WSGR ALERT

Citizen Petitions Aimed at Delaying Generic Competition Remain a Concern

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Despite Congress enacting legislation in 2007 to curb misuse, citizen petitions submitted by pharmaceutical companies to the Food and Drug Administration (FDA) may still provide a mechanism for competitors to delay the introduction of generic and biosimilar competition. This is evident from a recent report from the FDA to Congress and the settlement of a private antitrust suit.

In its November 2014 Sixth Annual Report to Congress following up on 2007 legislation,[1] the FDA warned that congressional efforts to curtail the use of citizen petitions as a delay tactic may be ineffective, stating that the legislation may not be "discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and that do not raise valid scientific issues."[2] Meanwhile, a $98 million settlement reached last month in a multidistrict antitrust litigation alleging illegal monopolization through a brand's filing of an "objectively baseless" citizen petition suggests that courts remain willing to entertain the misuse of a citizen petition as the grounds for an antitrust violation.

Relevant Background of 505(q) Citizen Petitions

In 2007, Congress introduced Section 505(q) to the Food, Drug, and Cosmetic Act (FDCA)[3] in an attempt to curtail the potential abuse of citizen petitions by parties seeking to delay FDA approval of generic, brand, or biosimilar drugs.[4] Section 505(q) prohibits the FDA from delaying such approval unless the FDA "determines, upon reviewing the petition, that a delay is necessary to protect public health."[5] The FDA must review all petitions to determine if the requested action would delay the approval of a covered application "under any reasonable theory"[6] within 150 days.[7] If the FDA determines that (1) a petition was filed with the "primary purpose" of delaying a covered application and (2) it "does not on its face raise valid scientific or regulatory issues," then the FDA may deny the petition at any point, including immediately.

FDA's Concerns

The FDA's November 2014 report to Congress highlights several concerns with the legislation, and suggests the agency has not seen an appreciable decline in citizen petitions. The wording of Section 505(q) limits its effectiveness in several ways. First, the statute applies only when delay would result for a "pending application," so 505(q) does not catch citizen petitions submitted before there is an ANDA on file and ready for approval. The FDA notes that it is frequently the case that this 150-day clock expires "before any [potentially delayed applications] are ready for approval."[8]

Second, requiring the FDA to determine that a petition does not raise any valid scientific or regulatory issues before denying it outright is challenging, as any well-crafted petition will at first glance likely raise at least one valid issue. As a result, the FDA has never employed this clause, despite the fact that, in the agency's estimation, "many 505(q) petitions do not in fact raise persuasive scientific or regulatory issues when those issues have been reviewed by FDA."[9]

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[1] Pursuant to 505(q)(3) of the FDA Act (21 U.S.C. 355), the FDA is required to submit an annual report to Congress reporting on Section 505(q) petitions. The FDA released its most recent report in late 2014, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM423291.pdf (hereinafter "Sixth Annual Report").

[2] Sixth Annual Report at 7.

[3] 21 U.S.C. 355(q).

[4] Section 505(q) governs petitions that request FDA action that may result in the delay of one of three types of pending applications: 1) ANDAs submitted under 21 U.S.C. 355(j); 2) Section 505(b)(2) NDAs; and 3) biosimilar applications submitted under 42 U.S.C. 262(k).

[5] Section 505(q)(I)(A).

[6] Food and Drug Administration, "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry," Nov. 2014, *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079353.pdf.

[7] Section 1135 of the Food and Drug Administration Safety and Innovation Act shortened this timeframe from 180 days to 150 days.

[8] *Id.* at 6.

[9] *Id.* at 7.

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Finally, the FDA notes that it has a particular problem with "serial" petitions. Serial petitions target the same specific drug or class of drugs, sometimes requiring several separate responses about different issues regarding the same product, and often come from the same petitioner. The FDA noted its belief that "innovator companies are . . . implementing strategies to file serial [petitions] in an effort to delay approval of ANDAs or 505(b)(2) applications for competing drugs."[10]

Recent Litigation Settlement

While the FDA's report to Congress notes its continued concerns regarding citizen petitions, the recent settlement of a private antitrust suit serves as a reminder that "objectively baseless" citizen petitions could potentially violate the antitrust laws.[11] In *In re Prograf Antitrust Litigation*, a class of direct purchasers alleged that Astellas, the brand manufacturer of the drug product Prograf, illegally monopolized the market for tacrolimus by filing a frivolous citizen petition to delay generic competition. The plaintiffs alleged that the petition caused the FDA to delay approval of a generic product by two years, forcing consumers to pay higher prices for tacrolimus than they otherwise would have.

At summary judgment, the defendants argued that the plaintiffs could not show antitrust causation and, in the alternative, that the Noerr-Pennington doctrine insulated the petition from antitrust liability. The court reviewed the evidence to determine whether Astellas' citizen petition was a "material cause" of the FDA's delay in approving a generic version of Prograf, and concluded that the plaintiffs cited sufficient evidence suggesting that "some, if not all, of the delay was attributable to Astellas' unsuccessful requests [and, as] a preliminary matter, it is evident that the petition itself did indeed delay the FDA's approval of Sandoz's ANDA."[12] Regarding the Noerr-Pennington argument, the court stated that questions of fact remained because the two sides both presented potentially convincing evidence about the objective basis for the requests, as well as the reliability of the underlying evidence submitted by Astellas as part of its petition.[13]

Having denied summary judgment on both issues, trial was set to begin on January 20, 2015. However, on the day trial was to begin, Astellas and direct purchasers informed the court they were close to a settlement, and they reached a $98 million settlement two days later.

Factors to Consider Moving Forward

The *Prograf* litigation, along with other prior court decisions in this area, indicates that citizen petitions may continue to face scrutiny under the antitrust laws.[14] These cases demonstrate that there are several key factors that come into play as part of the analysis of whether such conduct could run afoul of the antitrust laws:

1. *Suspect Timing* – Courts will look at the timing of the petition to help determine motive. For instance, if the brand files its citizen petition on the eve of generic entry, this may be indicative of intent to stall competition, rather than raising legitimate concerns.[15]
2. *Relief Requested* – Courts will consider the relief requested and whether the petitioner had reason to know that its requests were objectively baseless.[16]

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[10] *Id.*

[11] *In re Prograf Antitrust Litig.*, Civ. No. 1:11-md-02242 (D. Mass. Jan. 22, 2015).

[12] *In re Prograf Antitrust Litig.*, Civ. No. 1:11-MD-02242, 2014 WL 4745954 at *7 (D. Mass. June 10, 2014). The court also noted that the FDA itself stated that its delay in approving the Sandoz ANDA was "directly attributable to the need to evaluate and respond to a citizen petition submitted by Astellas…" *Id.* (*quoting* Defendant's Memorandum in Opposition to Plaintiff's Motion for a Temporary Restraining Order and a Preliminary Injunction, *Astellas Pharma US, Inc. v. Food & Drug Admin.*, 1:09-cv-01544 (D.D.C. August 12, 2009), at 2.

[13] *In re Prograf Antitrust Litig.*, Civ. No. 1:11-MD-02242, 2014 WL 4745954 at *9-10 (D. Mass. June 10, 2014).

[14] *See Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-CIV-7343, 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009); *In re Wellbutrin XL Antitrust Litig.*, Nos. 08-2431, 08-2433, 2012 WL 1657734 (E.D. Pa. May 11, 2012); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 304 (E.D. Pa. 2011); *see also* Seth C. Silber, Jonathan Lutinski, and Rachel Taylon, "Abuse of the FDA Citizen Petition Process: Ripe for Antitrust Challenge?" *Antitrust Health Care Chronicle*, Jan. 2012, *available at* https://www.wsgr.com/PDFSearch/silber0112.pdf.

[15] *See, e.g.*, *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-CV-7343, 2008 WL 169362, at *5 (S.D.N.Y. Jan. 18, 2008) (explaining that defendant filed a "petition 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"); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 304 (E.D. Pa. 2011)(denying summary judgment and noting that defendant only filed citizen petitions after it identified generic pharmaceutical manufacturers intending to file Flonase ANDAs).

[16] *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-CIV-7343, 2009 WL 2708110, at *4 (S.D.N.Y. Aug. 28, 2009)(expressing doubt as to whether defendants could reasonably have expected the relief sought); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009)(noting that the FDA "found that the citizen petition 'had no convincing evidence' and lacked 'any basis' for its arguments").

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3. *Tone of the FDA's Response* – The court will look at the language and tone of the FDA's response (for example, if the submitting party is scolded by the FDA for filing a seemingly baseless petition).[17]
4. *Actual Delay* – Finally, courts will verify that there was actual delay caused by the filing of an objectively baseless petition.

In the case of *Prograf*, based on the plaintiffs' allegations, the citizen petition at issue may have had elements of all four factors. First, regarding the timing of the citizen petition, Sandoz filed its ANDA in December 2006 with a targeted patent expiration date in April 2008. Astellas responded by filing a citizen petition in September 2007. Second, Astellas made four requests of the FDA, and based these requests on allegedly scientific white papers in academia. However, the plaintiffs asserted that this research was unreliable because it "contained no scientific or medical data, but [was] instead premised on theoretical and unsupported physician concerns."[18] Third, the plaintiffs introduced not only the FDA's response to the citizen petition into the record, but also the FDA's memorandum in a derivative lawsuit in which Astellas sought a temporary restraining order.[19] Both the FDA's response and the memorandum provided grounds for challenging Astellas' belief that it would prevail.[20] Finally, there was actual delay—the plaintiffs alleged that generic Prograf came to market two years later than it otherwise would have.

In light of the FDA's recent report and the *In re Prograf* settlement, the potential misuse of citizen petitions to delay generic drug competition remains an issue that will likely face further examination through an antitrust lens. While the legislation represents an effort to curb potential abuse, the FDA's report makes clear that the agency still views citizen petitions as means by which certain pharmaceutical manufacturers may seek to stall generic competition. *In re Prograf* further confirms that potential claims stemming from alleged abuse of the citizen petition process may be viable, particularly when there is evidence of the four key factors discussed above.

If you have any questions regarding these issues or pharmaceutical competition issues more generally, please contact Seth Silber at 202-973-8824 or Jonathan Lutinski at 202-973-8816. Seth is a partner in Wilson Sonsini Goodrich & Rosati's Washington, D.C., office, where he serves as counsel to numerous pharmaceutical companies regarding antitrust and litigation issues. He previously served at the Federal Trade Commission as an advisor to former FTC Chairman Jon Leibowitz, and investigated and litigated pharmaceutical patent settlement challenges while at the FTC. Jon is a senior associate in the firm's Washington, D.C., office, and also previously served at the FTC as a staff attorney in the agency's Health Care Division reviewing, investigating, and litigating pharmaceutical industry conduct.

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[17] *Id.*

[18] *In re Prograf Antitrust Litig.*, No. 1:11-MD-02242-RWZ, 2014 WL 4745954, at *8 (D. Mass. June 10, 2014).

[19] Defendant's Memorandum in Opposition to Plaintiff's Motion for a Temporary Restraining Order, *supra* note 14.

[20] The FDA's response to Astellas stated that "the current FDA standards and ANDA review process are sufficient to ensure that generic versions of immunosuppressant drugs, including tacrolimus and its branded counterpart, are equivalent with respect to their safety and efficacy for use []." FDA Letter Granting in Part and Denying in Part Astellas Citizen Petition at 14 (Aug. 10, 2009), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2007-P-0111-0013.

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