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Antitrust

Drug Industry May Face New Areas of Antitrust Scrutiny

By Dana A. Elfin and Madi Alexander

Citizen petitions, which ask the FDA to take action on pending generic drug applications, haven't gotten as much attention as other potentially anticompetitive conduct in the pharmaceutical industry.

But recent events indicate abuse of citizen petitions may join reverse payments in patent litigation settlements and product hopping as focuses of antitrust scrutiny, an antitrust law expert told Bloomberg BNA.

Snapshot

- Abuse of the citizen petition process at FDA is starting to receive antitrust attention
- Biosimilars could be next area of pharmaceutical industry to draw antitrust scrutiny

In February, the Federal Trade Commission sued Shire ViroPharma, a unit of Shire plc, for allegedly abusing the citizen petition process, marking the first time the FTC has sued over a citizen petition.

The FTC alleged the company filed a series of baseless citizen petitions to delay entry of a generic version of its medication Vancocin D (*FTC v. ShireViroPharma, Inc.*, D. Del., No. 17-131, *filed* 2/7/17). The FTC alleges the company sought to protect monopoly profits by filing "serial, repetitive, and unsupported filings" with the Food and Drug Administration, costing buyers hundreds of millions of dollars.

In the FTC's suit against ShireViroPharma, the FTC says the citizen petition filings delayed cheaper generic entry and cost consumers hundreds of millions of dollars.

Michael A. Carrier, distinguished professor at Rutgers Law School in Camden, N.J., who has authored two studies of citizen petitions, sat down with Bloomberg BNA's Dana Elfin to discuss the intersection of citizen petitions and antitrust law, and the next frontiers of antitrust actions in the pharmaceutical arena.

Bloomberg BNA: Why haven't citizen petitions received as much attention as other anticompetitive conduct in the pharmaceutical industry such as reverse payment settlements of patent litigation and product hopping?

Carrier: Reverse-payment settlements, by which brands pay millions to generics to delay entering the market, and product hopping, by which brands make trivial changes to drugs to delay generic entry, seem, on their face, to present more pressing competitive concern and to delay generic entry for a longer period of time than citizen petitions, which might not seem as questionable or to delay entry for as long a time.

Bloomberg BNA: If your contention that some pharmaceutical companies are abusing the citizen petition process is correct, why haven't there been more antitrust actions brought over citizen petitions?

Carrier: The FTC recently filed its first complaint challenging this conduct, which may result in this situation changing.

Bloomberg BNA: Why do you think it took the FTC until this year to pursue citizen petitions as an avenue of anticompetitive behavior?

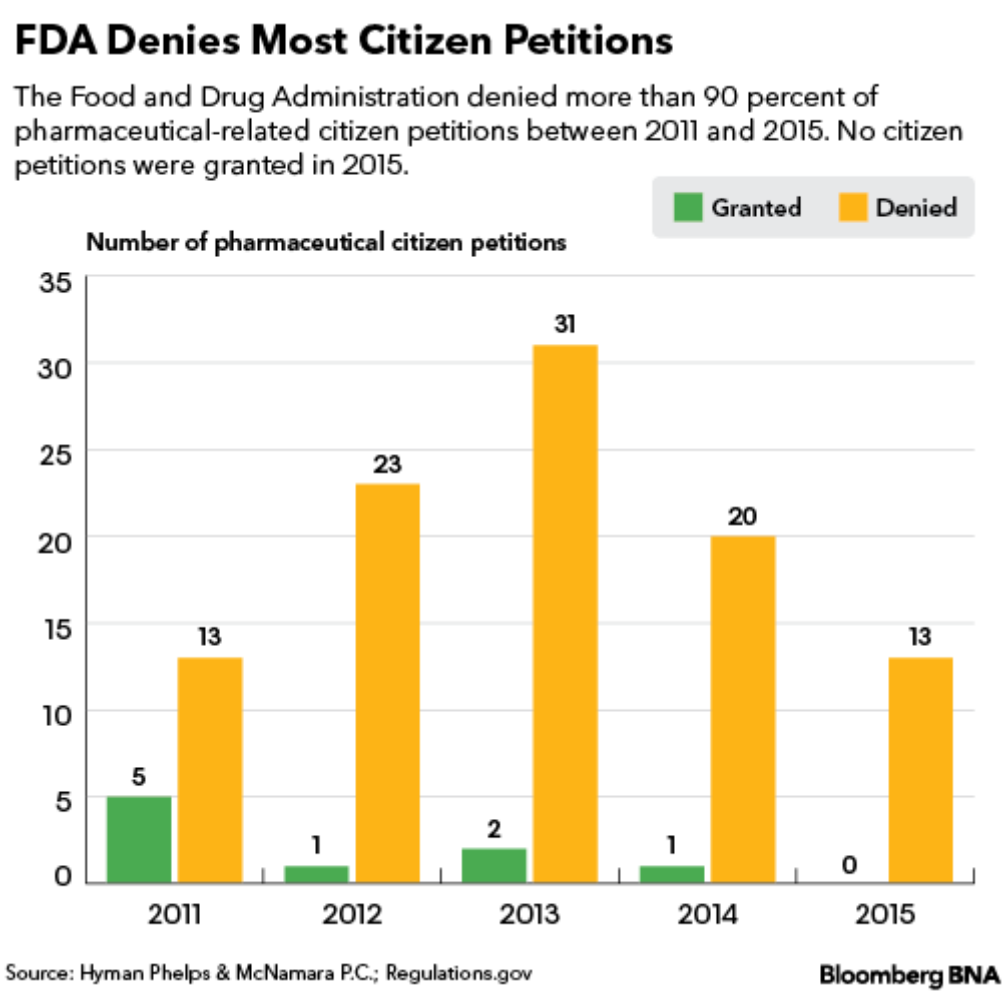
Carrier: To clear the "sham" exception to the Noerr-Pennington doctrine that provides immunity to petitioning activity, the FTC needed to have a strong case. The agency believed it cleared this threshold in this case, with Shire ViroPharma's 46 filings.

Bloomberg BNA: What is the status of the FTC case against Shire ViroPharma, and what are the next steps?

Carrier: The FTC filed a complaint in February 2017. Next, the defendant is expected to file a motion to dismiss.

Bloomberg BNA: Your most recent study of citizen petitions, which analyzed citizen petition filings between 2011 and 2015, found the Food and Drug Administration denies nearly 92 percent of all citizen petitions filed against pending generic applications. Can you explain the likely reasons behind why the Food and Drug Administration grants so few petitions?

Carrier: In denying 92 percent of citizen petitions, the FDA is concluding that the petitions do not raise valid safety concerns.



Bloomberg BNA: Don't some citizen petitions raise legitimate drug safety concerns?

Carrier: Some do, but the FDA denies the overwhelming majority of petitions targeting pending generic applications because they do not raise such concerns.

Bloomberg BNA: Given the high rate at which citizen petitions are denied, why is it worth drug companies' time to file citizen petitions?

Carrier: Even if a citizen petition is denied, the time it takes the FDA to review the petition could be time the generic is prevented from reaching the market.

Bloomberg BNA: What is the economic effect of delayed generic entry?

It's tough to prove that a citizen petition is an antitrust violation. A single denial may not be enough to show anticompetitive behavior, but a pattern of denials ... could raise competitive concerns."

Michael A. Carrier, Rutgers Law School, Camden, N.J.

Carrier: The economics of the pharmaceutical industry has long made clear that generic prices are lower than brand prices, dramatically so when multiple generics enter the market. Delayed generic entry means higher prices for consumers.

Bloomberg BNA: In your study, what percentage of citizen petitions did you find were filed late in generic application review process?

Carrier: We found that 98 percent of petitions were filed within six months of the expiration of a patent or FDA exclusivity period.

Bloomberg BNA: In the 2007 Food and Drug Administration Modernization Act, Congress made reforms to the citizen petition process aimed at curtailing abuses. Have those reforms been effective?

Carrier: As the FDA itself has acknowledged in its yearly reports to Congress, the reforms have generally not been effective, with the denial rate higher than ever and brands still able to obtain delay by filing petitions.

Bloomberg BNA: In November 2016, new FDA regulations provided that the agency cannot delay approval of a pending generic drug application unless a delay is needed is to protect the public health. Do you think the change has/will cut down on abusive petitions?

Carrier: I do not because it is unclear what constitutes "delay" and because the FDA likely will argue that delays are needed to protect public health.

Bloomberg BNA: Do you believe further reforms are needed? If so, what additional reforms would you suggest be implemented?

Carrier: Yes. For starters, increased transparency would be beneficial. The FDA issues yearly reports to Congress, but never explains which petitions delay generic entry or how it makes that determination. The agency could include a comprehensive list of 505(q) petitions—petitions targeting a pending generic—filed each year as well as the outcome for each. Second, the FDA's power to summarily dispose of petitions could be strengthened. Although section 505(q)(E)(1) allows the agency to summarily dispose of a petition that "on its face" does not raise a valid scientific or regulatory concern, it has never done so. Third, the FDA could calculate the cost in money and time it incurs in responding to citizen petitions.

Bloomberg BNA: Are there specific obstacles to establishing anticompetitive behavior based on use of the citizen petition process?

Carrier: It's tough to prove that a citizen petition is an antitrust violation. A single denial may not be enough to show anticompetitive behavior, but a pattern of denials or particular facts based on the timing of petitions or overall course of conduct could raise competitive concerns.

Bloomberg BNA: What avenues/remedies are available to generic companies to combat petitions they feel are improperly delaying their applications?

Carrier: The FDA has shown no interest in addressing competition concerns presented by petitions, referring such matters to the Federal Trade Commission. Such a course might become more frequent in the future.

Bloomberg BNA: What do you think will be the next frontier of antitrust actions in the pharmaceutical arena?

Carrier: With courts having addressed settlements and product hopping, three types of conduct will gain more attention in the future: citizen petitions, the denial of samples pursuant to Risk Evaluation and Mitigation Strategies (REMS) and behavior in the setting of large-molecule biologic medicines.

REMS is one of the next frontiers because brand name companies can offer an array of arguments as to why they shouldn't have to share samples with generics. For example, brand firms have claimed that they do not have a duty to deal with competitors and that they are justified in withholding samples because of safety or product liability concerns. Biosimilars will be fascinating because that's where the industry is headed, but it's not exactly clear how antitrust law should apply to biosimilars or what sort of analysis should apply. Biosimilars are more complex than small molecule drugs; perhaps there's more room for legitimate claims about safety.

Bloomberg BNA: With the new administration, do you think there will be changes in emphasis in the areas of enforcement actions against the pharmaceutical industry?

Carrier: Although enforcement priorities often differ between administrations, the new administration has highlighted the concern presented by high drug prices.

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