1 of 1 DOCUMENT

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ARTICLE: IS **A CURE ON THE WAY?** - THE BAD MEDICINE OF GENERICS, CITIZEN PETITIONS, AND NOERR-PENNINGTON IMMUNITY

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LEXISNEXIS SUMMARY:
... Notwithstanding these efforts, brand-name drug manufacturers have stymied the effective application of the sham exception and FDA regulations. ... The Generic Drug Approval Process The generic drug development process begins by identifying a brand-name drug whose patent is due to expire within three to five years. ... When a generic manufacturer submits an ANDA, it must also certify one of the following for each generic drug listed in the Orange Book: (1) no such patent information has been submitted to the FDA; (2) its patent has expired; (3) the patent is set to expire on a certain date; or (4) the patent is invalid or will not be infringed by the manufacture, sale, or use of the generic drug for which the ANDA has been submitted. ... When generic manufacturers challenge this anti-competitive tactic in court, brand-name manufacturers may avail themselves of the protection through the Noerr-Pennington doctrine. ... LWD alleged that the health and safety concerns raised by Aventis were a sham intended to delay the entry and approval of alternative generic drugs from entering the market.

TEXT:
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I. Introduction

Over the next five years, approximately 110 drugs, including blockbuster products such as Sanofi-Aventis's allergy medicine, Flomax; GlaxoSmithKline's herpes medication, Valtrex; and Pfizer's cholesterol medication, Lipitor, will lose their patent protection. [n1] In 2009 alone, brand-name drugs coming off patent were valued at more than 10.8 billion dollars. [n2] As market exclusivity for these drugs end, the doors for generic production will open. Generic drugs generally enter the market priced at least one-third less than their branded counterparts. [n3] This price competition from generic drugs threatens the profits of brand-name manufacturers and reduces their returns on innovative activity. As a result, some brand-name drug manufacturers have resorted to aggressive tactics to blunt the impact of this competition.

One strategy that has received considerable scrutiny by administrative agencies and courts is the aggressive petitioning activities of brand-name drug **[*99]** manufacturers. [n4] The concern is that these companies are abusing the government process by filing baseless petitions with the Food and Drug Administration ("FDA" or "Agency") to

artificially extend their monopolies. [n5] The effectiveness of this strategy lies in the inherent tension between a citizen's First Amendment right to petition the government and antitrust laws designed to prohibit anticompetitive economic behavior. [n6] Historically, courts and government enforcement agencies have relied on a trilogy of cases - collectively known as the Noerr-Pennington doctrine and its sham exception corollary - to lessen that tension and to curb abuse. [n7]

The Noerr-Pennington doctrine requires courts to interpret the fundamental antitrust law - the Sherman Antitrust Act - in a way that safeguards a citizen's right to request that the government pass legislation regardless of the action's anticompetitive effects. [n8] Grounded in the First Amendment, the doctrine immunizes businesses from potential liability; thus, a business may undergo efforts aimed at persuading the government to take action that would serve its business interests. [n9] While expansive, the doctrine is not absolute. The sham exception provides that a petition loses immunity if it is (1) objectively baseless and (2) born of a predatory intent that is "actually nothing more than an attempt to interfere directly with the business relationships of a competitor ... ." [n10]

However, the sham exception's objectively baseless requirement has been an insurmountable obstacle for courts to effectively police brand-name manufacturer's anticompetitive conduct. In an effort to fill the void, Congress recently passed legislation to reform the FDA's review of citizen petitions and generic drug applications. [n11] Notwithstanding these efforts, brand-name drug manufacturers have stymied the effective application of the sham exception and FDA regulations.

[*100] This Article explores the regulatory and adjudicatory impact of brand-name drug manufacturers' use of the governmental processes to delay the availability of generic drugs. In the current environment, brand-name drug manufacturers can engage in a two-tiered approach to extend their market share with little fear of facing antitrust liability. On the administrative agency level, manufacturers can file baseless petitions that can delay a generic drug's approval for six months or longer. If the FDA determines the petition is meritless, these manufacturers can avoid antitrust liability by relying on Noerr-Pennington immunity. While this Article recommends a robust application of the sham exception, even a reconfigured Noerr-Pennington doctrine cannot provide a complete solution. This Article argues that agency reforms are necessary to effectively curb this type of abuse. The Food and Drug Administration Amendments Act of 2007 ("FDAAA") is an initial step in that direction. [n12] This Article suggests ways to build on that foundation and more fully engage the FDA in actively policing the integrity of its own processes.

Given the unique regulatory framework for encouraging the development and market introduction of generic drugs, Part II of this Article provides an overview of the generic drug industry. It describes the Hatch-Waxman Act of 1984 - the legislation that modified antitrust laws and enabled production of generic drugs. [n13] Part III describes the Abbreviated New Drug Application ("ANDA") process for generic drugs. [n14] Furthermore, it describes the original intent behind the establishment of the citizen petition process and its role in generic drug approvals. [n15] Finally, this section discusses how FDA regulations and policies allow some brand-name drug manufacturers to manipulate this process.

Part IV examines the trilogy of cases that define the basic parameters and principles of the Noerr-Pennington doctrine. [n16] Additionally, it examines the doctrine's two-part inquiry on which courts rely to determine applicability of the sham exception. [n17] In particular, this Article comments on the difficulty courts have had policing the conduct of defendant manufacturers; many manufacturers have been accused of filing petitions that are both objectively baseless and born of predatory intent, but the cases addressing their delaying **[*101]** petitions go unpunished. [n18] As part of that examination, Part IV analyzes Louisiana Wholesale Drug Co. v. Sanofi-Aventis, a recent federal district court opinion. [n19] This case illustrates that even after the FDA determines a petition is baseless and without legal merit, it is still possible for a court to hold that the facts are insufficient to meet the sham exception criteria. This Article posits that Louisiana Wholesale is significant because it strongly suggests that under the court's current interpretation of the sham exception, regardless of the facts and agency determinations, the filing of baseless citizen petitions will remain immune from liability.

Finally, Part V considers other alternatives to discourage drug manufacturers from abusing the citizen petition

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

II. Origins of the Generic Drug Industry - Hatch-Waxman and the Generic Drug Approval Process

Consumers benefit greatly from the availability of generic drugs. [n20] According to the Congressional Budget Office, generic drugs save consumers on average eight to ten billion dollars a year. [n21] In 2009, generic drugs filled more than sixty percent of all prescriptions written. [n22] As the patents for more brand-name drugs expire, industry experts expect that percentage to rise. [n23] Brand-name manufacturers rely on the exclusive rights to market their drugs **[*102]** and for revenue. For example, in 2001, when Eli Lilly's patent expired on its blockbuster drug Prozac, the company's annualized revenues from the drug dropped from $ 2.7 billion to $ 1.8 billion in nine months. [n24] With so much at stake, it is not surprising that some brand-name manufacturers have resorted to filing petitions of questionable legitimacy to delay generic drug approvals and artificially extend their market share. [n25]

A. The Pre Hatch-Waxman Landscape

To fully grasp how and why the drug industry is particularly vulnerable to these petitioning actions, a brief discussion of the unique regulatory structure governing the pharmaceutical industry is required. In 1962, Congress amended the Federal Food, Drug, and Cosmetic Act ("FFDCA") to require drug manufacturers wishing to sell new pharmaceuticals to file a New Drug Application ("NDA"). [n26] The NDA process requires manufacturers to prove that the new drugs are safe and effective before FDA approval. [n27] Preparing an application is a time-consuming and expensive process that must include studies of the drug's chemistry, manufacturing information, patents, and labeling. [n28] A brand-name company typically requires more than eight years to prepare an NDA and obtain FDA approval. [n29] After completing the NDA, a team of FDA toxicologists, physicians, chemists, and microbiologists review the application. [n30] The time and expense associated with gaining FDA approval provided little incentive for a generic drug producer, who had to "re-prove" what the brand-name drug companies had already established, to enter the market. [n31] Between 1962 and 1984, 150 drugs went off patent with no generic **[*103]** equivalent. [n32] As a result, the brand-name drug companies retained de facto control over the market long after their patent term expired. [n33] The lack of competition kept the cost of drugs to consumers high. [n34] Although prices remained high, brand-name companies were often required to file for the patent before conducting the required clinical trials necessary for FDA approval. [n35] As a result, the patent clock began ticking immediately and continued to run throughout the entire FDA approval process, which often took place after patent acquisition. [n36] Increasing the speed and time associated with bringing generics to market threatened brand-name manufacturers' ability to recoup research and development costs while they were awaiting pre-market FDA approval. [n37]

In addition, patent restrictions provided another disincentive for generic manufacturers to enter the market. In Roche Products, Inc. v. Bolar Pharmaceutical Co., the court held that a generic drug company could not test or begin the clinical trial process required for FDA approval until after the brand-name drug company's patent expired. [n38] As a result, there was nearly a two-year lag between a patent's expiration and the introduction of a generic equivalent. [n39] Accordingly, it became obvious that Congress needed to re-work the balance between assuring consumers access to cheaper generic pharmaceuticals and providing brand-name manufacturers' incentive to invest in new drug innovation through patent extensions. [n40]

B. Pharmaceutical Drugs in the Hatch-Waxman Act Era

Congress's resolution of these conflicting goals was the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Act ("Act"). [n41] The Act sought to strike a balance between brand-name

manufacturers' desire to bring new drugs to market with adequate **[*104]** patent protection and generic drug manufacturers' desire for an approval process enabling them to compete with the brand-name manufacturers. [n42] Congress addressed delays and uncertainties in the drug approval process for brand-name and generic drugs alike. [n43] To encourage brand-name manufacturers to continue to develop new drugs, the Act extended patents to compensate for time lost during the FDA approval process. [n44] As a result, the Act provided brand-name manufacturers patent extensions of up to five years with total exclusivity time not exceeding fourteen years. [n45] Additionally, the Act reflected a change in Congress's attitude towards generic drugs by creating a process to assist generic drugs enter the market faster. [n46]

Since the Act's passage in 1984, the pharmaceutical drug landscape has changed dramatically. At that time, generic drugs filled nineteen percent of prescriptions. [n47] Since the Act's enactment, generic drugs have tripled in drug volume. [n48] In addition, generic drug prescriptions now exceed brand-name drug prescriptions; nearly all of the top-selling drugs on the market with expired patents now have a generic counterpart. [n49] Finally, the number of companies providing generics has also expanded since the creation of the Act. [n50]

1. Generics - Abbreviated New Drug Applications

To enable generics to reach the market sooner, the Act made substantial changes to the FDA's process for approving generic drugs. First, the Act revised the applicability of patent law on generic drug formulations. The Act permits generic manufacturers to begin experiments on a brand-name drug prior to its patent expiration. [n51] In what is referred to as the "Bolar Exemption," [n52] Congress specifically defined a generic manufacturer's use of clinical information already in an NDA as a "non-infringing use" as long as the purpose is solely for obtaining FDA approval. [n53] As a result, this statutory exemption allows the generic to enter the market as soon as the brand-name **[*105]** patent expires. [n54]

The second major regulatory change allows generic drug manufacturers to file Abbreviated New Drug Applications ("ANDAs"), rather than the slow and cumbersome NDA, for FDA approval. [n55] This streamlined process allows generic manufacturers to "piggyback on proprietary safety and effectiveness data submitted by the innovator to obtain approval from the [FDA] for the pioneer drug." [n56] This change substantially relaxed the regulatory testing requirements for generics and thereby increased competition in the drug market. [n57] By avoiding the costly and time-consuming expense of generating safety and efficacy data, generic companies avoid sizable research and development costs. As a result, generic companies are able to market lower-cost alternatives to consumers. [n58]

2. The Generic Drug Approval Process

The generic drug development process begins by identifying a brand-name drug whose patent is due to expire within three to five years. [n59] Next, the generic drug company submits an ANDA to the FDA in accordance with the statutory criteria. [n60] These criteria require an ANDA to demonstrate that the generic drug is the bioequivalent to a previously approved drug now on the market. [n61] Specifically, the generic company must show that the drug specified in the ANDA is the same in terms of active ingredients, dosage form, strength, and route of administration. [n62] The generic manufacturer must also meet the same standards for manufacturing practices; it must produce a drug with the same identity, strength, quality, and purity as the approved brand-name manufacturer. [n63] In addition, the drug label must contain the same information as its brand-name counterpart. ANDA applications that satisfy the FDA's safety and efficiency requirements through bioequivalence studies are a **[*106]** fraction of the cost of a larger clinical study and allow generic drugs to reach the market considerably sooner than prior to the passage of the Act. [n64]

Congress created the bioequivalence requirement to ensure the FDA only approves a generic drug that is the therapeutic equivalent to its brand-name counterpart. [n65] These evaluations are contained in a book the FDA publishes annually entitled Approved Drug Products with Therapeutic Equivalence Evaluations, also commonly referred to as the "Orange Book." [n66] The FDA updates this book monthly and lists information for more than 6,000 approved drugs. [n67] The book also contains lists of generic products that have not had their bioequivalence established and are not

considered therapeutically equivalent. [n68]

Provided there are no challenges, the generic approval process takes between three to five years [n69] and costs substantially less than the NDA process. [n70] Once the FDA approves an ANDA, the generic drug company receives an exclusive 180-day period during which no other generic company can market a generic version of the drug. [n71]

When a generic manufacturer submits an ANDA, it must also certify one of the following for each generic drug listed in the Orange Book: (1) no such patent information has been submitted to the FDA; (2) its patent has expired; (3) the patent is set to expire on a certain date; or (4) the patent is invalid or will not be infringed by the manufacture, sale, or use of the generic drug for which the ANDA has been submitted. [n72] These are commonly referred to as Paragraph I, II, III, and IV certifications. [n73] The FDA oversees the first three certifications while the courts administer the fourth certification because it necessitates a determination of whether the generic drug infringes a validly patented drug. [n74] If a generic manufacturer asserts a Paragraph I or II certification, the FDA may automatically approve the application. [n75] If an ANDA application claims a Paragraph III certification, the FDA will not **[*107]** approve the generic drug's application until the brand-name drug's patent has expired. [n76]

3. Paragraph IV Certifications

To increase competition, the Act encourages generic manufacturers to challenge the validity of a brand-name drug's patent by filing a Paragraph IV certification. [n77] Under the Act, generic manufacturers who challenge an active patent must give notice to the brand-name patent holder within twenty days of filing. [n78] The notice must include the legal and factual grounds underlying the generic manufacturer's assertion that its drug does not infringe the patent or that the patent is not valid. [n79] Paragraph IV certifications are approved unless the patent holder files an infringement action in district court within forty-five days of receiving notice. [n80] If suit is filed, the generic application is automatically stayed for thirty months, unless one of the following events occurs first: (1) the patent expires; (2) the court renders a final determination of non-infringement; or (3) the court determines the patent is invalid. [n81] Any final court ruling within the thirty-month stay upholding a Paragraph IV certification will include the ANDA approval date. [n82] During the forty-five day period that the patent holder can file an infringement action, the ANDA applicant cannot file a declaratory judgment action regarding the patent issue. [n83]

The Act also provides that the first ANDA applicant to file a Paragraph IV certification receives a 180-day period of marketing exclusivity. [n84] As originally enacted, the Act required a generic manufacturer to successfully defend its Paragraph IV certification before being granted the 180-day exclusivity period. However, in 2007, Congress removed this requirement. [n85] Throughout the length of the exclusivity period, the FDA will not approve a subsequent generic's ANDA application for the same product. [n86] During this time, the only competition that the generic drug has is the higher-priced brand-name drug; thus, generics have a financial incentive in challenging the validity of listed patents. [n87]

4. Abuses of Governmental Processes

By striking a balance between the interests of the brand-name and generic drug makers, the Act intended to provide the best and most cost-efficient **[*108]** medicines for American consumers. [n88] In practice, however, brand-name drug manufacturers often manipulated provisions of the Act to artificially extend their monopolies. According to the Federal Trade Commission ("FTC"), brand-name manufacturers have exploited the Act and the governmental processes to the detriment of generic manufacturers and consumers. [n89] Though beyond the scope of this Article, some of these abuses include: (1) improper Orange Book listing of invalid patents; [n90] (2) filing patents late to secure a 30-month stay; [n91] (3) use of the 180-day exclusivity period to prevent generic marketing; [n92] (4) payments to generic manufacturers to postpone market entry of their approved drugs; [n93] and (5) obtaining exclusive licensing agreements related to a patent. [n94] Moreover, brand-name drug manufacturers also seek to exploit the Act, as well as the governmental processes, through the filing of "sham" citizen petitions with the FDA. To understand fully what makes this particular strategy so effective, a brief review of the constitutional origins of citizen petitions is necessary.

III. Citizen Petitions

In 1975, the Administrative Procedure Act ("APA") created the ability for citizens - including drug manufacturers - to petition the FDA. [n95] Congress's intent was to correct the absence of a form or procedure for individuals to exercise their First Amendment right to petition the government. [n96] The APA **[*109]** requires that every government agency provide the public with the right to petition for the issuance, amendment, or repeal of a rule. [n97] As applied to the FDA, it guarantees citizens the right to contact the agency to "issue, amend, or revoke" a regulation or order. [n98] As originally enacted, citizen petitions were designed to benefit the FDA and the public by giving individuals a formal means to influence FDA regulations on matters of health and safety. [n99]

From the outset, individuals used citizen petitions to contact the FDA regarding a broad spectrum of health and safety issues, ranging from a food trade association's request for exemptions from certain labeling requirements to a consumer group's request that the FDA increase regulation of tobacco. [n100] The 1984 passage of the Hatch-Waxman Act expanded the health and safety concerns of citizen petitions to include the ANDA generic drug process. [n101] For the first time, the public had a right to request that the FDA "issue, amend, or revoke" its standards for ANDAs. [n102]

The dual responsibilities of the FDA to approve ANDAs and review citizen petitions create a two-tier opportunity for brand-name manufacturers to delay the introduction of a generic drug into the market through an abuse of governmental processes. The First Amendment protections inherent in a citizen petition provide brand-name manufacturers an effective vehicle to challenge a generic drug with virtual impunity. Furthermore, the combination of FDA regulations, procedures, and limited Agency resources create an opportunity for brand-name manufactures to file baseless claims that effectively halt an ANDA approval mid-stream. When generic manufacturers challenge this anti-competitive tactic in court, brand-name manufacturers may avail themselves of the protection through the Noerr-Pennington doctrine. [n103] The following section outlines how this process operates.

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A. Scope of the Citizen Petition

1. The FDA's Citizen Petition Process

Filing a citizen petition is the first administrative step toward resolving a health and safety concern with the FDA. [n104] Petitions must state the action requested, the grounds upon which its rests, and the environmental impact of the request. [n105] In addition, the petitioner must submit all data, information, and views that form the basis of the petition. [n106] To ensure a balanced and reasonable presentation, citizen petitions must also include a representative set of any unfavorable data. [n107]

Citizens are permitted to submit petitions at any time. [n108] Interestingly, however, the FDA reports an increasing number of citizen petitions filed by brand-name manufacturers regarding "health and safety" concerns about a pending generic's ANDA on the eve of their product's patent expiration. [n109] Due to the sharp increase in the number of petition filings and the FDA's limited staff, review of a citizen petition routinely takes six months or longer. [n110] Until recently, the FDA automatically suspended ANDA approval until all the issues in a citizen petition were resolved. [n111]

After receipt of a citizen petition, the FDA categorizes the petition by whether it raises scientific or legal concerns. [n112] Citizen petitions raising scientific issues generally challenge the bioequivalence standards. [n113] Petitions citing legal concerns typically question the ANDA approval process itself, the fundamental requirements for a generic drug patent certification and ANDA applicants, and areas of exclusivity. [n114] The petition's subject matter, availability of agency resources, and statutory time requirements determine the priority of the FDA's response to the petition. [n115]

[*111] Following the classification of the petition, the FDA can approve a citizen petition, [n116] deny the petition, [n117] or provide a tentative response indicating why the Agency has been unable to reach a decision on the petition

within the required 180-day response period. [n118] If the FDA denies the citizen petition, or does not respond in a timely manner, the petitioner can file a lawsuit seeking both preliminary and permanent injunctive relief against the Agency. [n119]

B. The First Benefit of Filing Sham Petitions: "Delayed Generic Competition"

There has been long-standing concern over the FDA's administration of its citizen petition review process. [n120] In 1999, the Agency issued a proposed rule to address questions that had "arisen [regarding] whether a citizen petition can be used for improper purposes such as delaying competition ... or delaying agency action." [n121] In particular, the Agency acknowledged growing concerns regarding "generic blocking petitions." [n122] The proposed rule identified several options to reduce backlog, address frivolous petitions, and protect the integrity of the process. [n123] Four years later, however, the Agency withdrew the proposed rule and announced "revision of the citizen petition regulations is not warranted at this time." [n124]

The FDA's decision not to reform its petition process had a significant impact on the changing pharmaceutical industry and the Agency's effectiveness. The advent of the streamlined generic drug approval process and the expiration of brand-name drug patents increased the number of ANDAs; correspondingly, the number of citizen petitions the FDA received has also increased. [n125] For example, during the five-year period between 2001 and 2006, the number of ANDAs submitted to the FDA's Office of Generic **[*112]** Drugs increased by 150%. [n126] During roughly the same period, the number of citizen petitions received by the FDA nearly doubled. [n127] By 2006, ANDAs were the subject of approximately one-third of all citizen petitions filed with the FDA. [n128] Consequently, by 2008, the steady trend of increased ANDA submissions resulted in a backlog of more than 1,300 petitions awaiting review. [n129]

Echoing the concerns expressed five years prior, the FDA indicated that numerous petitions were of dubious merit and appeared to be nothing more than attempts by brand-name manufacturers to exploit the Agency's processes and artificially extend their drug's market exclusivity. [n130] As noted by former FDA Chief Counsel Sheldon Bradshaw, a number of the petitions filed were "designed not to raise timely concerns with respect to legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the Agency to review arguments that could have been made months before." [n131] For example, between 2003 and 2006, the FDA ruled on twenty-one citizen petitions. [n132] The Agency determined that all but one of the petitions lacked merit. [n133] Moreover, ten of those filings were identified as "eleventh hour petitions" - submitted within six months of the anticipated entry date of the generic drug. [n134] None of the "eleventh-hour petitions" raised a meritorious health or safety concern. [n135] Between 2001 and 2005, the FDA dismissed seventy-eight percent of the petitions it reviewed for lack of merit. [n136]

In 2007, in response to these abuses, Congress amended the FDCA to limit the adverse impact of citizen petitions on the generic drugs. [n137] The Food and Drug Administration Amendments Act ("FDAAA") requires the FDA to **[*113]** resolve citizen petitions within six months of receipt. [n138] Furthermore, the Agency will not delay approval of an ANDA because of a citizen petition unless the delay is necessary to protect the public health. [n139] If the FDA decides to stay an ANDA, the Agency must notify the applicant within thirty days of that determination. [n140] In addition, the regulations require all citizen petitions be signed and contain attestations that all relevant information is included. [n141] Moreover, the regulations include a provision specifically addressing delaying or blocking petitions. [n142] A petition that is submitted for the primary purpose of delaying an ANDA, and on its face raises no valid regulatory or scientific issues, can be denied by the Agency at any time. [n143]

In 2008, a bipartisan group of legislators from both the U.S. House of Representatives and Senate expressed concerns that, notwithstanding the new regulations, abuses continued because the FDA was not aggressively implementing the new law. [n144] Following these statements, the FDA issued a Draft Guidance for Industry Citizen Petitions and Petitions for Stay of Action Subject to 505(q) of the Food, Drug and Cosmetic Act. [n145] While not binding, the draft guidance expounds on current Agency thinking and illustrates how it intends to implement the citizen petition reforms. [n146] Nevertheless, two recent cases make clear, despite regulatory reforms and the recent Agency guidance, abuses of the FDA's regulatory procedures continue to take place and are tolerated.

In In re Wellbutrin XL Antitrust Litigation, Anchen Pharmaceuticals ("Anchen") and other drug wholesalers filed a class action lawsuit against pharmaceutical manufacturers GlaxoSmithKline ("GSK") and Biovail Corporation ("Biovail"). [n147] In the complaint, Anchen alleged that GSK and Biovail conspired to improperly delay the sale of generic versions of the brand-name antidepressant Wellbutrin XL by filing a sham citizen petition with the FDA. [n148] In November 2005, the FDA approved Anchen's ANDA for a generic version of Wellbutrin XL. [n149] Approximately one month later, Biovail filed a citizen petition with the FDA requesting that all ANDA applications include **[*114]** additional bioequivalence studies - a request that was contrary to the Hatch-Waxman Amendments and the FDA's protocols. [n150] It took the FDA more than a year to rule on, and subsequently deny, GSK and Biovail's citizen petitions. [n151] During the FDA's review period, annual sales of Wellbutrin XL exceeded $ 450 million that year. [n152] Additionally, because of ongoing patent infringement litigation, Anchen was not able to manufacture or market its product. [n153] Every month the FDA spent reviewing Biovail's meritless petition, generic products were denied market entry; as a result, Biovail and GSK earned more than a billion dollars in revenues from consumers and direct purchasers. [n154]

At issue in Roxane Laboratories v. GlaxoSmithKline, currently awaiting trial in a Pennsylvania federal district court, are a series of citizen petitions GSK submitted to the FDA. [n155] In 2004, as the end of GSK's exclusivity period for Flonase approached, GSK filed four successive citizen petitions. [n156] These petitions requested that the FDA establish a complete methodology for Flonase before approving an ANDA. [n157] In denying this request, the Agency noted that neither the Food, Drug & Cosmetic Act nor regulation requires the FDA to issue final guidance before approving an ANDA. [n158] In addition, the FDA noted that GSK failed to provide any authority for its request. [n159]

In GSK's motion to stay, it argued once generics are approved for marketing "the balance of equities" shifts to GSK's detriment. [n160] The FDA found this justification to be unpersuasive and denied the motion to stay. It concluded that the policies of the Hatch-Waxman Act dictate that GSK "not be permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved under section 505(j) of the Act." [n161] Although GSK's claim lacked merit, the filing of a citizen petition, and subsequent FDA review, successfully delayed generics from entering the market for two years. [n162]

These two recent cases raise questions as to whether the recently enacted **[*115]** FDAAA will prevent brand-name manufacturers from improperly delaying generics from entering the market. As indicated in the 2009 FDAAA Implementation - Highlights Two Year Implementation, the Agency acknowledged that it failed to respond to all citizen petitions for that year within the regulatory timeframe. [n163] In addition, neither the draft guidance nor the new regulations contain provisions to address repetitive filings such as those at issues in In re Wellbutrin XL Litigation, misrepresentations, or petitions containing fraudulent claims. Thus far, the FDA has not defined what criteria it uses to determine "intent to delay" petitions. [n164] Moreover, the FDA has indicated that its failure to respond to a citizen petition within the required 180 days is not a petition denial, but rather constitutes a "final agency action." [n165] The regulations, however, fail to clarify what ramification this has on challenging such a "final agency action." [n166] In addition, the regulations fail to specify the types of serious health or safety concerns that would require staying an ANDA. [n167] Finally, the regulations and draft guidance fail to detail sanctions or penalties for submitting meritless or fraudulent petitions. As a result, filing sham petitions remains a relatively low-cost and risk-free strategy for brand-name manufacturers to retain their market share.

IV. The Second Benefit of Filing Sham Petitions: "Antitrust Immunity"

The filing of baseless petitions operates to eliminate competition and appears to fall within the conduct prohibited by the Sherman Antitrust Act. [n168] However, courts have historically provided little relief to manufacturers attempting to protect their pending generic drug applications against delays caused by meritless citizen petitions. Courts have generally held that filing these petitions is per se legal under the three Supreme Court cases that are credited with establishing the Noerr-Pennington doctrine. [n169] This doctrine **[*116]** provides immunity for conduct aimed at persuading the government of a position, even if the conduct interferes with competition in the market; "such conduct is classic petitioning activity protected by the First Amendment and such actions may not be limited by the Sherman Act."

[n170] However, this immunity is not absolute. This section introduces the origins of the doctrine, describes some of the difficulties encountered by lower courts in applying the doctrine's sham exception corollary, and addresses the shortcomings of current approaches to the doctrine.

A. The Noerr-Pennington Doctrine

In Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., the Supreme Court held that liability under the Sherman Act cannot be premised on activities comprising of "mere solicitation of governmental action with respect to the passage and enforcement of laws." [n171] In Noerr, a group of Pennsylvanian trucking companies alleged that several railroads and their public relations firms conspired to conduct a negative public relations campaign encouraging the passage of laws destructive to the trucking business and damaging to the existing relationship between the truckers and their customers. [n172]

The Supreme Court held that these claims failed to state a cause of action for the following two reasons. First, the Sherman Act does not regulate political activity nor infringe on the concept of representation. [n173] Second, the Court determined that holding against the railroads "would raise important constitutional questions" about the right to petition the government. [n174] The Court emphasized that groups with a significant stake in the passage of certain legislation often provide important information to Congress about issues in question. [n175] Whether the intent behind the petition was unethical or to harm competitors was irrelevant to the Court:

The right of the people to inform their representatives in government of their desires with respect to the passage or enforcement of laws cannot properly be made to depend upon their intent in doing so. It is neither unusual nor illegal for people to seek action in the hope that they may bring about an advantage to themselves and a **[*117]** disadvantage to their competitors. [n176]

Furthermore, the Court laid the foundation for what is the only widely recognized exception to Noerr-Pennington immunity - the sham exception. [n177] The Court noted there may be petition activity that, although "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." [n178] The Court explained that in such situations, application of antitrust laws would be appropriate. [n179]

Four years later, in the second of the Noerr-Pennington trilogy, the Supreme Court extended the Noerr protection beyond the legislative arena. In United Mineworkers of American v. Pennington, the Court held that persuasive efforts directed at executive officials or governmental agencies are also immune from antitrust liability. [n180] In Pennington, a miners' union and a group of large industry mines petitioned the Secretary of Labor and a federal agency to raise the minimum wage. [n181] The effect of the wage increase would squeeze out smaller firms that sold coal on the spot market. [n182] Reiterating that the party's intent under Noerr analysis is irrelevant, the Court held that "joint efforts to influence public officials do not violate antitrust laws even though intended to eliminate competition." [n183]

The Court rounded out the applicability of the doctrine in California Motor Transport Co. v. Trucking Unlimited by extending the doctrine to courts and administrative agencies. [n184] Additionally, the Court clarified that the immunity afforded by the doctrine is grounded in the constitutional right to petition the government for redress of grievances. [n185] Finally, the Court elaborated on Pennington's dicta concerning the sham petitioning. [n186]

In California Motor, a group of highway carriers alleged an antitrust conspiracy by a group of interstate carriers to institute state and federal proceedings, "with and without probable cause, and regardless of the merits of the cases" [n187] to defeat applications by the in-state carriers to acquire operating rights. [n188] The Court found this type of conduct to fall under the sham **[*118]** exception, rendering the Noerr-Pennington defense inapplicable. [n189] The Court determined "that a pattern of baseless, repetitive claims may emerge which leads a fact finder to conclude that the administrative

and judicial processes have been abused ... effectively barring respondents from access to agencies and courts." n190

The Court differentiated the exception's application in political and non-political arenas. n191 The Court reasoned that while unethical conduct in political contexts is traditionally protected, "there are many ... forms of illegal and reprehensible practice which may corrupt the administrative or judicial processes and which may result in antitrust violations. Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." n192

Because of the Court's distinction, it created two separate rules to determine the applicability of the sham exception. n193 For political matters, the sham exception applies to petitioning activity "not genuinely aimed at procuring favorable governmental action." n194 Furthermore, successfully influencing the legislature will never be considered a sham. n195 While the Court did not specify the precise parameters of the sham exception, it did identify several activities that might qualify. n196 It was not until more than thirty years later that the Supreme Court defined the test for the sham doctrine in the nonpolitical realm. n197

[*119]

B. Sham Exception

In Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., ("PRE") the Court outlined a two-part test to determine when litigation will be deemed a sham; thus, losing Noerr-Pennington immunity. n198 First, the court must determine whether the lawsuit is objectively baseless in the sense that "no reasonable litigant could realistically expect success on the merits." n199 If the lawsuit is "reasonably calculated to elicit a favorable outcome," the suit is immunized under the doctrine. n200 Second, the court must consider the "litigant's subjective motivation." n201 A lawsuit satisfies this inquiry if it "conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process - as opposed to the outcome of that process - as an anticompetitive weapon." n202

While the Court sets forth a two-part sham litigation test, the majority's articulation of the objectively baseless component is faulted as being unclear. n203 The majority first defined an objectively baseless petition as one that "no reasonable litigant could realistically expect success on the merits." n204 Later in the opinion, Justice Thomas likens an objectively baseless petition to a lawsuit "without probable cause in the malicious prosecution sense." n205 In another part of the opinion, the Court refers to the language in Federal Rule of Civil Procedure Rule 11 to define the standard. n206 In his concurring opinion, Justice Souter points out the inherent confusion contained in the majority's opinion noting that whether "probable cause" exists is a different inquiry than whether a reasonable litigant could realistically expect success on the merits. n207 **[*120]** Justice Stevens and Justice O'Connor also take issue with sections of the majority opinion for its "unnecessarily broad dicta." n208 Writing separately, they maintain "objectively baseless" should mean "objectively unreasonable." n209

One can draw a strong inference from these concurring opinions that the sham exception is unnecessarily restricted when the majority equates objectively baseless with a lack of probable cause. n210 Probable cause is a lesser standard than no reasonable expectation of success. Applying the Court's current objectively baseless test allows brand-name manufacturer to present a sufficiently weak citizen petition with no reasonable expectation of success, yet not so devoid of merit as to lack probable cause. Unless and until the Court corrects this standard, brand-name drug manufactures will continue to file baseless citizen petitions thereby protecting their patents and profits.

Because the Court refused to address how fraud or misrepresentation factored into the application of the sham exception, the Court created another problem. Unlike California Motor, which implied that fraud could render the doctrine inapplicable, in PRE, the Court stated, "[it] need not decide whether and, if so, to what extent Noerr-Pennington permits the imposition of antitrust liability for a litigant's fraud or misrepresentation." n211

Before the Court's decision in PRE, the lower courts were uniform in their application of the sham doctrine and stripped Noerr-Pennington immunity from plaintiffs who made misrepresentations in non-political forums. [n212] However, the Court, in PRE, called the rationale of these opinions into question. As a result, the courts' and administrative agencies' treatment of misrepresentation factors is now inconsistent. For example, the Ninth Circuit recognizes intentional misrepresentations as a subset of the sham doctrine when two criteria have been satisfied. First, the misrepresentations must occur in the adjudicatory setting; second, they must "deprive the litigation of its legitimacy." [n213] The Third Circuit has refused to recognize a distinct misrepresentation exception to the Noerr-Pennington doctrine, but does treat **[*121]** misrepresentation as a permutation of sham and applies a modified PRE test. [n214] The courts in this circuit inquire whether a petition is objectively baseless "without regard to those facts that [were alleged to be] misrepresented." [n215] If the court determines that the misrepresentations "did not infect the core of the [petitioner's] claim and the government's resulting actions," the petition is not objectively baseless and the sham exception will not apply. [n216] Additionally, the FTC recognizes that statements lose Noerr-Pennington immunity outside the political arena provided they are misrepresentations or omissions that are (1) deliberate (not a mere error); (2) subject to factual verification; and (3) central to the outcome of the proceeding or case. [n217]

The Supreme Court's decision in PRE has resulted in an inconsistent application of the sham exception's objectively baseless test. Consequently, generic manufacturers have only been granted sporadic judicial relief when pursuing Section 2 Sherman violations. However, a federal district court case - Louisiana Wholesale Drug Co. v. Sanofi-Aventis - indicates that perhaps the courts can change their interpretation of antitrust violations. [n218]

C. What Should Have Been a Light at the End of the Tunnel ...

In Louisiana Wholesale Drug Co. v. Sanofi-Aventis, the Court denied Louisiana Wholesale Drug Company's ("LWD") motion for a new trial after a jury concluded that Aventis Pharmaceutical's ("Aventis") citizen petition was not "objectively baseless" and thus did not violate the Sherman Antitrust Act. [n219] Aventis had five-and-a-half years of exclusive marketing rights for the drug Arava in 10-milligram, 20-milligram, and 100-milligram strengths. [n220] On March 10, 2004, the day Aventis patent expired, several generic wholesalers submitted ANDAs to the FDA seeking approval to market and sell the generic equivalents of Arava. [n221] One year into the Agency's review of the ANDAs, and on the eve of generic approval, Aventis filed a citizen petition with the FDA. [n222]

Aventis's petition raised bioequivalence and safety concerns. [n223] Specifically, Aventis requested the FDA withhold final approval of any applicant's ANDA that did not seek approval of a 100-miligram leflunomide **[*122]** tablet that was the bioequivalent to the Arava 100-milligram tablet or that failed to perform bioequivalence testing to confirm that five of its 20-milligram tablets were bioequivalent to one 100-milligram tablet. [n224] The petition also requested that an applicant failing to establish either of the above not be permitted either (1) to label its product to permit the use of five 20-milligram tablets as an alternative to the 100-milligram or (2) to reference a 100-milligram tablet that the generic did not manufacture. [n225] The FDA denied the petition six months later and approved the ANDAs the same day. [n226] In denying the petition, the FDA noted that the requested relief appeared to be "based on a false premise" and was not supported by the FDCA or regulations. [n227] Following the denial, LWD filed suit on August 17, 2007, alleging that the citizen petition by Aventis was objectively baseless and was submitted for the purpose of delaying generic competition. [n228] Aventis moved to dismiss the suit claiming Noerr-Pennington immunity. [n229]

In denying the defendant's motion, the court relied on California Motors to distill the issue. [n230] It stated, "the relevant issue is whether the legal challenges are brought pursuant to a policy of starting legal proceedings without regard for the merits [but rather] for the purpose of injuring a market rival." [n231] The court relied on precedent that held meritless petitions filed to impose delay and expense on a rival will subject a defendant to antitrust liability. [n232] The court went on to describe objectively baseless actions as "administrative or legal actions that do not request reasonable extensions or development of the law, as well as mischaracterization of the relevant issues or legal standards." [n233] The court held that Aventis' petition would lose Noerr-Pennington immunity "if it had no reasonable chance of success and was directed at harming the generic manufacturer's interest in some manner distinct from preventing any potential improper labeling of the generic **[*123]** leflunomide." [n234]

LWD alleged that the health and safety concerns raised by Aventis were a sham intended to delay the entry and approval of alternative generic drugs from entering the market. [n235] The FDA record showed that the primary concern raised in Aventis's citizen petition was that the ANDAs violated labeling regulations. [n236] Specifically, Aventis alleged that these applicants planned to cross-refer to other brands and strengths when they themselves did not manufacture either the drug or strength indicated. [n237] The FDA denied the petition in part because Aventis itself had used such cross-references in similar circumstances. [n238] In evaluating Aventis's motion to dismiss, the court noted, in addition to the FDA findings, that the petition did not raise any new health or safety issues or identify any new FDA regulations on labeling. [n239] The court found such deficiencies sufficient at the pleading stage to satisfy the sham exception and prevent dismissal of LWD's lawsuit. [n240] In elaborating on its sham exception analysis, the court determined Aventis was a sophisticated pharmaceutical manufacturer familiar with FDA regulations and practices. [n241] Thus, issues of fact existed concerning whether Aventis's petition was viable. [n242]

The court reiterated this reasoning when it denied Aventis' motion for summary judgment. [n243] The district court noted in its opinion an FDA letter detailing how each of Aventis' three requests for relief contradicted FDA regulations and practice. [n244] The court concluded that the record suggested Aventis was fully aware that neither law nor practice supported its claims. [n245] As a result, the court held that genuine issues of material fact existed regarding Aventis' objective basis for filing its petition and a trial on the merits was necessary. [n246]

At a trial, the jury was instructed that the objectively baseless determination turned on whether "a reasonable pharmaceutical manufacturer could have realistically expected the FDA to grant the relief sought by Sanofi- **[*124]** Aventis in the citizen petition." [n247] Applying this standard, the jury returned a verdict in favor of Aventis. [n248] Following the verdict, LWD filed a motion for judgment as a matter of law, or, in the alternative, for a new trial. [n249]

The court denied both motions. [n250] In denying LWD's request for a new trial, the court reviewed the jury's application of the sham exception to Aventis' conduct. [n251] Under the PRE inquiry, the jury was charged with determining whether Aventis had probable cause to institute legal proceedings. [n252] The court noted that probable cause included "actions arguably warranted by existing law" and that "even in the absence of supporting authority" a litigant is "entitled to press a novel claim so long as a reasonable litigant could have perceived some likelihood of success." [n253] The court could not find that the jury's conclusions were either "seriously erroneous" or the resulting verdict "a miscarriage of justice" sufficient to warrant a new trial. [n254]

V. The Right Prescription

The Louisiana Wholesale case illustrates the limitations of the judicial system's ability to adjudicate sham petition claims. These limitations range from a conflicting "objectively baseless" standard to a jury's ability to parse through the data substantiating legitimate health and safety concerns. So long as bad-faith actors can misuse the approval process for generic drugs, these actors have the power to hinder competition and reduce consumer access to lower-cost substitutes. As noted by Judge Robert Bork, "the modern profusion of ... government authorities offers almost limitless possibilities for abuse." [n255] He warns "predation by abuse of governmental procedures ... presents an increasingly dangerous threat to competition," [n256] and sham litigation is a particularly effective method of predation. [n257] Even when petitions are unsuccessful, they can inflict substantial costs on a competitor and delay that competitor's entry into the market. [n258] The following section makes a series of recommendations to safeguard the process and to assure the availability of lower-cost bioequivalent drugs.

[*125]

A. Two Parts Regulatory

Regulatory reforms are necessary to safeguard the citizen petition process. [n259] First, the Agency should define what constitutes a delaying petition. Second, the FDA should automatically dismiss serial petitions and petitions based on fraud or misrepresentations. Third, the FDA should classify petitions dismissed under these categories as "objectively

baseless." If the FDA has determined a petition is objectively baseless, courts should accept that determination and hold that the objectively baseless element of the sham exception test is satisfied.

Abusing government processes will continue so long as there is no penalty for engaging in this type of conduct. The FDA could discourage the most rampant abuse of sham petitions by exercising its discretion to refer unsuccessful citizen petitions to the FTC or Department of Justice. The Citizen Petition Fairness and Accuracy Act of 2006 would have given the Department of Health and Human Services the power to sanction those who abuse the citizen petition process. [n260] Possible sanctions would have included a fine of up to $ 1 million, a suspension or permanent revocation of the right of the violator to file future citizen petitions, and a dismissal of the petition. [n261] However, there was not sufficient support in Congress to pass this legislation. [n262] Congress should refer to this legislation for guidance in drafting a new bill to protect the citizen petition process from abuse.

Another area that must be improved is the adherence to the 180-day regulatory review requirement. Divorcing the ANDA approval process from the review process of citizen petitions has improved efficiency, but more must be done. In 2009, the FDA still did not complete all citizen petition reviews within the required 180 days. [n263] Stricter agency adherence to the regulatory time frames would increase efficiency and decrease brand-name manufacturers' ability to benefit from unofficial patent extensions due to the delay incurred during the FDA review process. Additionally, the FDA should seek to improve the speed of its internal review process. Rather than the current system of consecutive reviews by legal and scientific experts, the Agency should route a petition based on an initial determination as to whether it raised valid legal or scientific concerns. [n264] If the petition raised both valid legal and scientific issues, the FDA could forward the petition to the appropriate legal and scientific offices simultaneously to allow for parallel **[*126]** review of the concerns. [n265]

The FDA could make an additional regulatory improvement by imposing a time frame for citizen petition submissions. Similar to the predefined comment period for citizens to respond to a proposed FDA rule, [n266] citizens should be given a defined forty-five day comment period to raise health and safety concerns in response to ANDA applications. This would avoid eleventh-hour petitions and enable the FDA to rule in time for an approved generic to go to market without an unjust delay. These regulatory reforms would decrease the incentives for brand-name companies to submit sham petitions and help to safeguard the citizen petition process.

B. One Part Adjudicatory

A judicial approach to safeguarding the citizen petition process requires a blend of judicial deference and reformation of the PRE sham exception. Historically, courts afford deference to administrative agencies when interpreting congressional statutes. [n267] The Supreme Court has held that agency actions are presumed valid and a plaintiff seeking to overcome that presumption has the burden of establishing invalidity. [n268]

This deference extends to an agency's ability to formulate its own procedures. Agencies have broad discretion in defining and applying rules for public participation in agency matters. [n269] The Supreme Court requires courts to refrain from setting administrative agency procedures - even in cases when a proposed regulation would alter rights and obligations critical to the general public. [n270] Courts defer entirely to the agency determination as to what procedures are needed. [n271] Thus, the FDA has broad authority to create and enforce its rules. This authority is rooted in the belief that federal agencies are best suited to address the public's needs. [n272] Similar to the broad deference courts afford the FDA in establishing procedures for public involvement, federal courts generally defer to the FDA in lawsuits concerning scientific methodology for approving generic competitors. [n273] Given the FDA's **[*127]** expertise, that deference is justified.

Judicial deference extends to review of an agency's factual determinations as well. The Administrative Procedures Act requires courts to uphold factual determinations rendered in an informal proceeding unless they are "arbitrary, capricious, [or] an abuse of discretion" and in a formal proceeding, findings are reviewed under a "substantial evidence" standard. [n274] Pursuant to FDA regulations, citizen petition determinations, including "delaying petition" designations,

are final agency actions. Neither the regulations nor the industry guidance identifies the standard of review for "delaying petitions." Moreover, there is no set formant for the citizen petition review process. The FDA commissioner may use several different procedures in reviewing the petition including hearings, conferences, or any other applicable public procedure identified by the FDA. [n275] As a result, this process is analogous to an informal proceeding. As such, courts should review the Agency delaying determinations under the more deferential standard.

Under the new regulations, the FDA makes the determination regarding whether a citizen petition qualifies as a "delaying petition." [n276] As proposed in the previous section, the FDA should clarify that it bases this determination not only on the absence of a valid scientific or legal claim, but also on a determination of the claim's reasonableness. If a court finds that the FDA's determination was not arbitrary and capricious, then the Agency's determination should be admissible as satisfying the PRE's sham exception. The delaying petition designation could safeguard the integrity of the process by allowing the FDA to apply the "delaying petition" designation to claims that, on their face, raise a valid legal or scientific concern, but after analysis were found to be shams. This application could be especially relevant in analyzing claims that include fraudulent or misleading concerns.

If the Agency declines to adopt such an expansive application of the delaying petition provision, strengthening the deference courts afford to FDA determinations provides another mechanism to protect the integrity of the citizen petition process. The evaluation of citizen petitions that raise ANDA health and safety concerns involves a rigorous analysis of the scientific and legal claims by FDA staff. [n277] Based on their determinations, the FDA decides whether the claim has merit and warrants Agency action. [n278] During the citizen petition review process, parties can submit additional information and amend **[*128]** their responses. [n279] Courts, at a minimum, should uphold Agency findings of fact unless they are "unsupported by substantial evidence." [n280] In subsequent antitrust lawsuits, proper deference to these FDA finding could be determinative; as a result, the first prong of the sham exception - the objectively baseless requirement - would be satisfied.

The PRE standard for sham exceptions has been the subject of much scholarly ferment. [n281] It is unlikely that the debate regarding the appropriateness of the exception's requirements will be resolved in the near future. This Article supports the conclusion of other critics: the second prong of the test - establishing subjective intent to interfere with the business interests of a competitor - is redundant and should be eliminated. [n282] In the alternative, this Article proposes a compromise. Arguably, in rendering delaying petition determinations, the FDA may not analyze the petitioner's subjective intent to harm competition with the same scrutiny as required by PRE. In those cases, it may be appropriate for juries to make those factual determinations. As to the first prong, however, the FDA's evaluation of the petition is rigorous enough to determine the meaning of "objectively baseless" under either permutation of the standard. Moreover, given the Agency's knowledge of the pharmaceutical industry and the ANDA process, a strong argument exists that the Agency, rather than a jury, is in a better position to make either determination.

The history of judicial deference afforded to administrative agencies, and the recently enacted FDA regulations, provide the foundation for a new approach to prevent brand-name manufacturers from abusing government processes. As noted above, the PRE sham exception has thus far proven to be an ineffective tool to curb that type of conduct. To recast the parameters of the Noerr-Pennington doctrine and its sham exception and police bad-faith brand-name manufacturers would require a re-balancing of the First Amendment and Sherman Antitrust Act. History shows the Supreme Court is unlikely to take on such a task. Instead, this Article suggests an approach that builds on existing FDA reforms and capitalizes on the relationship between the FDA and the court to safeguard the citizen process without having to wage that formidable legal battle.

Legal Topics:

For related research and practice materials, see the following legal topics:
Patent LawClaims & SpecificationsEnablement RequirementGeneral OverviewPatent LawInequitable ConductGeneral OverviewPatent LawInfringement ActionsDefensesExperimental Use & Testing

FOOTNOTES:

n1. Patent Terms Extended Under 35 U.S.C. § 156, U.S. Patent and Trademark Office, http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html.

n2. Martha M. Rumore, The Hatch-Waxman Act 25 Years Later: Keeping the Pharmaceutical Scale Balanced, Pharmacytimes.com, http://www.pharmacytimes.com/supplement/pharmacy/2009/GenericSupplement0809/Generic-HatchWaxman-0809 (last visited Sept. 1, 2010).

n3. Facts at a Glance, Generic Pharmaceutical Ass'n, http://www.gphaonline.org/about-gpha/about-generics/facts, (last visited Sept. 25, 2010) (citing the National Association of Chain Drug Stores for the proposition that in 2007, the average retail price of a generic drug prescription was $ 34.34 while the brand name prescription drug was $ 119.51).

n4. See generally Mark D. Whitener, Competition and Antitrust Enforcement in the Changing Pharmaceutical Marketplace, 50 Food & Drug L.J. 301, 307 (1995) (noting the FTC has recognized that pharmaceutical companies are abusing judicial and government process to harm competition).

n5. Pharmaceutical Marketplace Reform: Is Competition the Right Prescription?: Hearing Before the Senate Special Comm. on Aging, 103d Cong. 123 (1993) (statement of Mark D. Whitener, Acting Deputy Director, Bureau of Competition, Federal Trade Commission).

n6. Fed. Trade Comm'n, Enforcement Perspective on the Noerr-Pennington Doctrine: An FTC Staff Report (2006) [hereinafter FTC Staff Report].

n7. The Noerr-Pennington doctrine is grounded in three Supreme Court cases: E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965); Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508 (1972).

n8. Sherman Antitrust Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§1-7 (1988) (prohibiting contracts and conspiracies in restraint of trade as well as efforts to monopolize trade). See id. §§1-2 (2006); FTC Staff Report, supra note 6, at 3, 6.

n9. Noerr, 365 U.S. at 137-38.

n10. Id. at 144.

n11. Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at 21 U.S.C. § 355 (Supp II. 2008)).

n12. Id.

n13. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat 1585. (codified as amended in relevant part at 21 U.S.C. § 355 (2006); 35 U.S.C. § 271 (2006)).

n14. Wendy H. Schacht & John R. Thomas, Cong. Research Serv., IB 10105, The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents 2 (2004).

n15. See Administrative Procedure Act, 5 U.S.C. § 553(e) (2006).

n16. E. R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965); Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508 (1972).

n17. Prof'l Real Estate Investors, Inc., v. Columbia Pictures Indus., Inc., 508 U.S. 49, 61 (1993).

n18. See, e.g., In re Wellbutrin XL Antitrust Litig., No. 08-2431, 2009 U.S. Dist. LEXIS 21286 (E.D. Pa. Mar. 13, 2009).

n19. La. Wholesale Drug Co. v. Sanofi-Aventis, 07 Civ. 7343 (HB), 2009 U.S. Dist. LEXIS 77206 (S.D.N.Y. Aug. 28, 2009).

n20. Press Release, Fougera.com, New Study on Generic Drug Savings is Proof that Industry is Critical to Reducing Nation's and Consumers' Health Care (May 7, 2009), http://www.fougera.com/news/release_detail.asp?id=1056 (estimating generic drugs have saved consumers and health care providers $ 734 billion over the past 10 years (1999 through 2008)).

n21. Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (1998) [hereinafter CBO Report]; Fed. Trade Comm"n., Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry (May 2, 2007).

n22. FDA Facts and Myths about Generic Drugs, U.S. Food & Drug Admin., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (last updated Oct. 13, 2009).

n23. See id.

n24. Rebecca S. Yoshitani & Ellen S. Cooper, Pharmaceutical Reformulation: The Growth of Life Cycle Management, 7 Hous. J. Health L. & Pol'y 379, 379-80 (2007).

n25. Marina Lao, Reforming the Noerr-Pennington Antitrust Immunity Doctrine, 55 Rutgers L. Rev. 965, 992-93 (2003).

n26. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.); Kristin E. Behrendt, The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?, 57 Food & Drug, L.J. 247, 249 (2002) (noting

that prior to 1962, the FDA required that drugs be approved for safety only. The Agency approved generic versions of pre-1962 drugs based on paper new drug applications containing scientific or medical research that demonstrated the drug's safety).

n27. Behrendt, supra note 26, at 249.

n28. Yoshitani & Cooper, supra note 24, at 382.

n29. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 864 (Fed. Cir. 1984) (emphasizing "it now can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements"). See also Yoshitani & Cooper, supra note 24, at 382.

n30. Id.

n31. Barbara J. Williams, A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry, 40 New Eng. L. Rev. 2 (2005); Fed. Trade Comm'n., Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002) [hereinafter FTC Study] ("Those seeking to market a generic version of an existing post 1962 brand-name drug had to perform their own safety and efficiency studies, much like the brand-name companies had to demonstrate the safety and efficiency of the brand-name drugs.").

n32. Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 Food & Drug L.J.187, 188 (1999).

n33. Pamela J. Clements, The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law, 48 IDEA 381, 387 (2008).

n34. FTC Study, supra note 31, at 9.

n35. Clements, supra note 33, at 386.

n36. Williams, supra note 31, at 3.

n37. See id.

n38. See Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984). In finding for Roche, the Federal Circuit held that "Bolar's intended "experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strict philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement ... ." Id. at 863.

n39. Id. at 864.

n40. See Glaxo, Inc. v. Novopharm, Ltd., 220 F.3d 1562, 1568 (Fed. Cir. 1997) (quoting H.R. Rep. No. 98-857, pt.1 at 14-15 (1984)).

n41. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat 1585. (codified as amended in relevant part at 21 U.S.C. § 355 (2006); 35 U.S.C. § 271 (2006)).

n42. Clements, supra note 33, at 386; Williams, supra note 31, at 3.

n43. Williams, supra note 31, at 3.

n44. 21 U.S.C. § 355(v)(2)(A)(i)(II)(ii) (2006); 35 U.S.C. § 156 (2006).

n45. Mossinghoff, supra note 32, at 190.

n46. Id.

n47. FTC Study, supra note 31, at i.

n48. Williams, supra note 31, at 4.

n49. Id.

n50. Id.

n51. The Hatch-Waxman Act modified the 1952 Patent Act by creating a safe harbor from certain types of patent infringement. Generic manufacturers can begin creating a generic version of an approved name drug any time during the life of the patent, so long as the manufacturer complies with FDA regulations. Schacht & Thomas, supra note 14, at 2.

n52. Paul Weigel, Was the FDA Exemption to Patent Infringement, 35 U.S.C. § 271(e)(1), Intended to Exempt a Pharmaceutical Manufacturer's Activities in the Development of New Drugs, 2007 B.C. Intell. Property & Tech. F. 112901 (explaining the FDA exemption of 35 U.S.C. § 271(e)(1) is also known as the Bolar exemption).

n53. 35 U.S.C. § 271(e)(1)(2006).

n54. Id.

n55. See Schacht & Thomas, supra note 14. For a more detailed discussion of the Hatch-Waxman Act, see Elizabeth Stotland Weiswasser & Scott D. Danzis, The Hatch-Waxman Act: History, Structure and Legacy, 71 Antitrust L.J. 585 (2003).

n56. Weiswasser & Danzis, supra note 56, at 585-86.

n57. Abbreviated New Drug Application (ANDA) Process for Generic Drugs, U.S. Food & Drug. Admin., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDA (last visited March 7, 2010) [hereinafter ANDA Process].

n58. CBO Report, supra note 21, at 38 (stating the Act reduced the time between the expiration of the brand-name drug and FDA approval of the generic drug from about three years to a few months).

n59. Richard J. Findlay, Symposium Issue - Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: Originator Drug Development, 54 Food & Drug L.J. 227, 229 (1999).

n60. 21 U.S.C. § 355(j) (Supp. II 2008) (discussing the application and approval process for abbreviated new drug applications).

n61. Justina A. Molzon, Generic Drug Approval Process, 5 J. Pharmacy & Law 275, 280 (1995).

n62. Id.

n63. Id.

n64. Id. at 277-78.

n65. Bioequivalence studies evaluate the rate and extent of drug absorption. The FDA determines different formulations of the same drug substance bioequivalent if the rate and extent of absorption differ by less than 20%. Dept. Health Human Servs., Public Health Serv., Food and Drug Admin., Ctr. for Drug Evaluation and Research, Office of Mgmt. Div. Info. Res., Approved Drug Products with Therapeutic Equivalence Evaluations (30th ed. 2010).

n66. Williams, supra note 31, at 4-5.

n67. Molzon, supra note 61, at 280.

n68. Lao, supra note 25, at 993-94. See generally 21 C.F.R. § 314.53(f) (2010) (describing how to contact staff of Orange Book in the event there is any dispute of patent information accuracy).

n69. Findlay, supra note 59, at 229.

n70. Molzon, supra note 61, at 275.

n71. 21 U.S.C. § 355(j)(5)(B)(iv)(Supp. II 2008).

n72. Id. § 355(j)(2)(A)(vii)(I)-(IV).

n73. Clements, supra note 33, at 389.

n74. 21 U.S.C. § 355(j)(5)(B).

n75. Id. § 355(j)(5)(B)(i).

n76. Id. § 355(j)(5)(B)(ii).

n77. Pharm. Research & Mfr. of Am., White Paper on the Implementation of the Hatch-Waxman Act by the U.S. Food & Drug Administration, 10 (2002).

n78. 21 U.S.C. § 355(j)(2)(B)(ii).

n79. Id. § 355(j)(2)(B)(iv).

n80. Mylan Pharm., Inc., v. Thompson, 268 F.3d 1323, 1327 (Fed. Cir. 2001).

n81. 21 U.S.C. § 355(j)(5)(B)(iii).

n82. Id. § 355(j)(B)(iii).

n83. Id. §§355 (j)(5)(B)(iii), (j)(5)(C)(i).

n84. Id. § 355(j)(5)(B)(iv)(I).

n85. 21 C.F.R. § 314.107 (2007).

n86. 21 U.S.C. § 355(j)(5)(B)(iv).

n87. See Clements, supra note 33, at 390; FTC Study, supra note 31, at 13.

n88. Molzon, supra note 61, at 283.

n89. Antitrust Enforcement Agencies: The Antitrust Div. of the Dep't of Justice and the Bureau of Competition of the Fed. Trade Comm'n: Hearing Before the Task Force on Antitrust of the House Comm. on the Judiciary, 108th Cong. 38-66 (2003) (statement of Timothy J. Muris, Chairman, Federal Trade Commission). While the Hatch-Waxman Act has increased generic drugs availability in the market, the Act "has been subject to some abuse, however. Some drug manufacturers have allegedly attempted to 'game' the system, securing greater profits for themselves without providing a corresponding benefit to consumers." Id. at 46.

n90. FTC Study, supra note 31, at 25.

n91. Id. at 44 ("If the brand-name company sues within 45 days of the generic applicant's re-certification, then a second 30-month stay will issue.").

N92. Id. at 57. See also Competition in the Pharm. Marketplace: Antitrust Implications of Patent Settlements Before the S. Comm. on the Judiciary, 107th Cong. 20-21 (2001) (statement of Molly Boast, Director, Federal Trade Commission Bureau of Competition) (stating Geneva Pharmaceuticals made a deal with Abbott Laboratories not to sell its generic equivalent of Abbott's brand-name drug to prevent the triggering of the 180-day exclusivity period from running).

n93. Williams, supra note 31, at 12.

n94. Id. at 13.

n95. Administrative Procedure Act, 5 U.S.C. § 553(e) (2006).

n96. U.S. Const. amend, I ("Congress shall make no law...abridging...the right of the people...to petition Government for a redress of grievances."); United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass'n, 389 U.S. 217, 222 (1967) ("[The right to] petition for redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights."); Thomas v. Collins, 323 U.S. 516, 529-30 (1945) (stating it shares the "preferred place" accorded in our system of government to the First Amendment freedoms, and has "sanctity and a sanction not permitting dubious intrusions."); United States v. Cruikshank, 92 U.S. 542, 552 (1875) (recognizing the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government).

n97. Welch v. Bd. of Educ. of Baltimore Cnty., 477 F. Supp. 959 (D. Md. 1979) (confirming that due process does not include the right to speak to government officials); Stengel v. City of Columbus Ohio, 737 F. Supp. 1457 (S.D. Ohio 1988) (holding due process does not include the right to an oral hearing); Smith v. Ark. State Highway Emp., Local 1315, 441 U.S. 463, 465 (1979) (holding right to petition does not require the government to act or investigate).

n98. 21 C.F.R. §§10.20, 10.30 (2010).

n99. Id. § 10.30(b).

n100. June Gibbs Brown, Dep't of Health and Human Servs., Review of the Food and Drug Administration's Citizen Petition Process (1998) [hereinafter OIG Citizen Petition Report].

n101. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat 1585 (codified as amended in relevant part at 21 U.S.C. § 355 (2006); 35 U.S.C. § 271 (2006)).

n102. 21 C.F.R. § 10.30 (2010).

n103. Lars Noah, Sham Petitioning as a Threat to the Integrity to the Regulatory Process, 74 N.C. L. Rev. 1, 3 (1995).

n104. Molzon, supra note 61, at 280.

n105. 21 C.F.R. § 10.30 (2010).

n106. Id.

n107. Id.

n108. The Generic Drug Maze: Speeding Access To Affordable Life-Saving Drugs Before the Spec. Comm. On Aging, 109th Cong. 665 (2006) (statement of Gary Buehler, Director, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration) [hereinafter Buehler Statement].

n109. Molzon, supra note 61, at 280.

n110. Id.

n111. Id.

n112. Id. at 281.

n113. Id. A typical bioequivalence challenge will assert that more rigorous testing requirements are necessary to ensure the drug's safety and product performance. Changes in bioequivalence guidance or testing protocol after an ANDA has been submitted could severely delay a generic drug's approval. Id.

n114. Id. at 281.

n115. See id. at 281-82; Administrative Procedure Act, 5 U.S.C. § 553(e) (2006). Even in the agency's zeal to provide the public with formal process to bring administrative activities before the agency, drafters of the rule were well aware that the scarcity of FDA resources would make timely disposition of petition a challenge. In the proposed rules, the Commissioner conceded that in a significant number of instances, petitions with relatively low priority would not be acted upon promptly. Id. See also Citizen Petitions, 64 Fed. Reg. 66,822 (Nov. 30, 1999) (codified at 21 C.F.R. § 10.30 (2010)). Though originally thought to be a problem that would only affect low priority claims, the FDA resources and resulting backlog of citizen petitions waiting review have become one of the major tools brand-name companies rely on to protect market exclusivity and delay ANDA approvals. Id.

n116. 21 C.F.R. § 10.30(e)(2)(i) (2010).

n117. Id. § 10.30(e)(2)(ii).

n118. Id. § 10.30(e)(2)(iii).

n119. Molzon, supra note 61, at 282.

n120. OIG Citizen Petition Report, supra note 101, at i (noting that the FDA did not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's).

n121. Citizen Petitions, 64 Fed. Red. 66,822 (Nov. 30, 1999).

n122. Id.

n123. Id. at 66,825. Notwithstanding these recommendations, the Agency acknowledged that existing regulations do not permit the Agency to withdraw petitions that are "illogical and a waste of agency resources." Id.

n124. Citizen Petitions, 68 Fed. Reg. 16,461 (April 4, 2003).

n125. See Buehler Statement, supra note 108.

n126. Id.

n127. Id. In 2006, there were approximately 170 citizen petitions before the FDA compared to 90 in 1999. Id.

n128. Benjamin Romano, Hurdles Block Generic Drugs, Seattle Times, Feb. 13, 2006 (noting that approximately 150 citizen petitions were filed in 2005, with at least 43 challenging a generic drug application).

n129. Martin Sipoff, FDA Approach to Citizen Petitions May be a Mixed Blessing, Managed Care, Feb. 2008, http://www.managedcaremag.com/archives/0802/0802.medmgmt.html. The ANDA backlog doubled from 2006 to 2008; in 2008, the average review time for an application was 17.3 months. Id.

n130. Letter from Kathleen Jaeger, President & CEO, GPhA, to Dr. Andrew C. Von Eschenbach, Office of the Commissioner, FDA (Dec. 15, 2005) (on file with author) (quoting Sheldon Bradshaw, Chief Counsel, Food & Drug Administration).

n131. Id.

n132. Press Release, U.S. Senate Special Comm. On Aging, Kohl, Leahy Introduce Bill to Top Frivolous Citizen Petitions, Speed Generic Drug Approval (September 28, 2006) http://aging.senate.gov/record.cfm?id=268246 [hereinafter Kohl Leahy].

n133. Id.

n134. Id.

n135. Id.

n136. Buehler Statement, supra note 108.

n137. Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at 21 U.S.C. § 355 (Supp II. 2008)).

n138. 21 U.S.C. § 355(q)(1)(F).

n139. Id. § 355(q)(1)(A).

n140. Id. § 355(q)(1)(B).

n141. Id. § 355(q)(1)(H).

n142. Id. § 355(q)(1)(E).

n143. Id.

n144. GPhA Citizen Petition Position, Generic Pharmaceutical Ass'n, http://www.gphaonline.org/issues/citizen-petitions (last visited Sept. 28, 2010).

n145. Dep't. of Health & Human Servs., Ctr. for Drug Evaluation & Research, Draft Guidance for Industry Citizen Petitions & Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, & Cosmetic Act (2009).

n146. Id.

n147. In re Wellbutrin XL Antitrust Litig., No. 08-2431, 2009 U.S. Dist. LEXIS 21286 (E.D. Pa. Mar. 13, 2009).

n148. Id. at 7.

n149. Id. at 11.

n150. Id.

n151. Id.

n152. Biovail 2006 Annual Report 15 (2006), http://www.biovail.com/local/files/FactSheets/Biovail%202006%20Annual%20Report.pdf.

n153. Id.

n154. Id.

n155. Roxane Labs. v. GlaxoSmithKline, No. 09-CV-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010).

n156. Id. at 1.

n157. Dept. of Health & Human Servs., FDA Consolidate Response to GlaxoSmithKline's Multiple Citizen Petitions, 2-3 [hereinafter FDA Response].

n158. See id. at 21.

n159. Id.

n160. Id. at 23.

n161. Id. at 24.

n162. Roxane Labs. v. GlaxoSmithKline, No. 09-CV-1638, 2010 WL 331704, at 1 (E.D. Pa. Jan. 26, 2010).

n163. 2009 FDAAA Implementation - Highlights Two Years After Enactment, U.S. Food & Drug Administration, http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministr (last updated Oct. 2, 2009). As of September 15, 2009, the FDA responded to 38 citizen petitions subject to new section 505(q) of the Act. The Agency reviewed thirty-six of those petition responses within the statutory deadline of 180 days or less. Id.

n164. 21 U.S.C. § 355(q)(1)(E)(2006 & Supp. II 2008).

n165. Id. § 355(q)(1)(F).

n166. Id.

n167. Id. § 355(q)(1)(A).

n168. 15 U.S.C. §§1-2 (2006). See generally Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993) (holding the Sherman Act seeks to prohibit activity that unfairly seeks to eliminate competition); D.R. Wilder Mfg. Co., v. Corn Prods. Ref. Co., 236 U.S. 165, 173-74 (1915) (stating the intended breadth of the Sherman Act).

n169. Eastern R.R. Presidents Conference v. Noerr Motor Freight Inc., 365 U.S. 127, 137-38 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965); Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508 (1972).

n170. La. Wholesale Drug Co. v. Sanofi-Aventis, 07 Civ. 7343, 2008 U.S. Dist. LEXIS 3611, (S.D.N.Y. Jan. 18, 2008) at 3.

n171. 365 U.S. at 138.

n172. Id. at 129.

n173. Id. at 137 ("To hold that the government retains power to act in this representative capacity and yet hold at the same time that people cannot freely inform the government of their wishes would impute to the Sherman Act a purpose to regulate, not business activity, but political activity, a purpose which would have no basis whatever in the legislative history of the Act.").

n174. Id. at 138.

n175. Id. at 139.

n176. Id. ("Indeed, it is quite probably people with just such hope of personal advantage who provide much of the information upon which governments must act.").

n177. See id. at 144.

n178. Id.

n179. Id.

n180. United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

n181. Id. at 660.

n182. Id.

n183. Id. at 670.

n184. Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 512 (1972).

n185. Id. at 510.

n186. Id. at 511-13.

n187. Id. at 512 (internal quotes omitted).

n188. Id. at 513.

n189. Id. at 516.

n190. Id. at 513.

n191. Id. at 512-13.

n192. Id.

n193. Id. See also Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499-500 (1988) (discussing the rules of the sham exception).

n194. 486 U.S. at 500 n.4; Eastern R.R. Presidents Conference v. Noerr Motor Freight Inc., 365 U.S. 127, 144 (1961); Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 511 (1972).

n195. See Allied, 486 U.S. 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 into a number of statutes and local ordinances."). See also Prof'l Real Estate Investors, Inc., v. Columbia Pictures Indus., Inc., 508 U.S. 49, 61 (1993) ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.").

n196. The court noted that conspiracy with a licensing authority to eliminate competition and bribing a purchasing agent are examples of conduct that may violate the Sherman or Clayton Acts. Allied, 486 U.S. at 502. See also Trucking Unlimited, 404 U.S. at 512-13 (stating that perjury in the adjudicatory process often results in sanctions). But see City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 381 (1991) (holding Noerr protections extends to lobbying in legislative context even when the manner is "improper or even unlawful" so long as the "regulatory process is being engaged genuinely").

n197. 508 U.S. at 49. While PRE only addresses the sham exception in the litigation context, the Court's opinion has been interpreted to apply in any adjudicatory process, including petitions before administrative agencies. See, e.g., Liberty Lakes Inv., Inc. v. Magnuson, 12 F.3d 155, 157-58 (9th Cir. 1993) (applying the PRE test in administrative and judicial processes); Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240, 1258 (9th Cir. 1982) ("The same dangers that the antitrust laws seek to prohibit flow from institution sham administrative proceedings as flow from instituting sham judicial proceedings.").

n198. 508 U.S. at 49.

n199. Id. at 60.

n200. Id.

n201. Id.

n202. Id. at 60 (quoting Eastern R.R. Presidents Conference v. Noerr Motor Freight Inc., 365 U.S. 127, 144 (1961)). See also City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 380 (1991) (discussing the situations where the sham exception would apply).

n203. 508 U.S. at 60 (Stevens, J. concurring). The justice accused the Court of setting up a "straw man" (i.e. the confusion among the lower courts over the sham litigation standard) to justify the promulgation of its two-part test. His chief criticism of the majority's opinion was that it articulated an overly broad holding that would be difficult to administer in complex cases. In Justice Steven's opinion, sham litigation should apply to "a case or series of cases in which the plaintiff is indifferent to the outcome of the litigation itself" and "seeking only to impose collateral harm on the defendant." Id. at 67-76. See also Robert P. Faulkner, The Foundations of Noerr-Pennington and the Burden of Proving Sham Petitioning: The Historical-Constitutional Argument in Favor of a "Clear and Convincing" Standard, 28 U.S.F. L. Rev. 681, 687-90 (1994) (noting the existence or non-existence of sham is still difficult to discern).

n204. 508 U.S. at 60.

n205. Id. at 62 n.7.

n206. Id. at 65. See also Fed. R. Civ. P. 11(b)(2)-(3) (requiring all pleadings, motions or other paper submitted to the court be supported by factual contentions and nonfrivolous arguments).

n207. 508 U.S. at 66-67 (Souter, J. concurring).

n208. Id. at 67.

n209. Id. at 67-68.

n210. See id. at 62-63.

n211. Id. at 61 n.6. Cf. Fed. R. Civ. P. 60(b)(3) (allowing the court to relieve a party from a final judgment due to fraud, misrepresentation, or misconduct by an opposing party).

n212. See, e.g., Potters Med. Ctr. v. City Hosp. Ass'n, 800 F.2d 568, 580-81 (6th Cir. 1986) (noting that a purposeful misrepresentation to an agency about a competitor required application of sham exception); St. Joseph's Hosp. Inc. v. Hosp. Corp. of Am., 795 F.2d 948, 955 (11th Cir. 1986); Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240 (9th Cir. 1982); Israel v. Baxter Labs., Inc., 466 F.2d 272, 278-79 (D.C. Cir. 1972); Woods Exploration & Prod. Co. v. Aluminum Co., 438 F.2d 1286, 1296-98 (5th Cir. 1971); Outboard Marine Corp. v. Pezetel, 474 F. Supp. 168, 179 (D. Del. 1979); Mktg. Assistance Plan, Inc. v. Associated Milk Prod., Inc., 338 F. Supp. 1019, 1023-24 (S.D. Tex. 1972).

n213. Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1060-61 (9th Cir. 1998) (quoting Liberty Lakes Inv., Inc. v. Magnuson, 12 F.3d 155, 157-58 (9th Cir. 1993)).

n214. Cheminor Drugs Ltd. v. Ethyl Corp., 168 F.3d 119, 123 (3d Cir. 1999).

n215. Id.

n216. Id.

n217. In re Union Oil Co. of Cal, F.T.C., Dkt. No. 9305, slip op. at 36 (Nov. 25, 2003) available at http://www.ftc.gov/os/adjpro/d9305/040706commissionopinion.pdf.

n218. La. Wholesale Drug Co. v. Sanofi-Aventis, 07 Civ. 7343 (HB), 2009 U.S. Dist LEXIS 77206 (S.D.N.Y. Aug. 28, 2009).

n219. Id. at 3-4.

n220. La. Wholesale Drug Co. v. Sanofi-Aventis, 07 Civ. 7374 (HB), 2008 U.S. Dist LEXIS 3611, at 4 (S.D.N.Y. Jan. 18, 2008).

n221. Id. at 4-5.

n222. Id. at 5-6.

n223. La. Wholesale Drug Co., 2009 U.S. Dist LEXIS 77206, at 6-9.

n224. Id. at 6.

n225. Id. at 7-8.

n226. Id.

n227. Id.

n228. Id. at 8-9.

n229. La. Wholesale Drug Co. v. Sanofi-Aventis, 07 Civ. 7374 (HB), 2008 U.S. Dist LEXIS 3611, at 2-3 (S.D.N.Y. Jan. 18, 2008).

n230. Id. at 10-11 (quoting Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 512 (1972).

n231. La. Wholesale Drug Co., 2008 U.S. Dist LEXIS 3611 at 11-12 (quoting USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council, 31 F.3d 800, 811 (9th Cir 1993)). See also Trucking Unlimited, 404 U.S. at 512; Primetime 24 Joint Venture v. Nat'l Broad. Co., Inc., 219 F.3d 92, 101 (2d Cir. 2000).

n232. La. Wholesale Drug Co., 2008 U.S. Dist LEXIS 3611 at 12 (summarizing New York Jets, LLC v. Cablevision Sys. Corp., 2005 U.S. Dist. LEXIS 23763, at 21-22 (S.D.N.Y. Oct. 17, 2005) ("Finding that the Jets stated a sham claim against Cablevision which funded support and promoted baseless litigation and present a sham bid designed solely to delay, increase the cost of and prevent the development of the Sports and Convention Center project.").

n233. Id. at 12-13.

n234. Id. at 13 (citing New York Jets, 2005 U.S. Dist. LEXIS 23763, at 21-22; ICOS Vision System Corp., N.V. v. Scanner Tech. Corp., 2006 U.S. Dist. LEXIS 13847, at 12 (S.D.N.Y. Mar. 29, 2006)).

n235. Id. at 14.

n236. Id. at 14-16.

n237. Id. at 14.

n238. Id. at 14-16.

n239. Id. at 16-17.

n240. Id. at 17.

n241. Id. at 14.

n242. Id. at 14.

n243. La. Wholesale Drug Co. v. Sanofi-Aventis, No. 07 CV 7343 (HB), 2008 U.S. Dist. LEXIS 81328, at 3 (S.D.N.Y. Oct. 14, 2008).

n244. Id. at 13-16.

n245. Id. at 14-16.

n246. Id. at 17-18.

n247. La. Wholesale Drug Co., Inc., v. Sanofi-Aventis, 07 CV 7473 (HB), 2009 U.S. Dist LEXIS 77206, at 14 (S.D.N.Y. Aug. 28, 2009).

n248. Id. at 3.

n249. Id. at 3-4.

n250. Id. at 26-28.

n251. Id. at 12-15.

n252. Id. at 14.

n253. Id.

n254. Id. at 27.

n255. Robert H. Bork, The Antitrust Paradox: A Policy at War with Itself 347 (1993).

n256. Id.

n257. Id. at 347-48.

n258. Id.

n259. See supra Part III.B for a discussion of several questions left unanswered by the recent passage of the FDAA.

n260. Citizen Petition Fairness and Accuracy Act of 2006, S. 3981, 109th Cong. (2006); Kohl Leahy, supra note 132.

n261. S. 3981, 109th Cong. (2006).

n262. See id.

n263. Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 355(q)(1)(F) (2006 & Supp. II. 2008).

n264. Letter from Kathleen D. Jeager, President, Generic Pharm. Ass'n, to Andrew C. Von Eschenbach, Comm'r of the Food and Drug Ass'n (Dec. 15, 2005) (on file with author).

n265. Id.

n266. 5 U.S.C. § 553(c) (2006).

n267. See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (requiring deference to agency determinations of statutes).

n268. Stuart Minor Benjamin & Arti K. Rai, Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law, 95 Geo. L. J. 269, 281 (2007).

n269. Statesville v. Atomic Energy Comm'n, 441 F.2d 962, 977 (D.C. Cir. 1969); see also Pasco Terminals, Inc. v. United States, 447 F. Supp. 201, 213 (E.D. Pa. 1979) aff'd, 634 F.2d 610 (C.C.P.A. 1980).

n270. See Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc., 435 U.S. 519, 524 (1978).

n271. Id.

n272. Jeffery E. Shuren, The Modern Regulatory Administrative State: A Response to Changing Circumstances, 38 Harv. J. On Legis. 291, 292 (2001).

n273. See Schering Corp. v. FDA, 51 F. 3d 390, 398-99 (3d Cir. 1995); Fissions Corp. v. Shalala, 860 F. Supp. 859, 866 (D.D.C. 1994); Schering Corp. v. Sullivan, 782 F. Supp. 645, 650 (D.D.C. 1992), vacated & remanded by Schering Corp. v. Shalala, 995 F.2d 1103 (D.C. Cir. 1993).

n274. See Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (E) (2006).

n275. 21 C.F.R. § 10.30(h)(1)-(5) (2010).

n276. 21 U.S.C. § 355(q)(1)(E) (2006 & Supp. II 2008).

n277. See FDA Response, supra note 157 (providing a comprehensive evaluation of a response to each of the scientific, mathematical, chemical, and regulatory claims raised in Biovail's petitions).

n278. 21 C.F.R. § 10.30(e)(2)(i)-(iii) (2010).

n279. Id. § 10.30(c).

n280. Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (E) (2006).

n281. See Faulkner, supra note 203; Prof'l Real Estate Investors, Inc., v. Columia Pictures Indus, Inc., 508 U.S. 49, 66-67 (1993) (Souter, J. concurring).

n282. Lao, supra note 25, at 1025-26. The subjective test of the sham exception was first articulated in a legislative setting. See City of Columbia v. Omni Outdoor Adver. Inc., 499 U.S. 365 (1991). Justice Thomas then folded it into his two-part test and applied it to litigation. This subjective inquiry is redundant and ill-suited for litigation. If a claim is objectively baseless, than the act of filing suit already demonstrates lack of good faith and brought to harass the other part. Accordingly, the subjective prong is unnecessary.