CITIZEN PETITIONS: A PROCESS HIJACKED BY BIG PHARMA?

Health care reform permeates American politics unlike any other issue, and no wonder; health care in the United States is the most expensive per capita among all developed nations in the world.\(^1\) Prescription drugs, which can be attributed to nearly a fifth of all expenses related to health care in the U.S., are a primary driver of the skyrocketing costs.\(^2\) Placed within this context, brand-name pharmaceutical products, usually protected by patents and government monopolies for a portion of their product life-cycle, are particularly troubling. While brand-name pharmaceuticals make up only 10\% of all prescriptions in the United States, they account for nearly three-quarters (72\%) of drug spending.\(^3\) Astoundingly, costs for the most common brand-name drugs rose by 165\% between 2008 and 2015, while the consumer price index rose merely 12\% during that same span.\(^4\) Obscure and seemingly innocuous to everyday consumers, the Food and Drug Administration’s (FDA) citizen petition process represents a stealthy and increasingly popular strategy for brand-name pharmaceutical manufacturers to delay the entry of cheaper generic competitors into the market, costing Americans hundreds of millions of dollars in the process.

Astronomical overnight price hikes and stories of “big-pharma” corporate greed steal headlines, stirring passionate debate over the duties brand drug companies owe to each party in the American health care system. In 2015 Turing Pharmaceuticals increased the price of Daraprim, used to prevent nervous system infection in AIDS patients, by 5,500\%.\(^5\) In 2016 Mylan, the maker of the epinephrine auto injector (EpiPen) initiated a 400\% price hike of the popular drug.\(^6\) Amidst a backdrop of the country’s opioid crisis, Kaleo Pharma recently increased the price of their emergency injector for a drug called naloxone, used to revive people overdosed on painkillers, approximately 600\%, bringing the price for one of the auto-injector devices to roughly $4,500.\(^7\) Thus, as brand-name drug prices can, and frequently do spike

\(^2\) Id.
\(^3\) Id.
\(^4\) Id.
\(^5\) Id.
\(^6\) Id.
dramatically in the blink of an eye, the question of whether the price of pharmaceuticals reflect the actual value to patients and the country’s healthcare system quickly sharpens into focus.

A popular answer is no; the price of brand-name drugs do not reflect actual value, big-pharma profits far outstrip R&D costs, and the price hikes are a result of corporate greed made possible by a variety of anti-competitive strategies aimed at keeping cheaper generic versions off the shelves. While strategies such as sham litigation, “pay for delay” settlements, patents obtained through data falsifications, and product hopping immediately conjure up mental images of shady executives in a smoky back room coolly calculating their next corrupt move, the term “citizen petition” sounds innocent and civically minded. In reality, however, the seemingly innocuous citizen petitions represent an increasingly popular low-risk method for brand-name drug manufacturers to delay the entry of cheaper generic competitors into the market.

Theoretically grounded in the First Amendment’s guarantee of the right to petition the government, citizen petitions are procedurally rooted in the Administrative Procedure Act’s grant to interested persons the power to “petition federal agencies regarding the adoption, alternations, or rejection of the agency’s rules.” In accordance with the Administrative Procedure Act, the FDA has adopted regulations opening an avenue for individuals to lobby the FDA on decisions regarding health, scientific, or legal concerns with a product via citizen petitions. While in theory individuals can file citizen petitions to influence the FDA, in practice, brand-name manufacturers are overwhelmingly the filers of such petitions. According to a study analyzing petitions from 2011 to 2015, brand-name drug companies filed 92 percent of 505(q) citizen petitions, a specific type related to pending generic drug applications, though 92 percent those brand-name filed petitions were ultimately rejected by the FDA. By petitioning the FDA to review voluminous materials and studies and ultimately make a decision on the safety of a drug, brand-name manufacturers force the FDA to expend considerable time addressing the merits of every petition filed, thus delaying generic approval and entry to the consumer market.


*Id.* at 121.

Though citizen petitions create only a temporary impediment to generic drugs hitting the shelves, and recently amended FDA rules require that citizen petitions with the potential to affect generic approval be considered within 150 days, there numerous examples of “big-pharma” employing multiple citizen petitions to block generic entry up to two years.\footnote{11} For example, in the \textit{In re Flonase Antitrust Litigation}, GlaxoSmithKline, producer of Flonase, a nasal spray for allergy treatment, achieved a twenty-three month delay of generic approval through the use of citizen petitions.\footnote{12} Those extra twenty-three months of monopoly profits were worth approximately $2.5 billion in sales.\footnote{13}

The delay’s impact, whether less than 150 days or up to two years, is significant and could be worth hundreds of millions of dollars in additional revenues for manufacturers, and costs for consumers.\footnote{14} Not only does the brand product lose 44\% to 90\% of its market share within the first twelve months of generic entry, but prices are dramatically driven down with the entrance of each additional generic product.\footnote{15} Drug prices lower approximately 50\% with the presence of the second generic option, and by the time six or more generics enter, prices fall to roughly 25\% of the original brand price.\footnote{16} These statistics highlight why brand-name pharmaceutical manufacturers are highly incentivized to try to delay the entry of generic competition by any means possible, and why stealthy and comparatively cheap-to-employ citizen petitions have become a popular low-risk strategy to achieve anticompetitive objectives.

While the idea of filing petitions that the FDA is required to review is made possible by the First Amendment and the Administrative Procedure Act, the \textit{Noerr-Pennington} doctrine makes the process amenable to pharmaceutical companies who wish to file citizen petitions in order to block the introduction of cheaper generics.\footnote{17} Furthermore, the \textit{Noerr-Pennington} doctrine generally immunizes “big-pharma” from anti-trust liability in connection with frivolous citizen petitions.\footnote{18} The doctrine emanates from two mid-twentieth century Supreme Court cases, \textit{Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.} and \textit{United Mine Workers v. Pennington}. In the cases, the Court

\begin{itemize}
  \item \footnote{12} \textit{Id} at 526.
  \item \footnote{13} \textit{Id}.
  \item \footnote{14} Carrier & Minniti, \textit{supra} note 10, at 311-312.
  \item \footnote{15} \textit{Id} at 312.
  \item \footnote{16} \textit{Id}.
  \item \footnote{17} Avery & Newsom & Hahn, \textit{supra} note 8, at 127.
  \item \footnote{18} \textit{Id}.
\end{itemize}
established that efforts to petition the government, including legislators, administrative agencies, and courts are immune from antitrust lability, even if the efforts were aimed towards anticompetitive purposes.\textsuperscript{19} The Court found the basis for such immunity to be grounded in the First Amendment’s right to petition the government, “finding that such immunity was necessary to protect a citizens ability to participate in government.”\textsuperscript{20} Thus, the Noerr-Pennington doctrine applies with full force to citizen petitions filed by drug manufacturers, even if they are filed for the purpose of delaying generic approval, because the process is a lawful, statutorily defined means of petitioning a government agency.\textsuperscript{21}

Though the breadth of the doctrine provides a robust, seemingly all-encompassing defense for brand-name pharmaceutical manufacturers against antitrust suits filed against them related to citizen petitions, “one widely recognized exception to this doctrine exists: the “sham exception.”\textsuperscript{22} Noerr-Pennington immunity does not shield attempts to influence government action when the conduct (filing of a citizen petition) is a “mere sham” actually aimed at harassment of a competitor.\textsuperscript{23} Thus, when a brand-name pharmaceutical company “uses the process of petitioning, as opposed to the outcome” to cause anticompetitive harm, Noerr-Pennington protection does not apply.\textsuperscript{24} The scope of the exception is fact-driven and determined by case-by-case context. For example, if the allegedly offense anticompetitive behavior “is the result of valid governmental action,” or it actually influences legislative action, the conduct will not fall into the sham exception.\textsuperscript{25} Attempts to influence the government through citizen’s petitions may fall into the “sham exception” under a two-part test the Supreme Court developed in Professorial Real Estate Investors v. Columbia Pictures Industries, which asks whether a petition is both objectively baseless and improperly motivated.\textsuperscript{26}

Citizen petitions, intended to provide a process for the public to raise legitimate concerns about unsafe drugs, has instead turned into a cheap, low risk strategy for brand-name drug manufacturers to use, often for the sole

\textsuperscript{20} Avery & Newsom & Hahn, supra note 8, at 128.
\textsuperscript{21} Id. at 130.
\textsuperscript{22} Id.
\textsuperscript{23} Id. at 129.
\textsuperscript{24} Id. at 131. See Prof’l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 61 (1993).
\textsuperscript{25} Avery & Newsom & Hahn, supra note 8, at 131.
\textsuperscript{26} Id.
purpose of delaying generic competition and extending legal monopoly profits. To combat the manipulation and abuse of the citizen petition process by “big-pharma,” I propose three changes to the FDA’s citizen petition process. First, to the extent that petitions are litigated on antitrust grounds, if a brand-name pharmaceutical manufacturer files a 505(q) petition that is judicially determined be a “sham” under the Noerr-Pennington analysis, a higher level of scrutiny should be applied by courts when analyzing future petitions filed by or on behalf of the same manufacturer. For example, if subsequent courts find the first prong of the sham exception under Noerr-Pennington to be satisfied, a strong presumption should arise in favor of the second prong being met—that the petition was improperly motivated.

Secondly, the citizen petition process itself should be altered. Crucial to brand-name manufacturers, the 150-day review limit in place under a 505(q) petition applies per petition. The 150 days do not represent the maximum period of time that generic approval can be put on hold in total. As a result, a single citizen petitioner can file multiple petitions about the same drug on a staggered basis, thus delaying generic entry past well past the initial 150-day review period. Tweaking 505(q) to mandate a maximum 150-day review period for each generic application, regardless of the number of petitions filed, would be ideal. Unfortunately, it would also be an impractical administrative burden upon the FDA. To fill this gap, a rule should be enacted preventing past serial petitioners from filing more than one citizen petition related to the same drug during a certain period of time, for example a year.

Finally, in response to some of the most egregious abuses of the citizen petition process, pharmaceutical manufacturers who raise concerns via the petition process that relate to their own product’s formulation, delivery system, or any other aspect should be estopped from continuing to market and sell their product as is. For example Reckitt, the manufacturer of Suboxone, a drug prescribed for opioid addiction, frantically filed citizen petitions as their Orphan Drug Act monopoly over the drug was expiring, citing pediatric expose issues. Reckitt’s petitions demanded that generic medications (which would soon hit the market) be packaged with “educational interventions on the risk of pediatric exposure” and unit-dose packaging. Meanwhile, Reckitt continued to sell Suboxone tablets in bulk without unit-dose packaging or

27 Feldman & Frondorf, supra note 11, at 548.
28 Id.
29 Id.
30 Id. at 544.
31 Id.
pediatric exposure labeling. 32 If a drug manufacturer files a 505(q) petition, the FDA should force the filing manufacturer to comply in regards to their own products with the suggested requirements they make for the generic competition.

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32 Id.

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