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

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Introduction

Over the next five years, approximately 110 drugs, including blockbuster products such as Sanofi-Aventis' allergy medicine Flomax, GlaxoSmithKline's herpes medication Valtrex, and Pfizer's cholesterol medication Lipitor will lose their patent protection.[1] In 2009 alone, brand-name drugs coming off patent were valued at more than 10.8 billion dollars.[2] As market exclusivity for these drugs ends, the doors for generic production will open. Generic drugs generally enter the market priced 20 to 80 percent lower than their branded counterparts, and generics can capture 44 to 80 percent of brand-name drug sales within a year after release.[3] 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 competition.

One strategy that has received considerable scrutiny by administrative agencies and the courts is the aggressive petitioning activities of brand-name drug manufacturers.[4] The concern is that these companies are abusing the government process by filing baseless petitions with the Food and Drug Administration (FDA) in order to extend artificially their monopolies.[5] 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.[6] 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 curb abuse.[7]

The Noerr-Pennington doctrine requires courts to interpret the fundamental antitrust law known as the Sherman Antitrust Act in a way that safeguards the government's ability to take and citizens' right to request government action - regardless of the action's

anticompetitive effects.[8] Grounded in the First Amendment, the doctrine immunizes from liability conduct aimed at persuading the government.[9] While expansive, the doctrine is not absolute. The "sham exception" provides that a petition loses immunity if it is objectively baseless and born of a predatory intent that is "actually nothing more than an attempt to interfere directly with the business relationships of a competitor." [10]

However, the sham exception's "objectively baseless" requirement has been an insurmountable obstacle to courts' effective policing of 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. Notwithstanding these efforts, brand-name pharmaceutical manufacturers have stymied the effective application of the sham exception and FDA regulations.

This Article explores the regulatory and adjudicatory impact of brand-name drug manufacturers' use of governmental processes to delay the availability of generic drugs.[11] 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, it is possible for manufacturers to file baseless petitions that can halt a generic drug's approval for six months or longer. After the FDA has determined that the petition is meritless, then on the judicial level, these manufacturers have been able to 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 to curb effectively this type of abuse, the solution must include adequate agency reforms. The Federal Drug Administration Revitalization Act of 2007 (FDARA) is an initial step in that direction. This article suggests ways to build on that foundation and more fully engage the FDA in actively policing the integrity of its own processes.[12]

Given the unique regulatory framework for encouraging the development and market introduction of generic drugs, Part I of this Article provides an overview of the generic drug industry. The first section describes the Hatch-Waxman Act of 1984, the legislation that modified antitrust laws to enable production of generic drugs. In the next section, the Article describes the abbreviated new drug application (ANDA) process for generic drugs.

Part II describes the original intent behind the establishment of the citizen petition process and its role in generic drug approvals. This section also discusses how FDA regulations and policies allow some brand-name drug manufacturers to manipulate this process. Part III of the Article examines the trilogy of cases that define the basic parameters and principles of the *Noerr-Pennington* doctrine. This section also focuses on the two-part inquiry that courts rely on to determine applicability of the "sham exception". In particular, the Article comments on the difficulty courts have had in policing the conduct of defendant manufacturers accused of filing petitions that are both "objectively baseless" and born of predatory intent in the pharmaceutical industry context. As part of that examination, this Article analyzes *Louisiana Wholesale Drug*

Co. v. Aventis Pharmaceutical, Inc. a recent federal appellate court opinion. [13] This case illustrates that even after an FDA determination that a petition is baseless and without legal merit, it is still possible for a court to hold that the facts are insufficient to meet "sham exception" criteria. This Article posits that the *Louisiana Wholesale* case is significant because it strongly suggests that under courts' current interpretation of the sham exception, regardless of the facts and agency determinations, the filing of baseless citizen petitions to prevent competition will remain immune from liability.

Finally, Part IV considers other alternatives aimed at making it unattractive for pharmaceutical manufacturers' to attempt to abuse the citizen petition process. These alternatives include regulatory and procedural reforms that build on the recently passed FDARA citizen petition provisions. These proposals enable the FDA to respond more directly and effectively to anticompetitive abuses of the regulatory process. In addition, the 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.

Part I - Origins of the Generic Drug Industry – Hatch-Waxman and the Generic Drug Approval Process

Consumers benefit greatly from the availability of generic drugs.[14] According to the Congressional Budget Office, generic drugs save consumers on average 8 to 10 billion dollars a year.[15] In 2009, generic drugs filled over sixty percent of all prescriptions written.[16] As the patents for more brand-name drugs expire, industry experts expect that percentage to rise.[17] Brand-name manufacturers rely on the exclusive rights to market their drugs for their revenue. For example, in 2001 when Eli Lilly's patent expired on its blockbuster drug Prozac, the company's annualized revenues from the drug went from 2.7 billion to 1.8 billion in nine months.[18] With so much at stake, it is not surprising that some brand-name manufacturers have resorted to filing petitions of questionable legitimacy with the FDA to delay generic drug approvals and artificially extend their market share.[19]

A. Pre Hatch-Waxman Landscape

To fully grasp how and why the drug industry is particularly vulnerable to these petitioning actions that threaten competition, 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) to "prove the new drugs are safe and effective prior to FDA approval." [20] Preparing such an application was, and is, a time consuming and expensive process that must contain studies of the drug's chemistry, manufacturing information, patents and labeling.[21] After completing the NDA, a team of FDA toxicologists, physicians, chemists and microbiologists reviews the application.[22] The time and expense associated with gaining

FDA approval provided little incentive for a generic drug maker, who had to "re-prove" what the brand-name drug companies had already established, to enter the market.[23] Between 1962 and 1984, 150 drugs went off patent with no generic equivalent.[24] As a result, a brand-name drug company retained *de facto* control over the market long after its patent term.[25] The lack of competition kept the cost of drugs to consumers high.[26]

Patent restrictions were another disincentive for generic manufacturers to enter the market. In *Roche Prods., v. Bolar Pharm. 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.[27] As a result, there was approximately a two-year lag between a patent's expiration and the introduction of a generic equivalent.[28]

In an effort to construct legislation enabling generics reach the market faster, Congress unintentionally created another problem. A brand-name company typically requires between eight to ten years to prepare an NDA and obtain FDA approval.[29] Companies however, were often required to file for the patent before conducting the required clinical trials necessary for FDA approval.[30] As a result, the patent clock began immediately and continued to run throughout the entire FDA approval process, which often took place after patent acquisition.[31] Increasing the speed and time associated with bringing generics to market threatened brand-name manufacturers' ability to recoup research and development costs lost while they were awaiting pre-market FDA approval.[32] Accordingly, if Congress was to provide cheaper pharmaceuticals for consumers through the availability of generic drugs, it also needed to provide brand-name manufacturers' incentive to invest in new drug innovation through patent extensions.

B. Pharmaceutical Drugs in the Hatch-Waxman Act Era

Congress' resolution of these conflicting goals was the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments to the FDCA or simply the Hatch-Waxman Act.[33] The goal of the Act was to strike a balance between brand-name manufacturers' desire to bring new drugs to market with adequate patent protection and generic drug manufacturer's desire for an approval process that enables them to compete with brand-name manufacturers by marketing generic versions of brand-name drugs. [34] In terms of regulatory reforms benefitting brand-name drug manufacturers, to encourage companies to continue to develop new drugs, the Act extended patents to compensate for time lost during the FDA approval process.[35] As a result, the Act provided brand-name manufacturers patent extensions of up five years with total exclusivity time not exceeding fourteen years.[36] Congress also addressed delays and uncertainties in the drug approval process for brand-name and generic drugs alike.[37] In addition, the Act created a process that would enable generic drugs to enter the market faster.[38]

Since the Act's passage in 1984, the pharmaceutical drug landscape has changed dramatically. At that time, generic drugs filled 19 percent of prescriptions.[39] Since the Hatch-Waxman Act's enactment, generic drugs have tripled in terms of drug volume.[40] In addition, generic drug prescriptions now exceed brand-name drug prescriptions, and nearly 100 percent of the top-selling drugs on the market with expired patents have a

generic counterpart.[41] Finally, the number of companies providing generic has also expanded since the creation of the Act.[42]

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. The first change was to revise the applicability of patent law on generic drug formulations. The Act permits generic manufacturers to begin experiments on a patent drug prior to its expiration.[43] In what is referred to as the "Bolar Exemption",[44] Congress specifically defined a generic manufacture's use of clinical information already in a NDA as a "non-infringing use" as long as the purpose is solely for obtaining FDA approval.[45] This statutory exemption allows the generic to enter the market as soon as the patent expires.[46]

The second major regulatory change allowed generic drug manufacturers to file Abbreviated New Drug Applications (ANDAs) rather than an NDA for FDA approval[47]. 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."[48] This process substantially relaxed the regulatory testing requirements for generics and thereby increased competition in the drug market.[49] By avoiding the costly and time consuming expense of generating safety and efficacy data, generic companies avoid sizable research and development costs and are able to market lower cost alternatives to brand-name drugs to consumers.[50]

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.[51] A generic drug company next submits an ANDA to the FDA in accordance with the statutory criteria.[52] These criteria require an ANDA to demonstrate that the generic drug is bioequivalent to a previously approved drug on the market.[53] Specifically, the generic company must then show that the drug specified in the ANDA is the same in terms of active ingredients, dosage form, strength, and route of administration.[54] The generic manufacturer must also meet the same standards for manufacturing practices, identity, strength, quality and purity as the approved manufacturer.[55] In addition, the labeling standards must contain the same information as its brand-name counterpart. ANDA applications satisfy the FDA's safety and efficiency requirements through bioequivalence studies that are a fraction of the cost of a larger clinical study.[56]

Congress intended that the bioequivalence requirement would ensure FDA approval only of a generic drug that is therapeutically equivalent to its brand-name counterpart.[57] 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".[58] The FDA updates this book monthly and lists information on more than 6,000 approved drug products that it considers therapeutic substitutes for each other.[59] The book also contains lists of generic products that have not had their bioequivalence established, and therefore, not considered therapeutically equivalent.[60]

Providing there are no challenges, the generic approval process takes between three to five years. [61] The cost to a generic drug manufacturer is substantially less than that of a brand-name manufacturer.[62] 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 that drug. [63]

When a generic manufacturer submits an ANDA, it must also certify one of the following for each of its generic versions of the 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.[64] These are commonly referred to as Paragraph I, II, III, and IV certifications.[65] 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.[66] If a generic manufacturer asserts a Paragraph I or II certification, the FDA may automatically approve the application.[67] If an ANDA application claims a Paragraph III certification, the FDA will not approve the generic drug's application until the brand-name drug's patent has expired.[68]

3. Paragraph IV Certifications

To increase competition, the Hatch-Waxman Act encourages generic manufacturers to challenge the validity of the brand-name drug's patent by filing a Paragraph IV certification.[69] Under the Act, generic manufacturers who challenge an active patent must give notice to the brand-name patent holder within twenty days of filing.[70] The notice must include the legal and factual grounds underlying the manufacturer's assertion that its drug does not infringe the patent or that the patent is not valid.[71] Paragraph IV certifications are approved immediately unless the patent holder files an infringement action in district court within forty-five days of receiving notice.[72] 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 invalid.[73] Any final court ruling within the thirty-month stay that upholds a Paragraph IV certification will include the ANDA approval date.[74] 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.[75]

The Act also provides that the first ANDA applicant to file a Paragraph IV certification receives a 180-day period of marketing exclusivity.[76] As originally enacted, Hatch-Waxman required a generic manufacture to successfully defend its Paragraph IV certification before being granted the 180-day exclusivity period. In 2007, however, Congress removed this requirement.[77] Throughout the length of the exclusivity period, the FDA will not approve a subsequent generic's ANDA application for the same product. [78] During this time, the only competition that the generic drug has is the higher

priced brand-name drug. Generics, therefore, have a financial interest in challenging the validity of listed patents.[79]

4. Abuses of Governmental Processes

By striking a balance between the interests of the brand-name and generic drug makers, the Hatch-Waxman Act was intended to be a practical approach to providing the best and most cost-efficient medicines for American consumers.[80] In practice, however, brand-name drug manufacturers often manipulated provisions of the Act to extend artificially their monopolies. According to the Federal Trade Commission ("FTC"), brand-name manufacturers have exploited the Hatch-Waxman Act and governmental processes to the detriment of generic manufacturers and consumers.[81] Though beyond the scope of this article, some of these abuses include: (1) improper Orange Book listing of invalid patents;[82] (2) filing patents late to secure a 30 month stay;[83] (3) use of the 180-day exclusivity period to prevent generic marketing;[84] (4) payments to generic manufacturers to postpone market entry of their approved drugs,[85] and (5) obtaining exclusive licensing agreements related to a patent. [86] Another area in which brand-name drug manufacturers exploit the Act, as well as governmental processes, is 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.

Part II – Citizen Petitions

In 1975, the Administrative Procedures Act created the ability for citizens, including drug manufacturers, to petition the FDA. [87] The intent of the Act was to correct the absence of a form or procedure for individuals to exercise their First Amendment right.[88] The Act requires that every agency provide the public with the right to petition for the issuance, amendment, or repeal of a rule.[89] As applied to the FDA, it guarantees citizens the right to contact the agency to "issue, amend, or revoke" a regulation or order.[90] As originally enacted, citizen petitions were designed to benefit the FDA and public by giving individuals a formal means to influence the FDA's regulations on matters of health and safety.[91]

From the outset, individuals used citizen petitions to contact the FDA on a broad range of health and safety issues ranging from a food trade association's request that the Agency establish exemptions from certain package labeling requirements to a consumer group's request that the FDA increase regulation of certain products like tobacco.[92] The 1984 passage of the Hatch-Waxman Act expanded the health and safety concerns of citizen petitions to include the ANDA generic drug process.[93] For the first time, the public's right to request the FDA to "issue, amend, or revoke" a regulation or order applied to the Agency's approving or denying standards for ANDAs. [94]

The dual responsibilities of the FDA to approve ANDAs and review citizen petitions have created a two-tier opportunity to delay the introduction of a generic drug through an abuse of governmental processes. First Amendment protections inherent in citizen petitions provide brand-name manufacturers an effective vehicle to file citizen petitions with virtual impunity. The combination of FDA regulations, procedures, and limited

Agency resources creates an opportunity to use objectively baseless claims to halt ANDA approvals mid-stream. When generic manufacturers challenge these anti-competitive tactics in court, brand-name manufacturers avail themselves of the protection of the *Noerr-Pennington* doctrine that immunizes these actions under the First Amendment. What follows is a discussion on how this is possible.

Scope of the Citizen Petition

A. 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.[95] Petitions must state the action requested, the grounds, and the environmental impact of the request. [96] In addition, the petitioner submits all data, information, and views that form the basis of the petition. To ensure a balanced and reasonable presentation, citizen petitions also include a representative set known by the petitioner of unfavorable data.[97]

Citizens can submit petitions at any time.[98] However, the FDA reports an increasing tendency to receive citizen petitions from brand-name manufacturers dealing with "health and safety" concerns about a pending generic's ANDA on the eve of their product's patent expiration.[99] Though not required, until recently the FDA automatically suspended ANDA approval until all the issues in a citizen petition were resolved.[100] Due to the sharp increase in the number of petition filings and the FDA's limited staff, review of a citizen petition can routinely take six months or longer.[101]

After receipt, the FDA categorizes petitions by whether they raise scientific or legal concerns.[102] Citizen petitions raising scientific issues generally challenge the bioequivalence standards.[103] Recent legal issues have included petitions directed towards the ANDA approval process itself, fundamental requirements for a generic drug patent certification and ANDA applicants, and areas of exclusivity.[104] The category of subject matter, availability of agency resources, and statutory time requirements determine the priority of the FDA's response to the petition.[105]

The FDA can approve a citizen petition,[106] deny the petition,[107] or provide a tentative response[108] indicating why the Agency has been unable to reach a decision on the petition within the required 180-day response period. If the FDA denies the brand-name manufacturer's petition, or does not respond in a timely manner, the manufacturer can file a lawsuit for both preliminary and permanent injunctive relief against the Agency.[109]

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

Concern over the FDA's administration of its citizen petition review process is long standing.[110] 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."[111] In particular, the Agency acknowledged growing concerns regarding "generic blocking petitions."[112] The proposed

rule identified several options to reduce backlog, address frivolous petitions and protect the integrity of the process.[113] Four years later, however, the Agency withdrew the proposed rule stating, "revision of the citizen petition regulations is not warranted at this time."[114]

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, and correspondingly, the number of citizen petitions the FDA received.[115] For example, during the five-year period between 2001 and 2006, the number of ANDAs submitted to the FDA's Office of Generic Drugs increased 150 percent.[116] During roughly the same period, the FDA experienced nearly a two-fold increase in the of number citizen petitions.[117] By 2006, ANDAs were the subject of approximately one-third of all citizen petitions filed with the FDA.[118] By 2008, the steady trend of increased ANDA submissions resulted in a backlog of more than 1,300 petitions awaiting review.[119]

Echoing 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 to extend artificially the period of their drug's market exclusivity.[120] As noted by former FDA Chief Counsel Sheldon Bradshaw a number of the petitions filed were "not designed 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." [121] Between 2003 and 2006, the FDA ruled on 21 citizen petitions.[122] The Agency determined that all but one of the petitions lacked merit.[123] Moreover, ten of those filings were identified as "eleventh hour petitions" – submitted within six months of the anticipated entry date of the generic drug.[124] None of those eleventh-hour petitions was found to raise a meritorious health or safety concern.[125] Between 2000 and 2005, the FDA dismissed seventy-six percent of the petitions it reviewed for lack of merit.[126]

In response to these types of abuses, in 2007, Congress amended the FDCA to limit the adverse impact of citizen petitions on the generic drugs. [127] The FDA is required to resolve citizen petitions within six months of receipt.[128] The Agency also will not delay approval of an ANDA because of a citizen petition unless delay is necessary to protect the public health.[129] If the FDA decides to stay an ANDA, the Agency will notify the applicant within thirty days of that determination.[130] In addition, the regulations require all citizen petitions to be signed and contain attestations that all relevant information is included.[131] Moreover, the regulations include a provision specifically addressing delaying or blocking petitions.[132] A petition that is submitted for the primary purpose of delaying an ANDA, and that on its face raises no valid regulatory or scientific issues, can be denied by the Agency at any time.[133]

In 2008, a bipartisan group from both the U.S. House of Representatives and Senate expressed concerns that notwithstanding the new regulations, abuses continued because the FDA was not moving aggressively enough to implement the new law.[134] Shortly

afterward, the FDA issued draft Guidance for Industry Citizen Petitions and Petitions for Stay of Action Subject to 505(q) and the Food Drug and Cosmetic Act. [135] While not binding, the draft guidance expounds on current Agency thinking and illustrates how it intends to implement the citizen petition reforms. [136] Two recent cases make clear that despite regulatory reforms and the recent Agency guidance, abuses of government processes involving the FDA's regulatory procedures are still possible.

In a recent case, *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").[137] In the complaint, Anchen alleged that GSK and Biovail conspired to delay improperly the sale of generic versions of the brand-name antidepressant Wellbutrin XL by filing a sham citizen petition with the FDA. [138] In November 2005, the FDA approved Anchen's ANDA for a generic version of Wellbutrin XL.[139] Because of ongoing patent infringement litigation, however, Anchen was not able to manufacturer or market its product at that time.[140] Approximately one month later, Biovail filed a citizen petition with the FDA requesting that all ANDA applications, include additional bioequivalence studies that were contrary to the Hatch-Waxman Amendments and the FDA's protocols.[141] It took the FDA more than a year to rule on and subsequently deny GSK and Biovail's citizen petitions.[142] Annual sales of Wellbutrin XL exceeded $1.8 billion a year.[143] Every month the FDA spent reviewing Biovail's meritless petition, generic products were denied market entry and Biovail and GSK earned more than a billion dollars in revenues from consumers and direct purchasers.[144]

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.[145] In 2004, as the end of GSK's exclusivity period for Flonase approached, GSK filed four successive citizen petitions.[146] These petitions requested that the FDA "establish a complete and methodology" for flonase before approving an ANDA.[147] In denying this request, the Agency noted that neither the Act nor regulation require the FDA to issue final guidance before approving an ANDA.[148] In addition, the FDA noted the GSK failed to provide any authority its request.[149] The FDA also found that GSK's assertion that in vitro tests required use of a geometric mean methodology "irrelevant."[150]

In denying GSK's motion to stay, the FDA found GSK's justification that it needed the stay because "the balance of equities" will shift to GSK's detriment once generics are approved for marketing unpersuasive.[151] The FDA 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."[152] The filing and FDA review of GSK's petition delayed successfully generics from entering the market for 2 years.[153]

These two recent cases raise questions as to whether the recently enacted 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.[154] 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. In addition, neither the regulations nor the draft guidance defines what criteria the FDA uses to determine "intent to delay" petitions.[155] The FDA also indicates that its failure to respond to a citizen petition within the required 180 days is not a petition denial, but a "final agency action".[156] The regulations, however, fail to clarify what this means for challenging such a "final agency action". In addition, the regulations fail to specify the types of health or safety concerns that would require staying the ANDA.[157] Finally, the regulations and draft guidance fail to detail sanctions or penalties for submitting delaying or fraudulent petitions. As a result, filing sham petitions remains a relatively cost and risk free strategy for brand-name manufacturers to retain market share.

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

As illustrated in the cases above, activities aimed at manipulating the government process by brand-name manufacturers to eliminate competition and harm customers would seem to be the exact conduct the Sherman Antitrust Act was designed to prevent.[158] 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 have come to be known as the *Noerr-Pennington* doctrine.[159] This doctrine provides immunity for conduct aimed at persuading the government of a position even if the conduct interferes with competition; "such conduct is classic petitioning activity protected by the First Amendment and such actions may not be limited by the Sherman Act."[160] However, this immunity is not absolute. This section introduces the origins doctrine, describes some of the difficulties encountered by lower courts in applying the *Noerr-Pennington* sham exception corollary, and finally addresses the shortcomings that arise in the courts' current approach.

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 "mere solicitation of governmental action with respect to the passage and enforcement of laws".[161] 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 to encourage the passage of laws destructive to the trucking business as well as damage the existing relationships between truckers and their customers.[162]

The Supreme Court held that these claims failed to state a cause of action based on two separate grounds. First, the Sherman Act does not regulate political activity nor infringe on the concept of representation.[163] Second, the Court determined that holding against the railroads "would raise important constitutional questions" about the right to petition the government.[164] 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.[165] 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 disadvantage to their competitors."[166]

In *Noerr*, the Court also laid the foundation for what is the only widely recognized exception to *Noerr-Pennington* immunity, the "sham exception". The Court stated that 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." [167] The Court explained that in such situations, application of antitrust laws would be appropriate.[168]

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 efforts directed at executive officials or governmental agencies are immune from antitrust liability.[169] In *Pennington*, a mine workers' union and a group of large industry mines petitioned the Secretary of Labor and a federal agency to raise the minimum wage.[170] The effect of the increase would squeeze out smaller firms that sold coal on the spot market.[171] Reiterating that the party's intent under *Noerr* analysis is irrelevant, the Court held that "[j]oint efforts to influence public officials do not violate antitrust laws even though intended to eliminate competition."[172]

The Court rounded out the applicability of the doctrine in *California Motor Transport Co. v. Trucking Unlimited* by extending the doctrine to protect petitions to courts and administrative agencies from antitrust liability. [173] The Court also clarified that the immunity afforded by the doctrine is founded in the constitutional right to petition the government for redress of grievances.[174] Finally, the Court elaborated on *Pennington's* dicta regarding limitations on the doctrine concerning sham petitioning.[175]

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"[176] to defeat applications by the in-state carriers to acquire operating rights.[177] The Court found that this type of conduct fell under the "sham" exception, which renders the Noerr-Pennington defense inapplicable.[178] 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."[179]

The Court differentiated the exception's application in political and non-political arenas.[180] The Court reasoned that while unethical conduct in political contexts is protected, "[t]here 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."[181]

Because of the Court's distinction, two separate rules were created to determine applicability of the sham exception. For political matters, the sham doctrine applies to petitioning activity "not genuinely aimed at procuring favorable governmental action".[182] In addition, a successful effort to influence the legislature is never a sham.[183] While the Court did not specify precise parameters of the "sham" exception, it did identify several activities that might qualify.[184] It took the Supreme Court over thirty years before it defined the test for the sham doctrine in the nonpolitical realm in *Professional Real Estate Investors, Inc. v, Columbia Pictures Industries, Inc.* (*"PRE"*).[185]

B. Sham Exception

In *PRE*, the Court outlined the two-part test to determine when litigation is a sham and thus stripped of Noerr-Pennington immunity.[186] 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."[187] If the lawsuit is "reasonably calculated to elicit a favorable outcome", the suit is immunized under the doctrine and the sham exception does not apply.[188] Second, in addition to the suit being objectively baseless, courts must also consider the "litigant's subjective motive".[189] A lawsuit is a sham when 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."[190]

While the *PRE* Court sets forth a two-part sham litigation test, the majority's articulation of the "objectively baseless" component is faulted as being unclear.[191] The majority first defined objectively baseless as one that "no reasonable litigant could realistically expect success on the merits." [192] Later in the opinion, Justice Thomas likens the first prong to a determination as to whether a lawsuit is "without probable cause in the malicious prosecution sense."[193] In another part of the opinion, the Court refers to the language in Federal Rule of Civil Procedure Rule 11 to define the standard.[194] In his concurring opinion, Justice Souter points out the inherent confusion contained in the majority's opinion. He notes that whether "probable cause" exists is a different inquiry than whether a reasonable litigant could realistically expect success on the merits.[195] Justices Stevens and O'Connor also take exception to the majority' opinion for its "unnecessarily broad dicta."[196] Writing separately, they maintain "objectively baseless" should mean "objectively unreasonable."[197] A strong inference from these concurring opinions is that to the extent that the majority equates objectively baseless with lack of probable cause, the sham exception is unnecessary restricted.[198] For example, applying the Court's current articulation of the first prong is to say that, a brand-name manufacturer's citizen petition maybe sufficiently weak to establish that there was no reasonable expectation of success, yet not so devoid of merit as to lack probable cause.

Another problem created by the *PRE* sham exception is that the Court flatly refused to address how fraud or misrepresentation factored into a determination of the two steps of

the sham litigation test. Unlike in *California Motor*, which implied that fraud could render the doctrine inapplicable, the *PRE* Court stated, "We 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."[199]

Prior to *PRE*, federal courts were uniform in their application of the sham doctrine to strip Noerr-Pennington immunity from plaintiffs who made misrepresentations in non-political forums.[200] The *PRE* Court, however, called the rationale of these opinions into question. As a result, courts' and administrative agencies' treatment of misrepresentation is inconsistent. For example, the Ninth Circuit recognizes intentional misrepresentations as a subset of the sham doctrine when two criteria are met. First, the misrepresentations must occur in the adjudicatory setting and second, they must "deprive the litigation of its legitimacy."[201] The Third Circuit has refused to recognize a distinct misrepresentation exception to the *Noerr-Pennington* doctrine, but does treat misrepresentation as a permutation of sham and applies a modified *PRE* test.[202] The courts in this circuit inquire whether a petition is objectively baseless, "without regard to those facts that [were alleged to be] misrepresented". If it is determined 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.[203] The FTC recognizes statements lose N*oerr-Pennington* immunity doctrine 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.[204]

A major result of the Supreme Court's *PRE* decision is disparity among the lower courts' application of the sham exception's "objectively baseless requirement." Another result is the articulation of a standard that has failed to afford generic manufacturer's judicial relief in pursuing Section 2 Sherman violations. An analysis of a recent case that showed early signs of changing this was *Louisiana Wholesale Drug Co. v. Sanofi-Aventis.*[205]

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 Section 2 of the Sherman Act.[206] Aventis had 5 ½ years of exclusive marketing rights for the drug Arava in 10-milligram (mg), 20-mg, and 100-mg strengths.[207] Arava is the branded version of leflunomide, a rheumatoid-arthritis drug.[208] On March 10, 2004, the day Aventis' patent expired, several generic wholesalers submitted ANDAs to the FDA seeking approval to market and sell generic equivalents of Arava.[209] One year into the Agency's review of the ANDAs, and on the eve of their approval, Aventis filed a citizen petition with the FDA. [210]

Aventis's petition raised bioequivalence and safety concerns.[211] Specifically, Aventis requested that the FDA withhold final approval of any applicant's ANDA that did not seek approval of a 100mg leflunomide tablet that was bioequivalent to the Arava 100-mg

tablet or that failed to perform bioequivalence testing to confirm that five of its 20-mg tablets were bioequivalent to one 100 mg tablet.[212] 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 mg tablets as an alternative to the 100mg; or (2) to reference a 100mg tablet that the generic did not manufacture.[213] The FDA denied the petition six months later and approved the ANDAs the same day.[214] In denying the petition, the FDA noted that Aventis' requested relief that appeared to be "based on a false premise" and not supported in the FDCA or regulations.[215]

LWD filed a suit on August 17, 2007, alleging that the citizen petition by Aventis was "objectively baseless" and submitted simply for the purpose of delaying generic competition, thereby preserving its ability to charge higher prices for Arava.[216] Aventis moved to dismiss the suit based on the *Noerr-Pennington* doctrine. [217]

In denying the defendant's motion, the court relied on *California Motors* to distill the issue.[218] "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."[219] The court relied on precedent that meritless petitions filed to impose delay and expense on a rival will subject a defendant to antitrust liability.[220] 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."[221] 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 leflunomide."[222]

LWD alleged that Aventis' health and safety concerns were a sham intended to delay the entry and approval of generics drugs into the market.[223] The FDA record showed that the primary concern raised in Aventis' citizen petition was that the ANDAs violated labeling regulations.[224] 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.[225] The FDA denied the petition in part because Aventis itself had used such cross-references in similar circumstances.[226] In evaluating Aventis' 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.[227] The court found such deficiencies sufficient at the pleading stage to satisfy the sham exception and prevent dismissal of LWD's lawsuit.[228] In elaborating on its sham exception analysis, the court determined that, as a sophisticated pharmaceutical manufacturer familiar with FDA regulations and practices, Aventis had no reasonable basis to believe its Citizen Petition was viable.[229]

The court reiterated this reasoning when it denied Aventis' motion for summary judgment.[230] The district court detailed how each of Aventis' three requests for relief contradicted FDA regulations and practice.[231] The court concluded that the record made clear that Aventis was fully aware that neither law nor practice supported their claims.

As a result, the court held that genuine issues of fact existed regarding Aventis' objective basis for filing its petition. [232]

At a trial on the merits, the jury was instructed that its objectively baseless determination turned on whether "a reasonable pharmaceutical manufacturer could have realistically expected the FDA to grant the relief sought by Sanofi-Aventis in the citizen petition."[233] The jury returned a verdict in favor of Aventis.[234] LWD filed a motion for judgment as a matter of law, or in the alternative, for a new trial.[235]

The court denied both motions. In denying LWD's request for a new trial, the court reviewed the jury's application of the sham exception to Aventis' conduct.[236] Under the *PRE* inquiry the jury was charged with determining whether Aventis had probable cause to institute legal proceedings.[237] The court noted that probable cause included "actions arguably warranted by existing law" and that "[e]ven 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."[238] 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.[239]

IV. The Right Prescription

The *Louisiana Wholesale* case illustrates the limitations in the judicial system's ability to adjudicate sham petition claims. These factors range from a conflicting "objectively baseless" standard to a jury's ability to parse through the data substantiating legitimate health and safety concerns. To the extent that 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 former Judge Robert Bork, "the modern profusion of . . . government authorities offers almost limitless possibilities for abuse,"[240] and that "predation by abuse of governmental procedures . . . presents an increasingly dangerous threat to competition." [241] He warns that sham litigation is a particularly effective method of predation. Even when the petitions are unsuccessful, they can inflict substantial costs on a competitor and delay that competitor's entry into the market.[242] What follows are recommendations to safeguard the process and thus the availability to consumers of lower-cost bioequivalent drugs.

A. Two Parts Regulatory

Safeguarding the citizen petition process requires additional regulatory reforms. Section II of this Article outlines several questions left unanswered by the recently enacted FDAAA. The Agency needs to define what constitutes a delaying petition. Similar to the Agency's disposition of delaying petitions, the FDA should dismiss automatically petitions based on fraud and misrepresentations as well as serial petitions. In addition, the FDA should pursue criminal penalties for false or misleading petitions under the False Claims Act.[243] The FDA should identify petitions dismissed under any of these categories as "objectively baseless". FDA determinations on citizen petitions are considered final and appealable in court.[244] A strong argument exists that unless the FDA

determination is arbitrary or capricious, that the Agency's decision should be admissible to establish the objectively baseless criteria in a future violation of Section 2 of the Sherman Section Act allegation.[245]

Abusing government processes will continue as 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 that concern ANDAs to the FTC or Department of Justice. In addition, 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.[246] Possible sanctions would have included a fine of up to one million dollars, a suspension or permanent revocation of the right of the violator to file future citizen petitions and a dismissal of the petition.[247]

Adherence to the 180-day regulatory review requirement remains an area for improvement. Unbundling the ANDA approval process from the process for review of other citizen petitions has improved efficiency. In 2009, however, the FDA still did not complete all citizen petition reviews within the required 180 days.[248] Stricter agency adherence to the regulatory timeframes would increase efficiency and decrease brand-name manufacturers' ability to benefit from unofficial patent extensions due to delay incurred during the FDA review process.[249]

The FDA can also improve the speed of its internal review process. Rather than the current system of consecutive reviews by legal and scientific experts, the Agency could route a petition based on an initial determination as to whether it raised valid legal or scientific concerns.[250] If the petition raised both legal and scientific issues, the FDA would forward the petition to the appropriate legal and scientific offices simultaneously to allow for parallel review of the concerns.[251]

Another regulatory improvement would be for the FDA to impose a timeframe for citizen petition submissions. Similar to the predefined comment period for citizens to respond to a proposed FDA rule, citizens would have 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 expeditiously and in time for an approved generic to go to market without an unjust delay. These regulatory reforms aimed at eradicating delays in the approval of ANDAs due to sham petitions would decrease the incentives for brand-name companies to submit these 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 in the areas of interpreting congressional statutes.[252] 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.[253]

That deference also extends to an agency's ability to formulate its own procedures. It has long been held by courts that agencies have broad discretion in defining and applying rules for public participation in agency matters.[254] The Supreme Court has established that courts must refrain from requiring procedural boundaries – even in cases when the proposed regulation would alter rights and obligations critical to the general public.[255] Courts defer entirely to the agency the determination as to what procedures are needed.[256] The FDA's broad authority is rooted in the belief that federal agencies are best suited to address the public's needs.[257] 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.[258] Given the FDA's expertise, that deference seems justified.

That sphere of deference extends to judicial review of agency factual determinations as well. The APA requires courts to uphold factual determination rendered in informal proceeding unless they are "arbitrary, capricious, [or] an abuse of discretion" and to review findings of fact in formal proceedings under a "substantial evidence" standard.[259] 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." However, the citizen petition review process is not set format. A commissioner may use several different procedures in reviewing the petition including hearings, conferences, or any other applicable public procedure identified by the FDA.[260] This process appears analogous to an informal proceeding. As such, an argument exists that 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."[261] 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* sham exception requirement. Depending on how expansively the Agency interprets this new provision, the delaying petition designation could provide a vehicle to safeguard the integrity of the process by allowing the FDA to apply the "delaying petition" designation to claims that may have on their face raised a valid legal or scientific concern but after analysis were found to be shams. This 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 including scientists, chemists, and attorneys.[262] Based on their determinations, the FDA decides whether the claim has merit and warrants Agency action.[263] During the citizen petition review process, parties

can submit additional information and amend their responses.[264] Similar to the reasoning expressed above, at a minimum, courts uphold Agency findings of fact unless they are "unsupported by substantial evidence."[265] In subsequent antitrust lawsuits, proper deference to these FDA determinations could be determinative in meeting the first prong of the sham exception.

The *PRE* standard for sham exceptions has been the subject of much scholarly ferment.[266] It is unlikely that this debate regarding the appropriateness of the exception's requirements will be resolved in the near future. This Article supports the conclusion of other critics that the second prong – that of establishing subjective intent - is redundant and should be eliminated.[267] In the alternative, this Article proposes a compromise. Arguably, in rendering delaying petition determinations, the FDA's citizen petition analysis of the petitioner's subjective intent to harm competition may not meet the *PRE* level of rigor. 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 "objectively baseless" under either permutation of the standard. [268] 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 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, so far, proven an ineffective tool to curb that type of conduct. To recast the parameters of the *Noerr-Pennington* doctrine and its sham exception and to police bad-faith brand-name manufacturers would require a re-balancing, or at least a more nuanced 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.

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[1] Patent Terms Extended Under 35 U.S.C. §156, *available at*, http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html.

[2] Pharmacytimes.com, *Hatch-Waxman Act 25 Years Later*, http://www.pharmacytimes.com/supplement/pharmacy/2009/GenericSupplement0809/Generic-HatchWaxman-0809 (last visited March 10, 2010).

[3] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at*

hhtp://www.cbo.gov/showdoc.cfm?index=655&seq=0). [hereinafter CBO, Report].

[4] Mark D. Whitener, Competition and Antitrust Enforcement in the Changing Pharmaceutical Marketplace, 50 FOOD & DRUG L.J. 301, 307 (1995).

[5] Pharmaceutical Marketplace Reform: Is Competition the Right Prescription":Hearing Before the Senate Special Comm. On Aging, 103d Cong., 1st Sess. 102 (1993) (statement of Mark D. Whitener, Acting Deputy Director, FTC Bureau of Competition).

[6] Federal Trade Commission, Enforcement Perspectives on the Noerr-Pennington Doctrine: An FTC Staff Report (2006) *available at* http://www.ftc.gov/reports/P013518enfperspectNoerr-Penningtondoctrine.pdf) [hereinafter FTC Staff Report].

[7] The *Noerr-Pennington* doctrine is grounded in three Supreme Court cases. *Eastern Railroad Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mineworkers of America v. Pennington*, 381 U.S. 657 (1965); and *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

[8] Sherman Antitrust Act, ch 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. 1-7 (1988)). The statute prohibits contracts, combinations and conspiracies in restraint of trade as well as efforts to monopolize trade. *See* 15 U.S. C. 1, 2 (2006). *See also* FTC Staff Report at 3, 6.

[9] *Eastern Railroad Presidents Conference v. Noerr*, 365 U.S. 127, 137-38 (1961).

[10] *Id.* at 144.

[11] FTC Staff Report; *see also Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis* 2009 U.S. Dist. LEXIS 77206 (S.D.N.Y. Oct. 14, 2009).

[12] Federal Drug Administration Revitalization Act of 2007 (FDARA) Public Law No.110-85.

[13] *Louisiana Wholesale Drug Co.,* 2009 U.S. Dist. LEXIS 77206.

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

[15] CBO Report *see infra*, note 3. See also Federal Trade Commission Statement, *Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry* Before the Subcommittee on Commerce, Trade and Consumer Protection Committee on Energy and Commerce United Sates House of Representatives (May 2, 2007), available at http://www.ftc.gov/os/testimony/P859910%20Protecting_Consume_%20Access_testimony.pdf (Generic drugs enter the market priced 20 to 80% lower than their brand-name counterparts. They typically acquire substantial market share from their brand-name competitor in a short period of time. Subsequent generic entrants may enter at even lower prices, normally 20% of the brand-name drug's price. This added competition prompts the initial generic drug to lower its price even more.)

[16] FDA Facts and Myths about Generic Drugs, available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm

[17] FDA Facts and Myths about Generic Drugs, available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Understanding

GenericDrugs/ucm167991.htm.

[18] Rebecca S. Yoshitani, Antrust and Health Care *Symposium: Pharmaceutical Reformulation: The Growth of Life Cycle Management*, *7* HOUS. J. HEALTH L. & POL'Y 379, 379-380 (2007).

[19] Marina Lao, Reforming the Noerr-Pennington Antitrust Immunity Doctrine, 55 RUTGERS L. REV. 965, 992-993 (2003).

[20] 21 U.S.C. §301-307;*see also* 1962 Amendments to the Food, Drug and Cosmetics Act, Pub. L. No. 87-781, 76 Stat. 780 (1962);Kristin Behrendt, The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest? 57 Food Drug, L.J. 247, 249 (2002) (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).

[21] *New Drug Application (NDA)* Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., New Drug Application, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited Feb. 26, 2010).

[22] Yoshitani, *supra* note 18, at 82.

[23] Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food Drug L.J., 187, 187 (1999); Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study [hereinafter FTC Study] (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf at 3 ("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").

[24] *Id.*

[25] Pamela J. Clement, *The Hatch-Waxman Act and the Conflict Between Antitrust Law& Patent Law*, 48 IDEA 381, 385 (2008).

[26] FTC Study at 4.

[27] See *Roche Products Inc., v. Bolar Pharmaceutical Co*., 733F.2d 858 (Fed. Cir. 1984)(Bolar was preparing a generic version of one of Roche's patented products. Because FDA approval could take more than two years, Bolar began its FDA required clinical trials prior to Roche's patent expired. Roche brought a patent infringement claim. In finding for Roche, the Federal Circuit held that "Bolar's intended 'experimental' use is solely for business reasons . . . to derive FDA required data is thus an infringement on 0533 patent. . . . unlicensed experiments conducted with a view to the adoption of the patented invention to the experimenter's business was a violation of the rights of the patentee to exclude others from using his patented invention.*") Id.* at 862-865.

[28] *Id.*

[29] *Id.* at 864 ("It can take an average of 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements . . .The remaining effective life of patent protections [essentially] may be a low as 7 years"). *See also* Rebecca S. Yoshitani & Ellen S. Cooper, Antitrust and Health Care Symposium*: Pharmaceutical Reformation: The Growth and Life Cycle Management*, 7 HOUSTON J. HEALTH L. POL'Y 379, 382 (2007).

[30] Clement, *supra* note 25, at 386.

[31] *Roche Prods*., at 846.

[32] 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. 1, 3 (Fall 2005).

[33] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No 98-417, 98 Stat 1585 (codified in sections 15 U.S.C§§ 68b-68c, 70b(1994)., 21 U.S.C.§§301, note 355, 360cc; 28 U.S.C. §201(1994); 35 U.S.C. §§156, 271, 282 (1994). The congressional sponsors are Senator Orrin Hatch and Representative Henry Waxman.

[34] Clement, *supra* note 25, at 386, Williams, *supra* note 33, at 3.

[35] 21 U.S.C. § 355(j)(2)(A)(vii) (Law. Co-op. 1998 & Supp.); 35 U.S.C. 156 (2006).

[36] Mossinghoff, *supra* note 23, at 1900.

[37]*Id.*

[38] *Id.*

[39] FTC Study at i.

[40] Williams, *supra* note 23, at 185.

[41] *Id.* at 4.

[42] *Id.*

[43] 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. Congressional Research Service: The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents, IB 10105 (Jan. 5, 2004).

[44] 35 U.S.C. §271(e)(1) (2000).

[45] *Id.*

[46] *Id.*

[47] Ctr. For Drug Evaluation and Research, U.S. Food & Drug. Admin., Abbreviated New Drug Application (ANDA Process for Generic Drugs available at http://www.fda.gov/cder/regulatory/applications/ANDA.htm (last visited March 7, 2010). For a more detailed discussion of the Hatch-Waxman Act, see Elizabeth Stotland Weiwasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure and Legacy*, 71 ANTITRUST L.J. 585 (2003).

[48] Weiswasser & Danzis, *supra* note 47, at 585-86.

[49] See Ctr. For Drug Evaluation, *supra* note 47.

[50] The Act is reduced the time between the expiration of the brand-name drug and FDA approval of the generic drug from an average of 3 ½ years to a matter of months. CBO Report at 38.

[51] 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).

[52] 21 U.S.C. §355(j) (1994) (discussing the application and approval process for abbreviated new drug applications).

[53] Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin. Approved Drug Products with Therapeutic Equivalence Evaluations , available at http://fda.gov.cder/ob/docs/preface/ecpreface.htm.; see also Justina A. Molzon, *"The Generic Drug Approval Process"* 5 J. PHARMACY & LAW 275, 280 (1995).

[54] Molzon, supra note 53, at 277-278.

[55] *Id.*

[56] *Id.*

[57] Approved Drug Products with Therapeutic Equivalence Evaluations, 15th ed. U.S. Dept. Health Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management Divisions Information Resources, 1995, p. xii section 1.3 Statistical Criteria for Bioequivalence (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 -20%/25% or less).

[58] Williams, *supra* note 33, at 4-5

[59] Molzon, *supra* note 53, at 280.

[60] Marina Lao, Reforming The FDA's role in listing the patents in the Orange Book is purely ministerial, the Agency does not review the propriety of the listings. In addition, the Agency will only "delist" a patent from the Orange Book at the brand-name manufacturer's request. *See generally* submission of Patent Information, 21 C.F.R §. 314.53(f) (2003).

[61] Richard J. Findaly, *Originator Drug Development*, 54 FOOD & DRUG L. J., 228, 229 (1999).

[62]Molzon, *see supra* note 53, at 275.

[63] 21 U.S.C. §355(j)(4)(B)(iv).

[64] 21 U.S.C.A. §355 (j)(2)(A)(vii)(I)-(IV) (2008).

[65] Clements, *supra* note 25, at 389.

[66] 21 U.S.C. §355(j)(5)(B)(i)-(viii)(Supp. 2005).

[67] *Id.*

[68] *Id.* at §355(j)(5)(B)(i)-(ii).

[69] Pharm. Research & Mfrs of Am., White Paper on the Implementation of the Hatch-Waxman Act by the U.S. Food & Drug Administration, Jan. 18, 2002, at 10.

[70] 21 U.S.C.A. §355 (j)(2)(B)(ii).

[71] *Id.* at §355(j)(5)(B).

[72] *Mylan Pharm., Inc., v. Thompson*, 268 F.3d1323,1327 (Fed. Cir. 2001).

[73] 21 U.S.C. §355 (j)(5)(B)(iii).

[74] *Id.* at §§544(j)(5)(B)(iii), (j)(5)(C).

[75] *Id.* at §355(j)(5)(B)(iii), (j)(5)(C).

[76] *Id.* at §355(j)(5)(B)(iv)(I).

[77] 21 C.F.R §314.107 (2007).

[78] *Id.* at §355(j)(5)(B)(iv).

[79]Clement, *supra* note 25 at 390; see also FTC Study at 13.

[80] Greene, *supra* note 37, at 315.

[81] Antitrust Enforcement Agencies: The Antitrust Division 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 H. Comm. On the Judiciary, 108th Cong. 20-21 (July 24, 2003) [hereinafter Antitrust Enforcement Hearing] (statement of Timothy J. Musi, Chairman, Fed. Trade Comm'n). The Chairman observed that while the Hatch-Waxman Act has increased generic drugs availability in the market, the Act "has been subject to 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.*

[82] FTC Study *supra* note 23 at 25; *see also* Markus H. Meir, Deputy Assistant Dir. Fed. Trade Comm'n, Presentation for the California Bar Association: The FTC's Pharmaceutical Industry Cases (June 2002), available at http://www.calbar.ca.gov/calbar/pdfs/sections/antitrust/2002-06-26_generic-drug_matrials-meier.pdf (describing the process as: shortly before the generic drug is to marketed, the name-brand manufacturer lists new patents in the Orange Book, which requires the generic ANDA applicant to file a new certification that can lead to a new stay. This strategy is success in part because the FTC does not evaluate the legitimacy of the patent listing).

[83] FTC Study *supra* note 23, at 44 ("If the brand-name drug company sues within 45 days of the generic's application re-certification, then a second 30 month stay will issue.")

[84] *Id.* at 57; *see also* Competition in the Pharm. Marketplace: Antitrust Implications of Patent Settlements: Hearings Before the S. Comm. On the Judiciary, 107th Cong. 20-21 (May 4, 2001) (statement of Molly Boast, Dir. of the Fed. Trade Commission's Bureau of Competition), available at http://ftc.gov/os/2001/05/pharmstmy.htm (stating that Geneva Pharmaceuticals, Inc., made a deal with brand-name manufacturer, Abbott laboratories that Geneva to not to sell its generic equivalent of Abbott's brand-name drug, in order to prevent the triggering of the 180-day exclusivity period from running).

[85] Markus Meir see *supra* note 82 (there are three types of settlement: (1) "Final Settlements with Delayed Licenses," where in exchange for a license to sell a licensed generic equivalent, the generic manufacturer agrees not to enter the market until a specified future date; (2) "Final Settlements with Immediate Licenses" where the brand-name and generic manufacturers enter a supply agreement that enables the generic manufacturer to go immediately to market, in exchange for the generic's agreement not to trigger the 180-day exclusivity period; (3) "Interim Settlements" in exchange for a monetary payment, the generic manufacturer agrees not to market its product until the conclusion of the lawsuit.

[86] *Id.* (noting the possible anticompetitive implications of brand-name manufacturer acquiring the sole

license to a patent that may delay a generic drug's entry or prohibit present or future competition by other manufacturers).

[87] Administrative Procedures Act, 5 U.S.C. §553(d) (1975).

[88] "Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances." U.S. Const. amend. I. *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, 530 (1945) (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. 541, 552(1875) (The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government.)

[89] Notwithstanding the applicability of citizen petitions to any administrative agency matter, certain restrictions, were always intended. For example, this due process does not include the right to speak to government officials. S*ee Welch v. Board of Education of Baltimore County*, 477 F. Supp. 959 (D. Md 1979). Nor does the right to petition provide the right to an oral hearing. *See Stengel v. City of Columbus Ohio*, 737 F. Supp. 1457 (S.D. Ohio 1988)). In addition, the right to petition does not create a corresponding responsibility of the government to act or investigate. *See Smith v. Arkansas State Highway Employees*, 441 U.S. 463, 465 (1979).

[90] 21CFR §§10.20, 10.30.

[91] *Id.* at §10.30 (b).

[92] June Gibbs Brown, HHH, OIG, Review the Food and Drug Administration's Citizen Petition Process, (1998) at 1.[hereinafter OIG Citizen Petition Report]

[93] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat 1585 (1984) (codified as amended at 21 U.S.C. §355 (1994)).

[94] 21 CFR §10.30.

[95]Molzon, *supra* note 53, at 280.

[96] *Id.*

[97] 21 C.F.R. §10.30(B).

[98] Molzon, *supra* note 53, at 280.

[99] FDA, Director of the Office of Generic Drugs, Gary Buehler Special Committee Statement before Special Committee on Aging, United States Senate (July 20, 2006).

[100] *Id.*

[101] *Id.*

[102] Molzon, *supra* note 53, at 281.

[103] *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.

[104] *Id.* at 281.

[105] *Id.* 281-282. *See also* Administrative Procedures Act, supra note 87 at § 2.7. (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.) *See also* Citizen Petitions 64 Fed. Reg. 66822 - 3 (Nov. 30, 1999) (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).

[106] 21 CFR §10.30(e)(2)(i)(2000).

[107] *Id.* §10.30 (e)(2)(ii).

[108] *Id.* §10.30(e)(2)(iii).

[109] Molzon, *supra note*, 53 at 282.

[110] For example an Office of Inspector General 1998 report noted 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. OIG Citizen Petition Report *supra* note 92 at i.

[111] Citizen Petitions 64 Fed. Reg. 66821, 66822 (Nov. 30, 1999).

[112] *Id.*

[113] *Id.* at 66825. (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").

[114] Citizen Petitions, 68 Fed. Reg. 16461 (April 4, 2003).

[115] Several patents of brand-named drugs approved in the 1990s are expiring. *See generally*, United States Patent and Trademark Office, Patent Terms Extended Under 35 USC §156 *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/term/156.html. In addition, new generic firms are entering the marketing and submitting ANDAs for these products. Gary Buehler, Director of the Office of Generic Drugs Center for Drug Evaluation and Research, FDA statement before the Special Committee on Aging, United States Senate July 20, 2006. [hereinafter Buehler Statement]

[116] *Id.*

[117] *Id.* In 2006, there were approximately 170 citizen petitions before the FDA compared to 90 in 1999.

[118] Benjamin Romano, "Hurdles lock Generic Drugs" SEATTLE TIMES, Feb. 13, 2006. Approximately, 150 citizen petitions were filed that 2005, with at least 43 challenging a generic drug application.

[119]Martin Sipoff, *FDA Approach to Citizen Petitions May be a Mixed Blessing*, Managed Care , Feb. 2008 *available at* 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).

[120] FDA Chief Counsel Sheldon Bradshaw, Speech before the Generic Pharmaceutical Association Annual Policy Conference (September 19, 2005).

[121] *Id*.

[122] Press Release, Senators Kohl, Leahy Introduce Bill to Top Frivolous Citizen Petitions, Speed Generic Approval Patrick (September 26, 2006) available at http://aging.senate.gov/record.cfm?id=268246

[123] *Id*.

[124] *Id*.

[125] *Id*.

[126] Buehler Statement, *supra* note 117.

[127] 21 U.S.C. 355(q). *See also* FDAAA § 914 (adding new section 505(q) to the FFDCA governing citizen petitions request that the Agency take action pertaining to a pending ANDA submitted under section 505(b)(2) or 505(j) of the FDC Act.

[128] *Id.* 505(q)(1)(F).

[129] *Id*. at 505(q)(1)(A).

[130] *Id*. at 505(q)(1)(B).

[131] *Id*. at 505(q)(1)(H).

[132] *Id*. at 505(q)(1)(E).

[133] *Id*.

[134] GPhA Citizen Petition Position, available at http://www.gphaonline.org/issues/citizen-petitions (last visited March 15, 2010).

[135] HHS, Center for Drug Evaluation and Research, Draft Guidance for Industry Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (January 2009).

[136] *Id*.

[137] 2009 U.S. Dist. LEXIS 21286 (Mar. 13, 2009).

[138] *Id*. at *3.

[139] *Id*. at *11.

[140] *Id*.

[141] *Id*.

[142] *Id*.

[143] Letter from Senators Debbie Stabenow and Trent Lott to FDA Acting Commissioner Andrew von Eschenbach, (June 2006) (the senators alleged that the delaying approving the generic version of Wellbutrin XL cost consumers approximately 37 million dollars a month.) *See also* Wellbutrin XL recap available at http://www.hagens-berman.com/frontend?command=Lawsuit&task=viewLawsuitDetail&iLawsuitId=2115

[144] *Id.*

[145] *Roxane Laboratories Inc., v. SmithKline Beecham Corp*., 2010 WL 331704 (E.D.PA. Jan. 26, 2010).

[146] *Id.* at 1.

[147] HHS, FDA Consolidate Response to GlaxoSmithKline's Multiple Citizen Petitions (2004P-206/CP1; 2004p-239CP1, & PSA1, SUP1, SUP2, 2004P-348/CP1 & SUP1; 2004P-0523/CP1 &PSA1 to the FDA (Feb. 22, 2006) at 1.

[148] *Id.*. at 21.

[149] *Id.*

[150] *Id.* at 11.

[151] *Id.* at 23.

[152] *Id.*

[153] *Roxane Laboratories*, at *1.

[154] 2009 FDAAA Implementation – Highlights Two Years After Implementation, available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm184271.htm (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).

[155] 21 U.S.C. §355 at 505(q)(1)(E).

[156] *Id.* at 505(q)(1)(F).

[157] *Id.* at 505(q)(1)(A).

[158] 15 U.S.C. §§1-2 Section. Section One of the Sherman Act prohibits concerted activities of two or more parties to restrain trade. Section 2 applies to unilateral and concerted behavior that produces or is intended to produce monopoly power. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993); *D.R. Wilder Manufacturing Co., v. Corn Products Refining Co*., 236 U.S. 165, 173-74 (1915)(stating the intended breadth of the Sherman Act).

[159] For cases establishing the Noerr-Pennington doctrine, *see supra* note 7.

[160] *Louisiana Wholesale, Co. v. Aventis Pharma*. 2008 U.S. Dist. LEXIS 3611, (S.D.N.Y., Jan. 18, 2008) at *3 (citing *Eastern Railroad Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127, 137-38 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965)).

[161] 365 U.S. 127, 138 (1961).

[162] *Id.* at 129.

[163] *Id.* at 137. Justice Black, for a unanimous Supreme Court stated, "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." *Id.*

[164] *Id.* at 135-44.

[165] *Id.* at 139.

[166] *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." *Id.*

[167] *Id.* at 144.

[168] *Id.*

[169] 381 U.S. 657(1965).

[170] *Id.* at 660.

[171] *Id.*

[172] *Id.* at 670.

[173] 404 U.S. 508 (1972).

[174] *Id.* 510 (check).

[175] *Id.* 512-513.

[176] *Id.* at 512 (internal quotes omitted).

[177] *Id.* at 516.

[178] *Id.*

[179] *Id.*

[180] 404 U.S. at 512-13

[181] *Id.*

[182] *Allied Tube & Conduit Corp. v, Indian Head, Inc*., 486 U.S. 492, 500 n. 4 (Citing *Cal. Motor*, at 404).

[183] *Id.* at 502 ("The effort to influence governmental action in this case certainly cannot be characterized as a sham given the actual adoption of the 1981 Code into a number of statutes and local ordinances").

[184] The Court noted that perjury in the adjudicatory process, conspiracy with a licensing authority to eliminate competition and bribing a purchasing agent are all conduct that may violate the Sherman or

Clayton Acts. Id at 512. *But see City of Columbia v. Omni Outdoor Advertising, Inc*., 499 U.S. 365 (1991) (*Noerr* protections extends to lobbying in legislative conduct even when the manner is "improper or even unlawful" so long as the "regulatory process is being engaged genuinely").

[185] 508 U.S. 49 (1993). 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 Invs., 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 form institution sham administrative proceedings as flow from instituting sham judicial proceeding").

[186] 508 U.S. 49 (1993).

[187] *Id.* at 60.

[188] *Id.*

[189] *Id.*

[190] *Id.* at 60-61.

[191] 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 such in when "objectively reasonable lawsuit itself violated antitrust laws.) 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." See also Robert Faulkner, *The Foundations of Noerr-Pennington and the Burden of Proving Sham Petitions: A Historical-Constitutional Argument in Favor of a Clear and Convincing Standard*; 28 USFLR 681, 687-690 (After the Supreme Court's PRE decision, the "existence or non-existence of sham is still a difficult line to discern and draw") *Id.* at 688.

[192] *Id.* at 60.

[193] *Id.* at 62-63 n.7.

[194] *Id.* at 65 Fed. R. Civ. P. 11(b)(3) (imposing sanctions on attorneys in some circumstanced for filing claims in federal court that are unsupported by evidence).

[195] Id at 66-67 (Souter, J. concurring) (agreeing with the objective baseless standard as it is used in the sense that no reasonable litigant could realistically expect success on the merits: but disagreeing with the "probable cause definition and reference to Rule 11 standards).

[196] *Id.* at 67.

[197] *Id.* at 67-68.

[198] "Under our decision today, therefore, a proper probably cause determination irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to Noerr immunity." *Id.* at 63. But the in the same opinion the majority stated that "probable cause" meant "no more than a reasonable belief that there is a chance that [a] claim may be held to valid upon adjudication." *Id.* at 62-63 (citations omitted).

[199] *Id.* at 61 n.6.

[200] *E.g., 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 & Producing Co. v. Aluminum Co. of Am.*, 438 F.2d 1286, 1298 (5th Cir. 1971); *Outboard Marine Corp. v. Pezete*l, 474 F. Supp. 168, 179 (D. Del. 1979); *Mktg. Assistance Plan, Inc. v. Associated Milk Producers, Inc*., 338 F. Supp. 1019, 1024 (S.D. Tex. 1972); *Potters Med. Ctr. v. City Hosp. Ass'n*, 800 F.2d 568, 580-81 (6th Cir. 1986).

[201] *Kottle v. N.W. Kidney Ctrs*., 146 F. 3d 1056, 1060-1 (9th Cir. 1998).

[202] *Cheminor Drugs Ltd. V. Ethyl Corp*., 168F.3d 119,123 (3d Cir. 1999).

[203] *Id*.

[204] Union Oil Co. of Cal (Unocal), FTC Dkt. No. 9305, slip op (2004) (opinion of the Commission) at 58. Available at http://www.ftc.gov/os/adjpro/d9305/040706commissionopinion.pdf.

[205] 2009 U.S. Dist. LEXIS 77206(S.D.N.Y 2009).

[206] *Id.* at *1.

[207] 2008 U.S. Dist. LEXIS 3611 (S.D.N.Y.) 3611 at *4.

[208] *Id*. *2

[209] *Id*. at *4-5.

[210] *Id.* at *5-6.

[211] 2008 U.S. Dist. LEXIS 8132 at *6-9.

[212] *Id*.

[213] *Id*.

[214] *Id*. at *10

[215] 2009 U.S. Dist. LEXIS 77206 at *7.

[216] *Id*. at *8.

[217] 2008 U.S. Dist. LEXIS 3611 (S.D.N.Y.) 3611 * 2-3.

[218] *California Motor Transp*. 404 U.S. at 512.

[219] *Id*.

[220] *Id.* at 12, see also New York Jets, 2005 U.S. Distr. LEXIS 23763, at *21-22 (holding 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).

[221] *Id*.

[222] *Id.* at 13.

[223] *Id.* *14.

[224] *Id.* *14-16.

[225] *Id.*

[226] *Id.*

[227] *Id.* * 16-17.

[228] Id *17.

[229] *Id.* at *14.

[230] 2008 U.S. Dist. LEXIS 8132 at *3.

[231] *Id.* at *13-17.

[232] *Id.* at *17-18.

[233] 2009 U.S. Dist. LEXIS 77206 at *14

[234] *Id.* at * 3.

[235] *Id.* at *3-4.

[236] *Id.* at 4.

[237] *Id.* at *14.

[238] *Id.*

[239] *Id.* at *12.

[240] Robert H. Bork, the Antitrust Paradox: A Policy At War with Itself 347 (1993).

[241] *Id.*

[242] *Id.* at 347 -78.

[243] See *supra note* 98.

[244] 21 C.F. R. §10.45(d).

[246] The Citizen Petition Fairness and Accuracy Act of 2006 S. 3981, 109th Cong. (2006); *see also supra* note 124.

[247] *Id.*

[248] *See supra* note 156.

[249] 21 C.F.R. §10.30 (e)(2) ("Commissioner shall furnish a response to each petitioner within 180-days

of receipt of the petition").

[250] Letter from Kathleen D. Jaeger, President Generic Pharmaceutical Association to Dr. Andrew C. Von Eschenbach, Commissions of the Food and Drug Association (Dec. 15, 2005) (on file with author)

[251] *Id.*

[252] *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S 837, 848-44 (1984) (requiring deference to agency determinations of statutes).

[253] 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).

[254] *Cities of Statesville, et. Al. v. Atomic Energy Commission*, 441 F.2d 962 (D.C. Cir. 1969); *Pasco Terminals, Inc., v. United States*, 477 F. Supp. 201 (1979) *aff'd* 634 F.2d 610.

[255] *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc*. 435 U.S. 519, 524 (1978).

[256] *Id.*

[257] Jeffery E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. LEGIS. 291, 292 (2001).

[258] See *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 651 (D.D.C. 1992), *vacated as moot*, sub. Nom., *Schering Corp. Shalala*, 995 F.2d 1103 (D.C. Cir. 1993); *Fissions Corp. v. Shalala*, 860 F. Supp. 859 (D.D.C. 1994); *Schering Corp. v. FDA*, 51 F. 3d 390 (3rd Cir. 1995); *cert. denied* 116 S. Ct. (1995).

[259] Administrative Procedure Act Section 706(2)(A); (E).

[260] 21 C.F.R. §10.30(40(h)(1-5).

[261] 505(q)(1)(E).

[262] *See supra* note 147(components of the FDA response's provide a comprehensive evaluation of and response to each of the scientific, mathematical, chemical, and regulatory claims raised in Biovail's petitions).

[263] 21 C.F.R. §10.30 (e)(2)(i-iii).

[264] *Id.* at §10.30(c).

[265] Administrative Procedure Act §§ 706(2)(A); (E).

[266] *Supra* notes 191 and 195.

[267] Lao, *see supra* note 19, at 1025.The subjective test of the sham exception was first articulated in a legislative setting. *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, then the act of filing suit already demonstrates lack of good faith and brought to harass the other party. Accordingly, the subjective prong is unnecessary.