acts).

220. *In re Flonase*, 795 F. Supp. 2d at 316.

221. *Id.*

222. See *id.* (stating that the email evidences subjective belief but does not answer the question whether the objective prong of the *Professional Real Estate* test is met).

223. See Ronald A. Cass & Keith N. Hylton, *Antitrust Intent*, 74 S. CAL. L. REV. 657, 732 (2000) ("[I]t is unlikely that every firm would gain [enough sophistication to avoid liability by watching their words]. At the same time, subjective intent to harm competition would be apt, in many instances, to be predicated on internal documents that . . . are far from compelling. This, however, is likely to be the direct evidence of subjective intent that is available."). Scholars have urged courts to consider internal documents and comments directly from corporate officers in discovering a monopolist's subjective intent. *Id.* at 658.

VI. SUGGESTIONS FOR REGULATING SHAM CITIZEN PETITIONS

In the midst of inconsistent and confusing application of the sham exception to *Noerr-Pennington*, the FDA and courts can work together to safeguard the citizen petition process from misuse. For example, the proposed Citizen Petition Fairness and Accuracy Act of 2006 would have given the FDA the power to sanction those who filed citizen petitions simply to keep competition off the market.²²⁴ The bill included possible sanctions such as a fine of up to one million dollars, permanent revocation of the right to file citizen petitions, and dismissal of the petition.²²⁵ The bill would also have ended excessive delays in generic entry by instructing the FDA to review all citizen petitions within six months of filing.²²⁶ Subsequently, many of these provisions were incorporated in the FDAAA.²²⁷ But recent research has suggested that the abuses FDAAA was meant to curb have not been affected.²²⁸ A number of reforms, both regulatory and judicial, could prove more effective.

A. REGULATORY REFORMS

To the extent that citizen petitions are being misused to delay generic competition, certain provisions of the Hatch-Waxman Act could be modified in order to deter misuse or to mitigate the effects of misuse. This was part of the intent of FDAAA, but it has not stemmed the tide of citizen petitions.²²⁹ Furthermore, as discussed in Part IV, some patentees continue to file sham petitions for anticompetitive purposes. The following regulatory reforms could be useful in preventing abuse of the citizen petition process.

1. Heighten Requirements for Disclosure of Information

The FDA should implement a multi-level review process to screen out improper or unfounded petitions based on disclosed conflicts. For example, to help the FDA evaluate whether a petition's main objective is to delay approval of an ANDA, the Agency could require submission of more information concerning the circumstances under which a petition is filed. Five requirements would be particularly useful to the FDA's initial review: (1) an accurate statement of procedural history, (2) an indication

224. Lee, *supra* note 48, at 125; Press Release, U.S. Senate Special Comm. on Aging, *supra* note 69. The bill specifically granted the sanctioning power to the Department of Health and Human Services. Presumably, sanctions would have been issued by the FDA in practice.

225. Press Release, U.S. Senate Special Comm. on Aging, *supra* note 69.

226. *Id.*

227. Pub. L. No. 110-85, 121 Stat. 823 (codified as amended in scattered sections of 21 U.S.C.); 21 U.S.C. § 355(q) (2011); see Lee, *supra* note 66, at 112-13.

228. See, e.g., Carrier, *supra* note 64, at 249 (discussing subsequent increase in filing of citizen petitions and decline in success rate from twenty percent to nineteen percent).

229. See, e.g., *id.* (noting that legislation has not been successful in reducing the number of petitions).

of any pending ANDAs or NDAs the citizen petition would affect, (3) a statement of financial interest, including financial relationships of any kind to the stakeholders, (4) a statement of likely financial impact, and (5) a corporate disclosure statement indicating any corporate relationships between affected parties. With this screening information at the outset, the FDA could quickly identify “suspect” petitions—such as those having a main purpose of delay—for secondary screening. Petitions involving large sums of money or that are filed shortly before ANDA approval is expected on a blockbuster drug might be subject to additional review to weed out clearly improper petitions, or to designate pressing petitions for immediate review to avoid financial loss. Falsification of screening information could be subject to harsh fines and outright denial of the citizen petition.

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

2. *Adopt More Efficient Methods of Review*

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

230. Letter from Jaeger, *supra* note 71.

231. *See id.* The fourth proposed requirement is already required by § 10.20 certifications.
21 C.F.R. § 10.30(b) (2013).

232. *See* Letter from Jaeger, *supra* note 71.

233. *See id.*

234. *See* Lee, *supra* note 48, at 125–26.

how the FDA handles citizen petitions, which would help to identify systemic deficiencies or potential improvements.²³⁵

3. *Time Restrictions on Submitting Citizen Petitions*

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

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

4. *Prima Facie Review of Intent*

The FDA should exercise its discretion to determine whether citizen petitions concerning ANDA review appear to be anticompetitive by determining whether such petitions are filed with an intent to delay ANDA approval. Under § 505(q)(1)(E), if the Agency finds that a petition's main purpose is to delay ANDA approval, then it may deny

235. See Letter from Jaeger, *supra* note 71.

236. *Id.*

237. 5 U.S.C. § 553(c) (2012) ("[T]he agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation."); Lee, *supra* note 48, at 126.

238. See Letter from Jaeger, *supra* note 71.

the petition at any time.²³⁹ However, the FDA has never actually denied a petition based on such a finding and has refused to issue guidance on how such an intent to delay might be determined.²⁴⁰ Consequently, it is not at all clear and when a citizen petition could be summarily denied based on the Agency's finding of intent to delay.

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

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

239. 21 U.S.C. § 355(q)(1)(E) (2011) (stating that if the FDA determines that a petition "was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues," the FDA may deny the petition at any time).

240. See Karst, *supra* note 76.

241. See 21 U.S.C. § 355(q)(1)(E) (2013) (using language such as "primary purpose of delaying the approval" and denial based on "intent to delay").

242. See *AstraZeneca Pharm. LP v. FDA*, 850 F. Supp. 2d 230, 242 (D.D.C. 2012).

243. *Id.* For example, on March 13, 2012, AstraZeneca sued the FDA to overturn the Agency's recent decision that rejected without comment two citizen petitions aimed at preventing approval of generic versions of Seroquel or Seroquel XR. *Id.* at 230. Ten days later, the court denied AstraZeneca's request for injunction. *Id.* at 251. The FDA only tentatively approved ANDAs referencing Seroquel, so AstraZeneca failed to show a likelihood of success on the merits. *Id.* at 244-48. The "'controversy' envisioned by AstraZeneca in this action may never ripen into a dispute amenable to judicial review." *Id.* at 248.

5. *Lengthen and Enforce the Time Period for Response*

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

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

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

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

244. Grittner, *supra* note 54, § 3833; see Lee, *supra* note 48, at 110; Brown, *supra* note 40, at 3; Karst, *OGD Finished 2010 on a High Note—Really High!*, *supra* note 25 (stating that the “FDA rarely ever meets that statutory requirement”). Note that the response time shrunk to 150 days in late 2012. See text accompanying *supra* note 73.

245. 21 U.S.C. § 355(q)(1)(B) (2011).

246. See *id.* § 355(q)(1)(A) (specifying that ANDAs will not be delayed by pending citizen petitions or petitions for stay of action unless “a delay is necessary to protect public health”); FDA, *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 3 (2012) (reporting that a particular delay in approving an ANDA was based on a concern that an *ex post facto* conclusion that an argument against approval had merit would negatively affect public health). Furthermore, the FDA has concerns that this rule “may not be discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products.” *Id.* at 6.

247. See Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 106, 1135, 126 Stat. 993 (2012); see also *supra* note 73 and accompanying text. Whether the reduction of the time limit to 150 days improves the response rate remains to be seen, however.

248. See *FDA Citizen Petition Tracker*, *supra* note 59.

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

B. JUDICIAL GUIDANCE

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

I. Reduce Judicial Participation

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

Nonetheless, courts should not, in the interim, analyze such determinations to see whether they should be set aside. Agencies are granted broad deference because they are considered best equipped to

249. See Lee, *supra* note 48, at 126.

250. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (“We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.”).

251. *Bellotti v. U.S. Nuclear Regulatory Comm’n*, 725 F.2d 1380, 1385 (D.C. Cir. 1983) (quoting *Cities of Statesville v. Atomic Energy Comm’n*, 441 F.2d 962, 963 (D.C. Cir. 1969)) (emphasizing that “an agency ‘should be accorded broad discretion in establishing and applying rules for . . . public participation’”).

252. 5 U.S.C. § 706 (2012); see *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983).

253. See 21 U.S.C. § 355(q)(1)(E) (2011) (using language such as “primary purpose of delaying the approval” and denial based on “intent to delay”).

respond to “changing circumstances.”²⁵⁴ Recent cases suggest, however, that courts have come to *ad hoc* conclusions regarding the merits of eleventh-hour citizen petitions and that the sham exception is not consistently applied to *Noerr-Pennington* cases.²⁵⁵

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

Another possible policy would be to create a rebuttable presumption in antitrust disputes that a petition is a sham if the FDA finds any of the claims to be late or suspicious. This rule could be especially relevant in claims that include fraudulent or misleading concerns.²⁶⁰ Such an approach would work in concert with the pre-screening processes proposed above in Part VI.A.I.

254. Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 292 (2001) (“[O]ne of the primary reasons for granting agencies broad judicial deference in the implementation of statutory mandates is that agencies are the governmental entities best equipped to respond to changing circumstances.”).

255. See generally *supra* Part IV.

256. Consider that the Supreme Court has constantly expanded the scope of the sham exception to include new circumstances. *Noerr-Pennington* initially immunized from the antitrust laws only attempts to persuade the legislature and the executive branches. See *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961). The doctrine was later expanded to apply in the context of speech geared toward influencing administrative agencies and the courts. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). The sham exception for litigation thus applies to all branches of government. And recently, the sham exception has been specifically applied to citizen petitions. See generally *supra* Part IV.

257. See 21 U.S.C. § 355(q)(1)(A)(ii) (2011); *supra* notes 74, 246 and accompanying text.

258. See, e.g., *Carrier*, *supra* note 64.

259. See *Lee*, *supra* note 48, at 126–27 (noting that the FDA has expertise in scientific methodologies).

260. See *id.* at 127 (noting that fraudulent or misleading claims are a concern).

2. Define the Court's Role

Courts can contribute by clarifying the second step of the *Professional Real Estate* test, which looks at the subjective intent of the filer. The *Professional Real Estate* standard has been the subject of scholarly debate,²⁶¹ and critics argue that the second prong is redundant and should be eliminated.²⁶² The argument is that the subjective prong arose out of early cases discussing the sham exception in a legislative setting and was then folded into the general test for the sham exception.²⁶³ It is arguably redundant because if a claim is objectively baseless, then the act of filing a lawsuit or citizen petition already demonstrates a lack of good faith and improper purpose.²⁶⁴

Until the courts can manifest a clear standard, judicial guidance could lead to better regulation of sham petitions. Similar to the FDA's rebuttable presumption proposed in Part VI.B.1, courts could develop a standard imposing strict liability on sham petitioners. For example, any citizen petition that fails to convince the FDA that it contains any scientifically valid arguments could be deemed a per se sham. This rule would remove the courts from making actual determinations as to the technical details contained in the petitions. Incentives like this will encourage petitioners to back up their submissions with valid scientific data, or not file them at all.

The benefit of shifting the evaluation of the scientific merits of citizen petitions away from the courts and onto the FDA is clear. The Agency is acknowledged as the more adept entity in understanding scientific reasoning and making scientific determinations. While working with the FDA, courts must also aim to remain in a judicial setting where they may apply the wisdom of the legislative and administrative branches as they have done in the past.

CONCLUSION

The FDA's citizen petition process is designed to allow anyone to raise concerns about any pending drug application.²⁶⁵ However, certain brand-name drug manufacturers have abused this process—using it instead for the sole purpose of delaying generic competition in violation

261. See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 69–70 (1993) (Stevens, J., concurring) (explaining that “the Court has set up a straw man to justify its elaboration of a two-part test describing all potential shams”).

262. See Lee, *supra* note 48, at 128; Marina Lao, *Reforming the Noerr-Pennington Antitrust Immunity Doctrine*, 55 RUTGERS L. REV. 965, 1025–26 (2003) (“[T]his subjective test is unsuited for use in litigation settings. If a lawsuit is already shown to be objectively baseless, the institution of suit itself implicitly shows a degree of lack of good faith.”).

263. Lee, *supra* note 48, at 128 n.282.

264. Lao, *supra* note 262, at 1026.

265. Administrative Procedure Act, 5 U.S.C. § 553(e) (2012).

of the antitrust laws. Such sham petitions typically ask the FDA to scrutinize a generic manufacturer's ANDA while raising baseless legal or scientific objections. Even if rejected, the petitions often succeed in delaying ANDA approval for significant periods of time.²⁶⁶

While the constitutional right to petition, in the guise of the *Noerr-Pennington* doctrine, broadly immunizes petitions from antitrust liability, the “sham” exception provides a basis for challenging such anticompetitive behavior.²⁶⁷ Currently, petitions are found unlawful only if they are initiated for objectively baseless and subjectively anticompetitive reasons.²⁶⁸ However, the current standards for the sham exception are unworkable. The sham exception has been applied inconsistently, and it is difficult to predict if and when a mere petition crosses the line to become an antitrust violation. Brand-name manufacturers must be careful to ensure that their petitions include a sound scientific basis. In order to make the citizen petition process more effective and maintain the spirit of the Hatch-Waxman Act, the focus should shift from creating antitrust liability in courts to installing preventive measures at the FDA, such as reforming FDA regulations to deter meritless challenges, as well as increased guidance and scrutiny on the FDA's part. Until these—or any—measures lead to a reform of the citizen petition process, practitioners must be well prepared to navigate the ups and downs of the *Noerr-Pennington* doctrine to their advantage.

266. See, e.g., *Carrier*, *supra* note 64.

267. *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); see *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

268. See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).