



## Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?

By Seth C. Silber,<sup>1</sup> Jonathan Lutinski,<sup>2</sup> and Rachel Taylon<sup>3</sup>



### Introduction

Several antitrust challenges have arisen in the context of brand name pharmaceutical companies blocking or delaying the introduction of generic pharmaceuticals through manipulation of FDA regulatory processes. Improperly impeding generic entry potentially costs American consumers billions of dollars, as it is estimated that generic drug use has saved

<sup>1</sup> Seth Silber is a partner in the antitrust group of Wilson Sonsini Goodrich & Rosati. Prior to joining the firm, Seth spent six years at the FTC, where he worked as a staff attorney in the Health Care Division, Assistant to the Director of the Bureau of Competition, and as an attorney advisor to Commissioner (now Chairman) Jon Leibowitz. Seth's bio is available at <http://www.wsgr.com/wsgr/DBIndex.aspx?SectionName=attorneys/BIOS/8902.htm>.

<sup>2</sup> Jonathan Lutinski is an associate in the antitrust group of Wilson Sonsini Goodrich & Rosati. Prior to joining the firm, Jonathan spent four years as a staff attorney in the Health Care Division of the FTC, where he worked almost exclusively on Hatch-Waxman settlements and other investigations in the pharmaceutical sector. Jonathan's bio is available at <http://www.wsgr.com/wsgr/DBIndex.aspx?SectionName=attorneys/BIOS/11702.htm>.

<sup>3</sup> Rachel Taylon is an associate in the health care group of Kutak Rock. Prior to joining Kutak Rock, Rachel worked in the antitrust group of Wilson Sonsini Goodrich & Rosati. Rachel's bio is available at [http://kutakrock.com/index.cfm?fuseaction=DspBio&id=5327&site\\_id=0&cat=0](http://kutakrock.com/index.cfm?fuseaction=DspBio&id=5327&site_id=0&cat=0).

consumers \$931 billion over the last 10 years.<sup>4</sup> With billions of dollars at stake, generic firms have alleged, with varying success, that their branded counterparts have used a number of different strategies to keep lower-priced generics out of the market in order to prolong exclusivity for their branded drug products.

For example, generic firms have alleged that brand companies have improperly listed patents—that do not, in fact, cover the drug product that they purport to cover—in the FDA's publication commonly referred to as the "Orange Book."<sup>5</sup> The Orange Book is the FDA's official listing of drugs, including the patents that could be infringed upon by an ANDA applicant seeking to market a generic version of the branded product.<sup>6</sup> Regardless of whether an Orange Book listing is proper (i.e.,

<sup>4</sup> See "The Generic Pharmaceutical Industry—Improving Lives For Less," The Generic Pharmaceutical Association (2011), available at <http://www.gphaonline.org/about-gpha/about-generics/case/generics-providing-savings-americans>.

<sup>5</sup> See, e.g., *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) (concerning whether Bristol-Meyers-Squibb (BMS) made false filings with the FDA that caused BMS's patents to be wrongfully listed in the Orange Book in an effort to obstruct generic competition).

<sup>6</sup> The official name for the "Orange Book" is the "Approved Drug Products List with Therapeutic Equivalence Evaluations." It is available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.



the patent actually covers the drug product for which it is listed), once listed, the brand may sue a Paragraph IV ANDA filer for infringement, obtaining an automatic 30-month stay of final FDA approval for the generic product in the process.<sup>7</sup>

Generic firms have also brought antitrust challenges where brand firms introduce new patented products with minor or no substantive therapeutic improvements in the hopes of preventing substitution to lower-priced generics.<sup>8</sup> This is referred to in the pharmaceutical industry as a “product hopping” or “switch” strategy. Because a branded drug can only be substituted for its AB-rated generic equivalent, these changes in formulation—and the subsequent shift of the market to the new formulation—may have the effect of destroying the market for the previous formulation, thereby defeating potential generic competition.

Moreover, plaintiffs have brought antitrust challenges against branded companies in the context of last minute labeling changes, which have the effect of delaying or impeding the ability of lower-priced generics to enter the market.<sup>9</sup> Again, since a generic product needs to be the same as its AB-rated branded equivalent, even minor changes to labeling or the products’ “use code” can have significant impact on the timing or ability of a generic firm to enter the relevant market.

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<sup>7</sup> Federal Food, Drug, and Cosmetic Act (FDCA), §§ 505(j), 21 U.S.C. §§ 355(j).

<sup>8</sup> See, e.g., *Abbott Labs v. Teva Pharms. USA*, 432 F. Supp. 2d 408 (D.Del. 2006) (alleging that through its strategy of reformulation and relabeling, Abbott foreclosed Teva from effectively competing with its AB-rated generic version of TriCor).

<sup>9</sup> *Novo Nordisk v. Caraco Pharm. Labs.*, 601 F.3d 1359 (Fed. Cir. 2010) (alleging Novo manipulated its patent use code in an effort to thwart anticipated generic entry).

Most recently, however, several antitrust challenges have been brought against branded drug companies allegedly seeking to use the FDA citizen petition process as a tactic to forestall generic entry.<sup>10</sup> Often filed on or near the eve of generic entry, citizen petitions can have the effect of delaying final ANDA approval while the FDA sifts through and evaluates if the petitioners’ arguments have merit. While, to date, the FTC has not brought an enforcement action in this area, it has expressed concern regarding the potential for misuse of citizen petitions. According to Commissioner (now-Chairman) Jon Leibowitz, the citizen petition process is “susceptible to systemic abuse. . . . It is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions are denied.”<sup>11</sup>

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<sup>10</sup> See *LA Wholesale Drug co. v Sanofi-Aventis*, No. 07-CIV-7343, 2009 U.S. Dist. Lexis 77206 (S.D.N.Y. 2009); *In re Wellbutrin XL Antitrust Litig.*, No. 08-2433 (E.D. Pa. 2011), 268 F.R.D. 539 (E.D. Pa. 2010), 260 F.R.D. 143 (E.D. Pa. 2009); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009); *In re Flonase Antitrust Litig.*, (No. 08-3149 (Direct), No. 08-3301 (Indirect), No. 09-1638 (Roxane) (E.D. Pa. 2008).

<sup>11</sup> Jon Leibowitz, Fed. Trade Comm’n, text based on speech given to Generic Pharmaceutical Annual Policy Conference, entitled “How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry,” (Sept. 29, 2006) available at <http://www.ftc.gov/speeches/leibowitz/060929GPHApubvers>. See also J. Thomas Rosch, Fed. Trade Comm’n, Remarks before the World Generic Medicine Congress, entitled “The Antitrust/Intellectual Property Interface: Thoughts on How To Best Wade Through the Thicket in the Pharmaceutical Context,” (Nov. 17, 2010) available at <http://www.ftc.gov/speeches/rosch/101117roschworldspech.pdf>.



## Strategy to Impede or Delay Generic Entry Through the Use of the Citizen Petition Process

Congress enacted federal regulations that allow individuals to express to the FDA genuine concerns about the safety, scientific, or legal issues regarding a product any time before, or after, its market entry.<sup>12</sup> Under these regulations, any person or entity, including a pharmaceutical company, may file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. The petition must describe the precise FDA action that the petitioner requests and must include a certification that the petition “includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.”<sup>13</sup>

While in most circumstances citizen petitions are filed for legitimate concerns regarding the safety and effectiveness of new drug products, citizen petitions also have the serious potential to delay and/or impede competition from lower-priced generic alternatives. For example, a party could embark on a strategy of filing baseless citizen petitions with the intent and effect of using the time in which it takes the FDA to respond to the petition (i.e., the *process*, rather than the *outcome*) to delay generic entry. Additionally, citizen petitions can also be used in conjunction with other exclusionary strategies, such as product hopping, to thwart generic entry. For example, a branded firm could file a citizen petition in an effort to “buy time” to shift the market to a new formulation of the branded product, impeding generic entry on the previous formulation.

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<sup>12</sup> 21 C.F.R. 10.30; FDCA § 505(j).

<sup>13</sup> FDCA § 505(q)(1)(H).

## Enactment of the Food and Drug Administration Amendments Act (FDAAA)

In part to deal with the potential anticompetitive abuse of the citizen petition process, Congress passed the FDAAA, which was enacted on September 27, 2007.<sup>14</sup> The FDAAA adds new section 505(q) to the Federal Food, Drug, and Cosmetic Act (FDCA) and governs certain citizen petitions and petitions for stay of FDA agency action. Importantly, Section 505(q)(1)(A) provides that the FDA may not delay approval of an ANDA application because of any request to take any form of action related to the pending ANDA unless “a delay is necessary to protect the public health.”<sup>15</sup> Moreover, the FDAAA authorizes the FDA to summarily deny any citizen petition whose primary purpose, as determined by the FDA, is to delay competition.<sup>16</sup>

In a report issued in June 2011, the FDA provided additional guidance on how it determines whether approval of an ANDA application may be delayed based on the filing of a citizen petition.<sup>17</sup> For example, if the petition cannot be summarily denied on its face, the FDA will use a “but for” test in determining whether the petition would be the cause of a delay for approval of a particular ANDA. If,

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<sup>14</sup> Public Law 110-85 (as amended by Public Law 110-316).

<sup>15</sup> FDCA § 505(q)(1)(A).

<sup>16</sup> 21 USC 355(q)(1)(E) states, “If the Secretary determines that a petition ... was submitted with the primary purpose of delaying the approval of an [ANDA] and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination...”

<sup>17</sup> FDA, Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug and Cosmetic Act (June 2011) [hereinafter FDA Guidance].



regardless of the petition, the ANDA *would not* be ready for final approval, then section 505(q)(1)(A) would not be implicated.<sup>18</sup> If, however, the ANDA *would* be ready for approval but for the petition, then the FDA will next determine if a delay of final approval is necessary to protect the public health.<sup>19</sup> If so, the Agency will delay the ANDA application until the public health concern is resolved. Finally, regardless of whether the FDA determines a delay is necessary to protect public health, the FDA will take final agency action on the petition within 180-days.<sup>20</sup>

To help assess whether the FDAAA effectively curbs abuses in the citizen petition process, Section 505(q)(3) requires the FDA to submit an annual report to Congress. That annual report provides relevant data on petitions covered by the provisions of the Act and whether these petitions have delayed approval of pending ANDA applications.<sup>21</sup> In its 2009 Report provided to Congress on July 29, 2010, the FDA stated that “[a]lthough FDA now has 2 years of experience implementing section 505(q), it believes it may still be too early to make a determination as to whether section 505(q) is effectively discouraging petitions submitted with the primary purpose of delaying approval of an ANDA or 505(b)(2) application.”<sup>22</sup> The

FDA 2010 report to Congress under 505(q)(3) has not yet been issued.

While the enactment of the FDAAA will likely curb some of the most egregious abuses of the citizen petition process (i.e., delays of 1-2 years while the brand files a series of successive and baseless citizen petitions as in *Flonase* discussed below),<sup>23</sup> there is still some potential for the anticompetitive use of citizen petitions to delay generic competition. For example, a carefully crafted citizen petition, drafted by a party with sophisticated regulatory counsel, may be able to successfully attempt to implicate issues relating to public health—such as “whether a proposed generic drug product is bioequivalent to the reference listed drug” or “whether an indication can be safely omitted from the labeling because that indication is protected by a patent”<sup>24</sup>—as a pretext to delay generic entry under 505(q).

Moreover, certain types of petitions are specifically exempted from the FDAAA. Notably, the FDAAA does not apply to petitions that “relate solely to the timing of approval of an application pursuant to the 180-day exclusivity provision at section 505(j)(5)(B)(iv) of the Act.”<sup>25</sup> In addition, pursuant to the FDA guidance issued earlier this year, Section 505(q)

<sup>18</sup> FDA Guidance at 8.

<sup>19</sup> *Id.* In determining if public health is at issue, the agency considers “[i]f the application were approved before the Agency completed the substantive review of the issues in the petition and, after further review, the Agency concluded that the petitioner’s arguments against approval were meritorious, could the presence on the market of drug products that did not meet the requirements for approval negatively affect the public health?”

<sup>20</sup> FDA Guidance at 3 (discussing Section 505(q)(1)(F)).

<sup>21</sup> FDCA § 505(q)(3).

<sup>22</sup> FDA Report to Congress, “Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2009,” (Jul. 29,

2010) available at

<http://www.hpm.com/pdf/FDA%20FY2009%20505q%20CP%20Report.PDF>.

<sup>23</sup> According to the FDA’s reports to Congress, only two ANDAs were delayed by 505(q) petitions from September 27, 2007 through September 30, 2008 and only one ANDA was delayed by a 505(q) petition from October 1, 2008 through September 30, 2009. *Id.* See also FDA Report to Congress, “Delays in Approvals of Applications Related to Citizen Petitions and Petition for Stay of Agency Action for Fiscal Year 2008,” (Apr. 28, 2009).

<sup>24</sup> FDA Guidance at 8.

<sup>25</sup> FDCA § 505(q)(4).



will not apply to petitions submitted before September 27, 2007. To the extent that a plaintiff sued a defendant—based on a scheme to monopolize a particular market dating back several years—it is possible that petitions filed before this cut-off date may have caused delay in generic approval under the pre-FDAAA regime.

Finally, a branded firm may still be able to delay generic approval while the FDA considers whether the relevant citizen petition implicates issues of public health.<sup>26</sup> In the high stakes world of pharmaceuticals, even relatively short delays of a few days or a couple weeks can cost generic firms and consumers millions of dollars in lost sales and overpayment of prescription drugs, respectively. Thus, with the relatively small costs of filing a citizen petition, brands may still utilize this tactic as a strategy to extend their drugs' life cycles, particularly when coupled with other exclusionary tactics used to maintain and extend their monopolies for blockbuster drugs.

### Analyzing Citizen Petition Under the Antitrust Laws

An antitrust plaintiff alleging that a branded firm is using the citizen petition process to unlawfully monopolize the market for a particular drug faces a number of challenges, including the establishment of relevant market definition, market power, and antitrust injury.

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<sup>26</sup> See Section 505(q)(1)(B). If the FDA determines that a delay of approval of an ANDA or 505(b)(2) application is necessary to protect the public health, the FDA is required to provide to the applicant *not later than 30 days* after making the determination: (1) that notification that the determination has been made, (2) if applicable, any clarification or additional data that the applicant should submit to the petition docket to allow FDA to review the petition promptly, and (3) a brief summary of the specific substantive issues raised in the petition which form the basis of the determination. *Id.*

One of the most significant hurdles for plaintiffs in this area, however, continues to be bypassing *Noerr-Pennington* immunity. The *Noerr-Pennington* doctrine generally immunizes efforts to petition the government from antitrust liability.<sup>27</sup> The doctrine is based on the premise that parties should be able to exercise their First Amendment right to petition the government without penalty. However, not all conduct is immunized under the doctrine.

While petitioning is generally protected, a party is not entitled to *Noerr-Pennington* immunity where the petitioning activity “ostensibly directed toward influencing governmental action [ ] is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor....” *Noerr*, 366 U.S. at 144. In other words, when the sole goal of petitioning is to interfere with the business of one’s rival, it is not protected. To prove that the petitioning is a sham, a plaintiff must demonstrate that it is both *objectively* and *subjectively* baseless.<sup>28</sup>

The sham exception to *Noerr-Pennington* was first set forth in the Supreme Court’s decision in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 60 (1993). In that case, the Court explained that under the objective prong the plaintiff must show that the petition is “objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits.” However, to the extent that “an objective [party] could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under *Noerr*, and an antitrust claim premised on the sham exception

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<sup>27</sup> *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961). *See also* *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

<sup>28</sup> *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) [hereinafter PRE].



must fail.”<sup>29</sup> Moreover, under the subjective prong, the Court determined that plaintiffs must show that the subjective intent of the petitioning party is to inhibit competition rather than to petition the government for redress. If the plaintiff is able to prove *both* prongs, the relevant petitioning activity will not be entitled to *Noerr-Pennington* immunity.

### Recent Cases Challenging Citizen Petition Under the Antitrust Laws

In recent years, there have been several cases brought by generic firms alleging that branded firms have used the citizen petition process as a way to impede generic entry and maintain and extend their monopoly power. In these cases, plaintiffs allege that the branded companies pursued baseless petitioning activity for which the singular goal was to impede competition, rather than to influence the FDA to take action. These cases are discussed in more detail below.

#### *In re DDAVP Direct Purchaser Antitrust Litigation*

On February 18, 2005, direct and indirect purchasers (collectively, “Plaintiffs”) of DDAVP (desmopressin acetate tablets), an antidiuretic prescription medication, filed complaints against Ferring B.V., Ferring Pharmaceuticals, Inc. (collectively “Ferring”), and Aventis Pharmaceuticals, Inc.<sup>30</sup> The complaints alleged that Ferring, the owner of U.S. Patent No. 5,047,398 (“‘398 patent”), which claims to cover DDAVP, and Aventis, the marketer and NDA-holder for DDAVP (collectively, “Defendants”), unlawfully monopolized the market for desmopressin tablets by: (1) committing fraud or inequitable

conduct on the PTO in procuring the ‘398 patent; (2) improperly listing the ‘398 patent in the Orange Book; (3) filing and prosecuting a patent infringement action against Barr Laboratories and Teva Pharmaceuticals, who had each filed ANDAs for desmopressin; and (4) filing a sham citizen petition with the FDA to further delay approval of generic desmopressin. The crux of the Plaintiffs’ complaint was that lower-priced generic entry was significantly delayed as a result of Defendants’ anticompetitive acts.

Ferring’s citizen petition, filed on February 2, 2004 while Ferring was prosecuting its patent infringement suit against Barr, requested that the FDA require Barr to submit additional testing to demonstrate bioequivalence to DDAVP.<sup>31</sup> Specifically, Ferring wanted the FDA to require Barr to conduct and submit more tests—pharmacodynamic (“PD”) studies measuring urine osmolarity—in order for Barr to establish the bioequivalence of Barr’s desmopressin product to DDAVP. Ferring claimed that the conventional PK bioequivalence tests did not adequately address safety and efficacy of oral desmopressin therapy for nocturnal enuresis in children. On July 1, 2005, FDA rejected Ferring’s citizen petition. The FDA stated that Ferring “offer[ed] no convincing evidence (i.e. data or other information) that any of [its] proposed changes were needed” and denied Ferring’s petition in its entirety.<sup>32</sup>

In dismissing all claims by the direct and indirect purchasers of DDAVP, the district court

<sup>29</sup> *Id.*

<sup>30</sup> Complaint, Meijer, Inc. et al. v. Ferring B.V. et al., No. 7:05-cv-02237 (S.D.N.Y. Feb. 18, 2005).

<sup>31</sup> See *Ferring B.V. v. Barr Labs., Inc.*, No. 7:02-CV-9851, 2005 WL 437981, at 10 (S.D.N.Y. Feb. 7, 2005); *Ferring B.V. v. Barr Labs. Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).

<sup>32</sup> See FDA Letter Rejecting Ferring Citizen Petitions (July 1, 2005) [hereinafter “Ferring FDA Rejection Letter”] at 2.



found that Ferring's citizen petition did not rise to the level of sham petitioning.<sup>33</sup> Indeed, the court found that the citizen petition was "First Amendment protected activity even though delay of Barr's access to the market was foreseeable."<sup>34</sup>

The Second Circuit, however, reversed. The Court disagreed with the district court's apparent rationale that "plaintiffs could not plausibly show the petition to be a sham, *i.e.*, objectively and subjectively baseless."<sup>35</sup> In its rejection of Ferring's citizen petition, the FDA had "found that the citizen petition 'had no convincing evidence' and lacked 'any basis' for its arguments."<sup>36</sup> Moreover, in finding that the '398 patent was unenforceable due to inequitable conduct, the district court noted that the petition may have been a "hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent." The court found these allegations to be enough for the plaintiff to plausibility demonstrate that the citizen petition was a sham. In August 2011, Plaintiffs submitted a settlement to the court in which Ferring and Aventis agreed to pay \$20.25 million to the plaintiff class.

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

Drug wholesaler Louisiana Wholesale filed a complaint against Aventis, alleging that Aventis unlawfully delayed generic competition to its drug Arava (leflunomide) through the filing of a

sham citizen petition with the FDA. Aventis had the exclusive right to market Arava in 10mg, 20mg, and 100mg strengths until March 10, 2004. On that date, five generic manufacturers submitted ANDAs seeking permission to sell generic versions of 10mg and 20mg Arava, but not 100mg Arava.

Nearly one year later, on March 31, 2005, Aventis filed a citizen petition with the FDA. The citizen petition, filed on the eve of final generic approval for 10mg and 20mg Arava, requested that the FDA not approve any ANDA for generic leflunomide unless the ANDA (1) contained bioequivalence studies confirming that five of the generic applicants 20mg leflunomide tablets are bioequivalent to one 100 mg Arava tablet, or (2) sought approval to market the 100 mg loading dose strength of Arava. The FDA denied Aventis' citizen petition on September 13, 2005 and, on the same day, approved ANDAs for six generic manufacturers to market generic leflunomide.

In denying the citizen petition, the FDA noted that Aventis' request for relief "seem[ed] to be based on a false premise," namely that if a generic manufacturer recommended the 100 mg loading dose as part of its label it either had to produce its own 100 mg tablet, or recommend using five 20 mg tablets. Aventis "seem[ed] to ignore a third possibility" that a generic leflunomide product could simply recommend a 100 mg loading dose in the label that it did not itself manufacture. The FDA noted that it was "not uncommon" for makers of brand drugs to reference in their labels drugs made by other manufacturers. Moreover, there was nothing in the FDCA or the regulations that requires a generic applicant to seek approval for all strengths of a particular drug.

Louisiana Wholesale alleged that, as a result of Aventis' citizen petition, which was both objectively and subjectively baseless, generic

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<sup>33</sup> PRE, *supra* note 28; In re DDAVP Direct Purchaser Antitrust Litig., No. 05-cv-2237, slip op. at 15 (S.D.N.Y. Nov. 2, 2006).

<sup>34</sup> *Id.*

<sup>35</sup> In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009).

<sup>36</sup> *Id.*



competition to Arava was delayed from March 2005 to September 2005, or a period of at least 5 months.<sup>37</sup>

In denying Aventis' motion to dismiss,<sup>38</sup> the court found that Aventis' conduct could fall within the "sham" exception to *Noerr-Pennington* immunity. The court found persuasive the arguments of Louisiana Wholesale, specifically that Aventis as a sophisticated pharmaceutical manufacturer familiar with FDA regulations and practices could have had no reasonable belief that its citizen petition was viable. Indeed, Aventis had in the past referred to other drugs and strengths on its own generic and brand labels when Aventis itself did not manufacture either the drug or the strength indicated.

However, after a full trial on the merits, the jury unanimously sided with Aventis.<sup>39</sup> Additionally, Louisiana Wholesale's motion for a reversal of the verdict or new trial was denied.<sup>40</sup>

### *In re Flonase Antitrust Litigation*

Flonase, previously one of the nation's top-selling drugs, is a steroid nasal spray produced by Defendant SmithKline Beecham Corporation (later known as GlaxoSmithKline or GSK) with the active ingredient fluticasone propionate. Roxane Laboratories (a generic manufacturer of Flonase), and indirect and direct purchasers of

Flonase all filed suit claiming that GSK filed a series of sham citizen petitions in order to delay the entrance of Roxane Laboratories' generic Flonase.<sup>41</sup>

In 1994, the FDA approved the NDA for GSK's Flonase nasal spray for sale within the United States. After a six-month extension, GSK's exclusive right to market Flonase in the United States ended on April 14, 2004. In the meantime, Roxane Laboratories filed an ANDA seeking approval to market an AB-rated generic version of Flonase in October of 2002.

During the period of May 2004 through June 2005, GSK made a series of petitions to the FDA regarding the FDA's approval of ANDAs for Flonase. On February 22, 2006, the FDA responded with a 24-page letter rejecting GSK's entire series of petitions stating, among other things, that "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved."<sup>42</sup> The same day the FDA issued this determination to GSK, it approved Roxane Laboratories' ANDA for Flonase. Moreover, after receiving this rejection letter, GSK filed suit in Maryland asking for a temporary restraining order ("TRO") and preliminary injunction seeking to

<sup>37</sup> Complaint at 7, *LA Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-cv-7343 (S.D.N.Y. Aug. 17, 2007).

<sup>38</sup> See *LA Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-cv-7343(HB), 2008 WL 169362, 1 (S.D.N.Y. Jan. 18, 2008) (motion to dismiss); *LA Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-cv-7343(HB), 2008 WL 4580016, (S.D.N.Y. Oct. 14, 2008) (summary judgment).

<sup>39</sup> Judgment, *LA Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-cv-7343 (S.D.N.Y. Dec. 9, 2008).

<sup>40</sup> *LA Wholesale Drug Co., Inc. v. Sanofi-Aventis*, 2009 U.S. Dist. Lexis 77208 (S.D.N.Y. 2009).

<sup>41</sup> The three suits are: (1) direct purchasers of Flonase in *American Sales Co., Inc. v. SmithKline Beecham Corp.*, No. 08-cv-3149 (E.D. Pa. July 3, 2008); (2) indirect purchasers of Flonase in *IBEW-NECA Local 505 Health & Welfare Plan v. SmithKline Beecham Corp.*, No. 08-cv-3301 (E.D. Pa. July 14, 2008); and (3) a generic manufacturer of FP in *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. 09-cv-1638 (E.D. Pa. April 17, 2009). The suits are grouped up under *In re Flonase Antitrust Litig.* [hereinafter *Flonase Litig.*].

<sup>42</sup> FDA Letter Rejecting GSK Citizen Petitions at 24 (Feb. 22, 2006) [hereinafter "GSK FDA Rejection Letter"], available at <http://www.regulations.gov/#!documentDetail;D=FDA-2004-P-0152-0005>.



reverse the FDA's denial of its citizen petition and to enjoin Roxane Laboratories sale of generic Flonase. The court originally granted the TRO, but, on March 6, 2006, it denied GSK's motion for a preliminary injunction.

GSK moved for summary judgment in all three suits claiming that its conduct of filing citizen petitions was immune from antitrust liability under the *Noerr-Pennington* doctrine. On June 2, 2011, the court denied GSK's motion for summary judgment.<sup>43</sup>

GSK conceded on summary judgment that plaintiffs had provided enough evidence to fulfill the second, subjective prong necessary to demonstrate sham petition. Thus, the only issue at hand was whether GSK's conduct was "objectively baseless" in that GSK could not realistically expect its petitions to succeed. In reasoning through each of the series of six citizen petitions filed by GSK, the court found that genuine issues of material fact remained as to whether GSK's conduct was objectively baseless and therefore constituted a "sham."

In *Request 1*, GSK requested the FDA to refrain from approving ANDAs prior to issuing final guidance on nasal aerosols and nasal sprays and a statistical appendix.<sup>44</sup> The court responded that this request could be objectively baseless based on evidence that the FDA is not obligated to issue any guidance and ANDA applicants are not required to use the guidance. Additionally, in regard to issuing the statistical appendix, this request is often impossible as the FDA often lacks data to do so. The FDA also rejected this

request, explaining that it "is desirable" to issue the final guidance before ANDA approval but "it is not always possible" to do so.<sup>45</sup>

In *Request 2*, GSK requested the FDA require ANDAs to include data from perennial allergic rhinitis (PAR) and perennial non-allergic rhinitis (PNAR) studies.<sup>46</sup> The court reasoned that genuine issues of fact remain as FDA guidance cannot require ANDA applicants to perform specific tests unless the tests are required by law. Additionally, the FDA rejected this request stating that there is no reason that drug performance would be different in PNAR or PAR patients.<sup>47</sup>

In *Request 3*, GSK requested the FDA to require pharmacokinetic data to be collected over the entire dosage interval of in vivo tests.<sup>48</sup> The court stated that this petition could be a sham by pointing both to the FDA's rejection letter stating that four consecutive samples during the dosage are sufficient and to expert evidence stating the same.<sup>49</sup>

In *Request 4*, GSK requested the FDA to reconsider its in vitro test for plume geometry

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<sup>43</sup> See *Flonase Litig.*, *supra* note 41.

<sup>44</sup> In 1999 the FDA issued a draft guidance entitled *Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* [hereinafter *2003 Draft Guidance*]. This guidance was amended in 2003, but was never finalized.

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<sup>45</sup> GSK FDA Rejection Letter, *supra* note 42, at 22.

<sup>46</sup> The FDA approved Flonase to treat the nasal symptoms of seasonal allergic rhinitis (SAR), PAR and PNAR. The *2003 Draft Guidance* provided that an ANDA could be approved to treat all three indications even if the application only included data from SAR patients.

<sup>47</sup> GSK FDA Rejection Letter, *supra* note 42, at 12.

<sup>48</sup> The FDA analyzes pharmacokinetic data generated from a single dose treatment over time. The *2003 Draft Guidance* required an applicant to take measurements at least four consecutive times during the dose interval.

<sup>49</sup> GSK FDA Rejection Letter, *supra* note 42, at 13-14 ("FDA believes that four consecutive sampling times using the maximum clinical dose is sufficient to detect whether two [FP] nasal spray suspension products [are bioequivalent.]").



and container shelf life.<sup>50</sup> The plaintiffs submitted evidence that plume geometry is a relevant factor for ANDA applicants as well as pointed to the FDA's letter stating the same.<sup>51</sup> The plaintiffs also argued that GSK's proposed alternative test for shelf life was impossible and directed the court to the FDA's letter stating that its method for testing shelf life was sufficient.<sup>52</sup> Therefore, the court found that genuine issues of fact remained.

In *Request 5*, GSK requested the FDA reconsider its endorsement of the geometric mean ratio method. Here the court responded that genuine issues remained because GSK's criticisms were irrelevant to Flonase because the request was relevant for solution-based nasal sprays and Flonase is a suspension based spray.

In *Request 6*, GSK asked the FDA to tighten specifications for droplet size distribution (DSD) which measures the size of individual droplets in the spray and spray pattern (SP) which describes the cross-sectional shape of the spray emitted.<sup>53</sup> The court reasoned that genuine issues of fact remained because these methods are proprietary and therefore differ based on different equipment and manufacturers. Additionally, plaintiffs presented expert testimony stating the existing

standards were sufficient to ensure public safety.

Finally, the court looked at the Maryland lawsuit in which GSK had filed for a TRO and preliminary injunction.<sup>54</sup> GSK argued that because it was granted the TRO, the lawsuit was not objectively baseless. The court rejected this assertion finding that a court's granting of a TRO does not, by itself, establish an objective basis for petitioning activity. Furthermore, the court stated that the overt denial of a preliminary injunction, and the plaintiffs' evidence of baseless citizen petition, raise genuine issues of fact as to whether the Maryland lawsuit was objectively baseless.<sup>55</sup>

The court therefore denied GSK's motion for summary judgment because genuine issues of fact remained on whether GSK's citizen petition constitute a sham and are not entitled to *Noerr-Pennington* immunity. This suit is still pending.

### ***In re Wellbutrin XL Antitrust Litigation***

On January 7, 2011, purchasers of Wellbutrin XL filed a complaint against Biovail Corporation.<sup>56</sup> The plaintiffs sued Biovail, the producers of Wellbutrin XL (a once-a-day antidepressant) for conspiring to prevent generic

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<sup>50</sup> Plume geometry describes the cross-sectional shape of the spray emitted from the device, measured on a plane parallel to the direction of the spray.

<sup>51</sup> GSK FDA Rejection Letter, *supra* note 42, at 18 ("Studies in literature have indicated that the spray angle is one aspect of product performance that determines where in the nasal cavity drug is deposited.").

<sup>52</sup> GSK FDA Rejection Letter, *supra* note 42, at 17 ("[FDA studies] are adequate to ensure that generic versions of the [FP] nasal spray product preserve identity, strength, quality, and purity over their shelf life.").

<sup>53</sup> DSD and SP provide an internal measure of the production quality of any given batch of a drug.

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<sup>54</sup> *Glaxo Grp. Ltd. v. Leavitt*, No. 06-cv-649 (D. Md. Feb. 23, 2006). Responses to citizen petitions constitute final agency action and are subject to immediate review by the courts.

<sup>55</sup> The court denied GSK's Motion stating, "If I had any hesitation, and a man without hesitation is a dangerous man, I understand that. But if I had any hesitation whatsoever that you had any kind of likelihood of prevailing in this case, I would not hesitate. But I simply don't have it. ... I just don't see any likelihood that you're going to prevail." Prelim. Inj. Hr'g 124:4-17 Mar. 6, 2006.

<sup>56</sup> Second Amended Consolidated Class Action Compl. and Jury Demand for End Payors, *In re Wellbutrin XL Antitrust Litig.*, No. 2:08-cv-2433 (E.D. Pa. Jan. 7, 2011) [hereinafter "Wellbutrin Compl."].



versions of Wellbutrin XL from entering the market. Specifically, the plaintiffs allege that the defendants have: (1) filed three sham patent litigation cases, (2) filed a sham listing with the Orange Book, (3) filed a baseless FDA citizen petition, and (4) formed potentially illegal agreements with generic competitors.

In reference to the citizen petition, the plaintiffs alleged that Biovail submitted its citizen petition requesting the FDA to require ANDA applicants to perform additional studies beyond those previously submitted to prove bioequivalence. Specifically, Biovail requested that the ANDA prove bioequivalence to not only Wellbutrin XL, but also Wellbutrin IR and Wellbutrin SR. The plaintiffs complained that FDA regulations required ANDA applicants only show bioequivalence to the referenced listed drug and therefore the requests were baseless.<sup>57</sup> Further the plaintiffs claimed the citizen petition was a sham because “it relied on unsubstantiated theories, lacked scientific support, misapplied governing legal and regulatory standards, and was nothing more than a last-minute attempt to extend Defendants’ monopoly...”<sup>58</sup>

In denying the citizen petition, the FDA stated that the brand manufacturers did not have “the right to be free of generic competition” once the patents had been held unenforceable, and that “Biovail [should] not be permitted to shield its market share.”<sup>59</sup> In turn, the plaintiffs claimed that this citizen petition delayed approval of its ANDA for four months. Notably, according to a letter sent by United States Senators Debbie

Stabenow (D-Mich.) and Trent Lott (R-Miss) this delay in the ANDA approval cost consumers \$37 million per month.<sup>60</sup>

The case is currently pending in the Eastern District of Pennsylvania<sup>61</sup> and the court has yet to reach the question of whether Biovail’s citizen petition will be given immunity under *Noerr-Pennington*.<sup>62</sup>

### “Plus” Factors that Make Monopolization Claims Based on Citizen Petition Theory More Likely to Survive Motion to Dismiss or Summary Judgment

While there is a high standard to prove the sham exception to *Noerr-Pennington* immunity, as described above, some plaintiffs have successfully survived at the motion to dismiss and/or summary judgment stages. While there is no “formula” for a successful claim for monopolization based on the filing of baseless citizen petition, the courts have discussed certain factors that make the success of these claims more likely.

#### *Suspect Timing*

In considering whether the sham exception has been met, courts look to the timing of the filing

<sup>57</sup> *Id.* at 38.

<sup>58</sup> *Id.* at 39.

<sup>59</sup> FDA Letter Rejecting Biovail Citizen Petition at 16 (Dec. 14, 2006) [hereinafter “Biovail FDA Rejection Letter”], available at <http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0366-0004>.

<sup>60</sup> Wellbutrin Compl., *supra* note 56, at 3.

<sup>61</sup> The indirect purchasers were recently granted class certification. *See* Meijer Inc. et al. v. Biovail Corp. et al., No. 2:08-cv-0243 (E.D. Pa. Aug. 11, 2011).

<sup>62</sup> There are two additional case filed recently which claimed a brand manufacturer filed a sham citizen petition. *In re Ditropan XL Antitrust Litig.*, No. M:06-CV-01761-JSW (2007) was dismissed on standing grounds and the court never reached an analysis of the citizen petition. *In New Mexico UFCW Union’s and Employers’ Health and Welfare Trust Fund v. Astellas Pharma U.S., Inc.*, Case No. 1:11-cv-11621 (D. Mass. Sept. 14, 2011), the plaintiffs claim that Astellas filed a baseless citizen petition to extend its market exclusivity of Prograf.



of the citizen petition. Courts have reasoned that a NDA holder filing a citizen petition on the eve of an ANDA approval can be suspect.

For example, in *Louisiana Wholesale* discussed above, the court seemed to suggest that the timing of the petition was a factor in determining whether it was a sham. In deciding whether triable issues of fact existed with respect to the “reasonability and viability” of Aventis’s citizen petition, the court held that additional discovery may clarify the circumstances surrounding Aventis’ filing “one year after the generic manufacturers submitted their ANDAs for FDA approval when no new health and safety information on the loading dose or leflunomide in general and no new FDA regulations on labeling had occurred.”

Although it would seem that the timing would be more probative in determining the brand’s subjective state of mind in filing a citizen petition (i.e., whether the petition raise legitimate safety issues or was intended as a vehicle to delay generic entry), it appears that the court considered this as part of the threshold question of whether the petition was objectively baseless.

Additionally, in *Flonase* the court noted that GSK did not file its first citizen petition until 2004, on the eve of potential generic entry and approximately two years after Roxane Laboratories had filed its ANDA application. Indeed, as the plaintiffs complained, “... just days after the expiration of the statutory exclusivity period for GSK’s Flonase, and on the eve of what could have been the FDA’s approval of Roxane Laboratories’ ANDA, GSK filed the first in a series of objectively baseless citizen petitions...”<sup>63</sup>

### ***Relief Requested Contrary to FDA Regulations and Practice***

Another significant factor is whether the party filing the citizen petition made requests for relief with the FDA that were contrary to FDA regulations and practice. Arguments made by sophisticated parties in the face of clear and contradictory FDA regulations may provide further evidence of an objectively baseless petition.

For example, in rejecting Aventis’ motion for summary judgment, the *Louisiana Wholesale* court found it significant that Aventis’ citizen petition requested relief that it knew was contrary to FDA regulations and practice. First, Aventis demanded that generic manufacturers produce their own 100 mg tablets in order to succeed with their ANDAs, but Aventis knew that the FDA permitted generics to receive approval for some—but not all—dosage strengths of a branded drug, and cited nothing to contrary. Second, Aventis demanded that if the generics tried to substitute five 20 mg tablets to achieve the loading dose, they had to demonstrate bioequivalence between those tablets and the 10 mg tablet. But again, Aventis knew it was not required to establish bioequivalence between different dosage strengths of the same drug. Finally, Aventis insisted that the generics not be able to reference the 100 mg loading dose in the label, but Aventis knew that the FDA permitted manufacturers to cross-reference other drugs or other dosages because it did so in two other instances. Not only did Aventis cross-reference other drugs in manufacturing other brands and generics, but also, with respect to its own authorized generic leflunomide product, Aventis did not produce a generic 100 mg loading dose and referenced the brand tablet in the label.

In *Flonase*, the plaintiffs contended that GSK’s requests did not address the adequacy of Roxane

<sup>63</sup> Complaint of Roxane Laboratories, Inc. at 7, *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. 09-cv-1638 (E.D. Pa. April 17, 2009) [hereinafter “Roxane Compl.”].



Laboratories' ANDA, present any evidence that the ANDA failed to demonstrate bioequivalence, or raise any public health concerns.<sup>64</sup> Moreover, in the GSK FDA Rejection Letter, the FDA stated that the tests and factors it uses in determining bioequivalence were sufficient. The plaintiffs in *DDAVP*, made the same types of claims stating that the citizen petition lacked scientific basis and was contrary to current practices. The FDA specifically stated that the citizen petition requests made in *DDAVP* lacked "any basis" for its arguments.

The vast majority of companies involved in these law suits are large pharmaceutical companies which have substantial experience in complying with FDA procedures and regulations. In turn, there is an expectation that these companies have knowledge of FDA practices and procedures. Therefore, if the citizen petition requests action that the company knows is contrary to FDA practice, courts may use this as a telling factor that the petition was baseless and part of a scheme to delay generic entry.

### ***Tone of FDA Rejection of Citizen Petition***

The tone of the FDA rejection letters also appears to play a role in plaintiffs surviving a dispositive motion. When the FDA harshly criticizes the citizen petition filer, the court may use it as a relevant factor in making its decision. For example, in *DDAVP*, the FDA found that the citizen petition lacked "any basis" and "had no convincing evidence."

Further, in *Louisiana Wholesale*, the FDA noted that Aventis' requested relief "seem[ed] to be based on a false premise." Additionally in *Wellbutrin*, the FDA stated, that the brand manufacturers did not have "the right to be free

of generic competition" once the patents had been held unenforceable, and that "Biovail [should] not be permitted to shield its market share."<sup>65</sup> In *Flonase* the FDA stated, "[t]he policies behind the Hatch-Waxman dictate that GSK should not be permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved..."<sup>66</sup> The court in *Flonase* also took into account the Maryland Court's outright rejection to GSK's request for a preliminary injunction.<sup>67</sup>

The FDA's response to citizen petition undoubtedly plays a major role in the determination if a petition is considered objectively baseless. Obviously if the FDA takes action based on the citizen petition, the petition will not be found to be baseless.<sup>68</sup> On the other hand, as is present in these cases, the fact that the FDA strongly criticized the requests may tend to show that a petition is objectively baseless and therefore not entitled to *Noerr-Pennington* immunity. While not expressly called out as a factor, the courts in these cases have recited and quoted extensively from the language contained in the FDA's letters

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<sup>65</sup> Biovail FDA Rejection Letter, *supra* note 59, at 16.

<sup>66</sup> GSK FDA Rejection Letter, *supra* note 42, at 24.

<sup>67</sup> The court denied GSK's Motion stating, "If I had any hesitation, and a man without hesitation is a dangerous man, I understand that. But if I had any hesitation whatsoever that you had any kind of likelihood of prevailing in this case, I would not hesitate. But I simply don't have it. ... I just don't see any likelihood that you're going to prevail." Prelim. Inj. Hr'g 124:4-17 Mar. 6, 2006.

<sup>68</sup> Although the plaintiffs in *Louisiana Wholesale* successfully passed the preliminary motions stage, the defendants were able to present evidence at trial showing the FDA took action based in part on one of the citizen petition requests. This is one factor the court later pointed out in subsequently denying Plaintiffs JNOV after the jury had sided with Defendants.

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<sup>64</sup> *Id.* at 8.



rejecting the branded firms' citizen petition. Clearly, a strongly worded rejection from the FDA—chastising petition for the lack of foundation for the citizen petition filed—is likely to play a role in the fact finders' analysis of baselessness.<sup>69</sup>

### ***Petition Actually Caused Delay***

In all four of the cases above, the courts found it important that the FDA granted final approval of the ANDAs on the same day as it rejected the brand manufacturer's citizen petition, suggesting that the citizen petition was indeed holding up generic entry and competition. Indeed, the court in *Louisiana Wholesale* specifically remarked on the FDA's statement that it would not grant the generic ANDA applicants approval while it addressed the Aventis' citizen petition. Moreover, in *Flonase*, the FDA seemed likely to approve Roxane's generic, then reversed its thinking and issued a deficiency based on the citizen petition, and finally approved the ANDA based primarily on Roxane's original ANDA submission.

While a consideration of whether the citizen petition actually delayed generic entry may relate more to the establishment of antitrust injury—rather than the establishment of the sham exception to *Noerr-Pennington* immunity—it is important to note that causation is a critical component to successful monopolization challenges based on the filing of baseless citizen petitions. In other words, to the extent that other factors—such as failure to obtain bioequivalence or manufacturing issues—may have caused delay in the generic firm's ability to obtain FDA approval,

defendants may have strong arguments that their citizen petition, even if baseless, had no adverse effect on competition.

Although the four factors reviewed above are certainly not all a court takes into account in its decision, facts that represent egregious examples of most or all of these factors have pushed courts to find that claims based on the filing of baseless citizen petition can, in some circumstances, survive dispositive motions and proceed towards trial.

### **Conclusion**

The abuse of the citizen petition process is an area of flux in the world of pharmaceutical antitrust. With the enactment of the FDAAA, there is a potential that the most egregious abuses of the ANDA process are likely to be curbed as the FDA may no longer delay approval of a pending ANDA application, as a result of a citizen petition, unless “a delay is necessary to protect the public health.”<sup>70</sup> That said, it appears that the jury is still out on whether the FDAAA will effectively eliminate the potential for anticompetitive use of citizen petitions to impede or delay generic entry. According to the FDA's most-recent report to Congress, it is “too soon to determine whether section 505(q) is discouraging petitions submitted with the primary purpose of delaying approval of an ANDA.”<sup>71</sup> Moreover, there are key exceptions to the FDAAA, including agreements relating solely to 180-day exclusivity as well as agreements that predate September 2007, which, as discussed above, could be relevant as part of a continued conspiracy to monopolize a particular drug market.

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<sup>69</sup> Conversely, a letter from the FDA tending to show that petitioner's argument had legitimate bases that were carefully considered by the FDA is also likely to factor into the judge's analysis, as it tends to show that the citizen petition was not objectively baseless.

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<sup>70</sup> FDCA § 505(q)(1)(A).

<sup>71</sup> FDA Report to Congress, *supra* note 22.



To the extent that the FDAAA does not fully reign in the anticompetitive use of citizen petitions, there are several examples of cases filed in recent years that have survived dispositive motions—bypassing *Noerr-Pennington* immunity and proceeding through discovery—based on this conduct. Synthesizing those cases, it is apparent that several of the “plus” factors described above are predictive of whether a monopolization claim based on the manipulation of the FDA regulatory process through the filing of baseless citizen petitions is likely to be viable. While only time and continued monitoring of the FDAAA will tell whether these types of abuses are likely to be eradicated in the future, it is clear that potential plaintiffs pursuing these types of claims should emphasize these “plus” factors in any prospective litigation.