UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF NEW YORK

IN RE RESTASIS (CYCLOSPORINE OPHTHALMIC EMULSION) ANTITRUST LITIGATION	**18-MD-2819 (NG) (LB)**

THIS DOCUMENT APPLIES TO:

1199SEIU National Benefit Fund et al. v. Allergan, Inc., 17-cv-6755;

American Federation of State, County & Municipal Employees District Council 37 Health & Security Plan v. Allergan, Inc., 17-cv-6684;

Sergeants Benevolent Association Health & Welfare Fund v. Allergan, Inc., 17-cv-7300;

Philadelphia Federation of Teachers Health & Welfare Fund v. Allergan, Inc., 17-cv-7377;

St. Paul Electrical Workers' Health Plan v. Allergan, Inc., 18-cv-41;

FWK Holdings, LLC v. Allergan, Inc., 18-cv-677;

Rochester Drug Co-Operative, Inc. v. Allergan, Inc., 18-cv-970;

KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., v. Allergan, Inc., 18-cv-974;

International Union of Operating Engineers Local 501 Security Trust Fund v. Allergan, Inc., 18-cv-749;

United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund et al. v. Allergan, Inc., 18-cv-816;

Self Insured Schools of California v. Allergan, Inc., 18-cv-968;

Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund v. Allergan, Inc., 18-cv-969; and

Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund v. Allergan, Inc., 18-cv-972.

OPINION AND ORDER ON DEFENDANT'S MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6) FOR FAILURE TO ALLEGE CAUSATION

GERSHON, United States District Judge:

TABLE OF CONTENTS

I. INTRODUCTION

This multi-district litigation arises out of defendant Allergan's alleged actions to improperly delay the Food and Drug Administration ("FDA") in approving generic competitors to its dry-eye medication Restasis®. The plaintiffs purchased Restasis® after the date that Allergan's original, lawfully obtained patent had expired. They contend that the price they paid for Restasis® would have been lower if Allergan had been required to face competition from generic manufacturers. Plaintiffs bring claims under the Clayton Act, 15 U.S.C. §§ 15(a) and 26, for violations of sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, as well as various state laws.

There are two separate groups of plaintiffs, Direct Purchaser Plaintiffs ("DPPs") and End-Payor Plaintiffs ("EPPs"). The DPPs purchased Restasis® directly from Allergan, and the EPPs purchased Restasis® at another point in the chain of sale. Plaintiffs originally filed 13 separate cases in various courts around the country, and the Judicial Panel on Multi-District Litigation transferred all of the matters to the Eastern District of New York, where they were consolidated before me.[1] After I appointed separate lead counsel for the DPPs and the EPPs, each group filed a consolidated class action complaint on behalf of the plaintiffs in that group. Thus, instead of 13 class action complaints in this case, there are two (the "Consolidated Complaints").[2]

The complaints are substantially identical with respect to what Allergan is alleged to have done. Plaintiffs allege that Allergan engaged in a number of unlawful, anticompetitive measures

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[1] Three cases that were transferred to me have been voluntarily dismissed.

[2] There are three additional complaints—one on behalf of Walgreen Co., The Kroger Co., Albertsons Companies, Inc., and HEB Grocery Company L.P.; one on behalf of CVS Pharmacy, Inc.; and one on behalf of Rite Aid Corporation and Rite Aid Hdqtrs. Corp.—that are not filed as class actions. Those actions, on behalf of direct purchasers of Restasis®, are not subject to defendant's current motion.

to delay generic drug manufacturers from entering the market and to allow Allergan to continue charging inflated monopoly prices for Restasis®. These measures include: (1) filing frivolous citizen petitions with the FDA to delay its approval of generics; (2) defrauding the U.S. Patent and Trademark Office ("USPTO") into issuing second-wave patents on Restasis® by submitting a false and misleading affidavit; (3) wrongfully listing those patents in the FDA's Orange Book, which delayed the generic approval process; (4) suing generic manufacturers for infringing on those fraudulently obtained patents without a good-faith belief that its suits could succeed; and (5) transferring the patents to the Saint Regis Mohawk Tribe (and then leasing them back) in order to avoid their invalidation by "renting" the Tribe's sovereign immunity.

Defendant now moves to dismiss the Consolidated Complaints for failure to adequately allege causation. For the reasons set forth below, Allergan's motion is denied.

II. PLAINTIFFS' ALLEGATIONS

A. Allergan's Development of Restasis®

The allegations of the Consolidated Complaints, taken as true for purposes of this decision, are as follows. In 1993, Allergan bought a license from another pharmaceutical company for a patent that covered the use of the drug cyclosporine to treat dry eyes. Cyclosporine is insoluble in water, and therefore difficult to deliver in an aqueous solution, such as an eye drop. While the idea of using cyclosporine to treat dry eyes was covered by the existing patent, nobody had yet developed a method to get cyclosporine into a person's eyes. Allergan solved this problem by using an oil-in-water emulsion that contained a small amount of castor oil, which would dissolve the cyclosporine, together with glycerin, an emulsifier, and an emulsion stabilizer, in water.

Allergan obtained a patent—referred to by the parties as the "Ding I" patent—covering the cyclosporine/castor oil emulsion on December 12, 1995.[3] This patent expired on May 17, 2014.

The Ding I patent covered a range of ratios between cyclosporine, castor oil, glycerin, the emulsifier, the emulsion stabilizer, and water. In relevant part, the patent covered any solution containing: between .05% and .4% cyclosporine and between .625% and 5.0% castor oil. It also listed four examples (labeled 1A-1E) as potential formulations. Two such examples relevant to this case were: .1% cyclosporine to 1.25% castor oil and .05% cyclosporine to .625% castor oil.

After obtaining the Ding I patent, Allergan began clinical trials of several combinations of cyclosporine and castor oil. In the first clinical trial, known as the "Phase 2" study, Allergan tested all four of the combinations listed as examples in the Ding I patent—plus a control group using no cyclosporine and, instead, just castor oil, glycerin, and the emulsifiers—on a total of 88 patients with moderate-to-severe dry-eye disease. The goal of Phase 2 was to determine the safety and efficacy of particular doses of the drug in order to settle on an appropriate dosage level for large-scale clinical trials ("Phase 3"). The results of the Phase 2 study were published in May 2000. All tested combinations, including the castor-oil-only solution, improved the symptoms of dry-eye disease, and all the cyclosporine solutions outperformed the castor-oil-only group. Importantly, the Phase 2 study concluded that the drug's efficacy *did not increase* when more than .05% cyclosporine was present. The .1% cyclosporine formulation "did not perform better" than the .05% formulation. (DPP Compl. ¶ 107.) That said, there were differences in how the .05% and .1% cyclosporine formulations performed. The .1% formulation "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the .05% formulation "produced the most consistent improvements in

[3] U.S. Patent No. 5,474,979. There is also a "Ding II" patent, but it is not relevant to this decision.

patient symptoms (such as sandy/gritty feeling and ocular dryness)." (DPP Compl. ¶ 108.) Therefore, the authors of the Phase 2 study recommended that subsequent clinical studies should focus on those two formulations.

Allergan's Phase 3 trials did just that. Those trials compared each of the formulations to the castor-oil-only control group, but not directly to each other. Three solutions were tested—.05% cyclosporine to 1.25% castor oil, .1% cyclosporine to 1.25% castor oil, and the control group of no cyclosporine and just castor oil. The Phase 3 results, which were also published in 2000, showed that both cyclosporine formulations outperformed the castor-oil-only control group, but that neither outperformed the other.

In February of 1999, following the Phase 3 trials, but before the results were published, Allergan filed a New Drug Application ("NDA") with the FDA seeking to market the .05% cyclosporine to 1.25% castor oil formulation tested in the Phase 3 trials. This formulation, which would become the Restasis® formulation, falls within the ratios covered by the Ding I patent, though it is not one of the specific examples listed. The FDA approved that application in December 2002, and Allergan launched Restasis® in 2003. Since then, Restasis® has been the only FDA approved therapeutic treatment for dry eyes available on the U.S. market. Restasis® owns 100% of the market share and has annual sales of approximately $1 billion. According to plaintiffs, every month that Allergan maintains its monopoly results in another $125 million in revenue.

B. Allergan's Unsuccessful Attempts to Obtain a Second-Wave Patent on Restasis®

Anticipating that the Ding I patent would expire on May 17, 2014, Allergan made several attempts between 2004 and 2009 to obtain a "second-wave" patent that would continue to cover Restasis® after the Ding I patent expired. Because all of these attempts were unsuccessful, they

are not the basis for any of plaintiffs' claims. Nevertheless, they provide important context for Allergan's later, successful effort.

In August of 2004, Allergan attempted to obtain a patent on dry-eye medication with less than .1% cyclosporine and greater than .625% castor oil. This application was rejected, because it was obvious in light of the Ding I patent, which covered those ratios. In response, Allergan amended the application to include only the exact formula of Restasis®: .05% cyclosporine and 1.25% castor oil, which was again rejected as obvious in light of Ding I. Allergan both appealed this rejection and filed a new application that was similar but added claims regarding new conditions that the method was asserted to treat, such as corneal graft rejection.[4]

In June of 2009, however, Allergan withdrew its appeal and conceded that the claims for which it sought a more specific patent covering the Restasis® formulation were obvious in light of Ding I. Specifically, Allergan wrote to the USPTO that "[t]he applicants concede that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at [the Restasis® formula]. The differences are insignificant." Allergan also wrote that the claimed formulas for which it sought second-wave patents were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise." Allergan did add a new claim, however, for a patent on a composition of less than .05% cyclosporine combined with no more than 1.25% castor oil. On September 1, 2009, this new claim was also rejected as obvious in light of Ding I. After that, Allergan stopped pursuing second-wave patents for several years.

[4] A narrow patent was issued on December 21, 2013, U.S. Patent No. 8,618,064, limited to the use of a cyclosporine formulation to treat corneal graft rejection. It does not affect the market for dry-eye medication.

C. Applications for FDA approval of Generic Versions of Restasis®

Normally, drug companies that wish to sell a new drug must file an NDA with the FDA that includes certain specific data on the safety and effectiveness of the drug. However, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") allows manufacturers to file Abbreviated New Drug Applications ("ANDAs") with the FDA for generic versions of already approved drugs. The generic manufacturers are not required to prove the drugs' safety and efficacy, as that has already been done by the brands. All these manufacturers need to show is that their generic copies share the same active ingredients and are bioequivalent to the brand name drug. The premise is that two drug products containing the same active pharmaceutical ingredient, in the same dose, and delivered in the same way, are equally safe and effective.

Plaintiffs identify five generic manufacturers who submitted ANDAs for generic Restasis® by January of 2014. The earliest known ANDA was filed on November 14, 2011 by Watson Pharmaceuticals, followed by Teva Pharmaceuticals, Akorn Pharmaceutials, Mylan Pharmaceuticals, and finally InnoPharma on January 13, 2014. Plaintiffs allege that, by the summer of 2015, the FDA had concluded that at least some of those ANDAs were substantially complete at the time they were first filed. For example, InnoPharma has stated that, in mid-2015, the FDA deemed its ANDA to be substantially complete as of the January 2014 filing date. The Food, Drug, and Cosmetic Act ("FDCA") defines a "substantially complete" application as one that "on its face is sufficiently complete to permit a substantive review and contains all the information required." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc).

The FDA, therefore, could have performed a substantive review as soon as January of 2014, and possibly even earlier for the other ANDAs. The substantive review could have allowed it to approve (or reject) the proposed generic. Plaintiffs allege that it is likely the FDA would have

approved one or more of the ANDAs for several reasons: (1) they were submitted by "[s]ome of the largest and most sophisticated drug companies;" (2) the ingredients "are commonly known, easily available, and unprotected by patents;" and (3) the actual production of cyclosporine ophthalmic emulsion poses "little manufacturing or formulation obstacles." (DPP Compl. ¶ 283.)[5] As of yet, however, the FDA still has not issued a decision on any ANDA. Plaintiffs allege that Allergan is responsible for at least some part of the delay.

D. Allergan's Alleged Improper Efforts to Delay Generic Versions of Restasis®

1. Submitting Sham Citizen Petitions to the FDA

A generic drug is deemed bioequivalent to an already approved drug if any differences in formulation, *i.e.*, differences in preservatives or other inactive ingredients, do not impact the rate and extent to which the active ingredient (here, cyclosporine) becomes available at the site of action (here, the eye). 21 U.S.C. § 355(j)(8)(B)(i). The FDA has flexibility in determining how the bioequivalence requirement is tested. The testing may use *in vitro* data (from laboratory studies), *in vivo* data (from live subjects), or both. *See id.* § 355(j)(7)(A)(i)(III). The selection of the method is case-by-case and "depends upon the purpose of the study, the analytical methods available, and the nature of the drug product." 21 C.F.R. § 320.24(a). Applicants are required to use "the most accurate, sensitive, and reproducible approach available" that is capable of establishing bioequivalence for the product being studied. *Id.*

In June of 2013, with less than a year left on the Ding I patent, the FDA issued a draft guidance, on which it sought public comment, containing recommendations to applicants seeking to gain approval for generic versions of Restasis®. Such guidance is not required, and plaintiffs

[5] Allergan argues that this is untrue, and that Restasis® is difficult to copy. The question of which party is correct is not suitable for resolution on a motion to dismiss.

allege that the FDA often approves generic versions of drugs without issuing any guidance. However, according to plaintiffs, by posting a draft guidance, and seeking comment on it, the FDA showed that it was well underway in evaluating the circumstances under which it would approve a generic version of Restasis®.

The draft guidance for generic versions of Restasis® recommended the use of *in vitro* testing where: (1) the quality and quantity of the proposed ingredients, both active and inactive, of the generic were the same as that used for Restasis®; (2) a comparative physiochemical characterization between Restasis® and the generic was performed on six separate specified dimensions; and (3) the drug-release-rate tests were compared based on *in vitro* tests. Unless all those criteria were met, the proponent of the generic drug would be required to use *in vivo* testing.

On August 17, 2013, Allergan submitted a comment to the FDA asserting that the FDA should not approve any generic version of Restasis® relying on *in vitro* testing. It told the FDA that it should "replace the Draft Guidance with a revised guidance document that explains *in vivo* comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to" Restasis®. Allergan also caused its position to be echoed in comments submitted by several doctors who, unbeknownst to the FDA, had received payments from Allergan for "consulting" services and "travel and lodging," some of which specifically related to Restasis®. For example, three doctors who submitted comments critical of an *in vitro* bioequivalence option received over $125,000 combined from Allergan.

Plaintiffs allege that Allergan knew that these comments to the draft guidance would not necessarily delay generic entry. This is because the FDA is required only to consider these comments; it is not required to respond to them. Therefore, starting in January of 2014, Allergan

began to file with the FDA a series of "citizen petitions" attacking the FDA's draft guidance, which do require a response.

Before addressing the specifics of Allergan's citizen petitions, it is helpful to review what a citizen petition is. The FDCA allows any person to file a "citizen petition" requesting that the FDA take, or refrain from taking, administrative action. 21 C.F.R. § 10.25(a)(2). FDA regulations require the agency to respond to a petition within 150 days of receipt. *Id.* § 10.30(e)(5). Plaintiffs allege that reviewing and responding to citizen petitions is a resource-intensive and time-consuming task, because the FDA must research any scientific, medical, legal, and/or economic issues raised by the petition, and must coordinate internal review and clearance of the response to the petition.

According to plaintiffs, brand companies frequently use the citizen petition process to delay FDA approval of a competing generic. In addition to requiring the FDA to prepare a response, the filing of these petitions by brand companies signals to the FDA that the company is likely to file litigation against the FDA if it approves an ANDA and denies the petition. These petitions, therefore, can result in a considerable delay in the ANDA approval process while the FDA ensures that it is adequately prepared for potential litigation. Plaintiffs allege that the FDA thus has a well-known, longstanding practice of withholding ANDA approval until after the agency has authorized a response to a citizen petition that bears on the subject of the pending ANDA, even where the petition may lack merit. Indeed, the FDA has long acknowledged the problem of citizen petition abuse, stating in 2005 that it had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving an [ANDA], but rather to delay approval . . . ." 153 Cong. Rec. 127 (Jan. 4, 2007) (statement of FDA Chief Counsel Sheldon Bradshaw in 2005). Plaintiffs allege that these concerns continue despite

a recent amendment to the FDCA, 21 U.S.C. § 355(q)(1)(A), which requires the FDA not to delay approval of a pending ANDA because of a citizen petition unless it determines that the delay is "necessary to protect the public health."

Allergan's first citizen petition was filed on January 15, 2014, and it filed another petition on February 28, 2014, which added to and repeated the requests and arguments of the January petition. Allergan eventually withdrew the January petition, allowing the February petition to replace it. The petition largely reiterated Allergan's August 2013 comments to the FDA's June 2013 guidance, and made six requests of the FDA, including that it: (1) withdraw the draft guidance for generic approval and make clear that bioequivalence for a proposed generic version of Restasis® can be demonstrated only through *in vivo* clinical studies; (2) reject as incomplete any ANDA referencing Restasis® that does not include data from at least one *in vivo* study; and (3) make clear that it will not approve any ANDA based exclusively on *in vitro* data until clinical studies have been performed to validate that the *in vitro* studies correlate to relevant *in vivo* bioavailability. In support of the petition, Allergan cited to the public comments submitted by the doctors who had been paid by Allergan, again without disclosing that it had paid those doctors. Allergan supplemented this petition on May 29, 2014 and on October 31, 2014.

The FDA rejected every substantive request made in the citizen petition on November 20, 2014. The agency provided a thorough explanation of the scientific basis for the draft guidance. In sum: (1) for drugs like Restasis® that have a modest clinical benefit, *in vitro* studies are likely to be more sensitive, accurate, and reproducible than comparative clinical studies; (2) *in vivo* studies could require more than 2,000 subjects with dry-eye disease to pass the statistical tests; and (3) a proposed generic that contains the same ingredients, in the same proportions, and shows the same release rate in *in vitro* tests should be sufficiently bioequivalent. The FDA also stated that the

guidance was consistent with its policies to protect the public health, including refraining from unnecessary human research when other methods of demonstrating bioequivalence meet the regulatory standards for approval. Additionally, although it did not waver from its positions, the FDA noted on a few occasions in its response that it was considering revising its draft guidance to clarify certain topics addressed by Allergan in its petition. The FDA granted only Allergan's requests for: (1) an opportunity to comment on the guidance (which Allergan had already been given); and (2) an articulation of the basis of the FDA's guidance decision (which the FDA's response to the petition accomplished and which the FDA was required to do in response to any petition on the subject).

Allergan did not appeal the November 2014 rejection to a federal court, as it could have done. *See* 5 U.S.C. § 702; 21 C.F.R. § 10.45. While an appeal of the FDA's decision might have resolved the issues, it would not have interfered with the FDA's review of the pending ANDAs, which plaintiffs allege to have been Allergan's true goal.

Instead, Allergan filed another citizen petition on December 23, 2014. This second petition largely repeated the positions and requests in the initial petition. Allergan supplemented the second petition four times, including on August 26, 2015, when it requested that the FDA convene a committee of outside experts to evaluate the use of *in vitro* methods, and refuse to receive, review, or approve any generic Restasis® ANDAs until the outside committee's evaluation was complete. Plaintiffs contend that, given the FDA's rejection of Allergan's first petition, there was no realistic expectation that the second petition or its supplements would succeed, because they did not provide new, clinically relevant information.

On February 10, 2016, the FDA issued a lengthy letter denying all the substantive requests made by Allergan in its second petition and its supplements. In addition to disagreeing with

Allergan's assertion that it "cannot receive or approve any ANDA submitted to the FDA that contains only in vitro test results," the agency found characterizations in Allergan's petition to be "misleading," research data it cited to be "insufficient," and scientific methods on which Allergan relied to be invalid and unreliable. It also wrote that Allergan had "repeat[ed] many of the assertions" from the first petition, and it concluded that Allergan's arguments "lack legal support" and "rest on flawed logic." In the letter's final sentences, the FDA granted two of Allergan's requests—that the agency: (1) disclose the *in vitro* bioequivalence methods it intended to accept for ANDAs; and (2) respond specifically to Allergan's testing of nine experimental test emulsions. It then stated that the letter itself fulfilled these requests and specifically noted that it had found Allergan's experimental data to be deficient. Again, Allergan elected not to appeal the denial of its petition to the courts. On February 10, 2016, the same day that it issued its response to Allergan's petition, the FDA posted a revised version of its draft guidance. The FDA published a notice about its revised draft guidance in the *Federal Register* on February 16, 2016.

In August of 2017, Allergan filed a third citizen petition to the FDA.[6] The petition again requested that the FDA refuse to accept or approve any pending ANDAs unless supported by *in vivo* clinical studies. Allergan supplemented the petition on October 13, 2017. Plaintiffs allege that there was no realistic expectation that the petition would be successful, as it merely rehashed arguments and scientific evidence already considered and rejected by the FDA in denying the prior petitions. The third petition was denied on January 2, 2018, in a brief letter which, after noting that the FDA is obligated to respond to a petition within 150 days, primarily stated that the third petition was substantially the same as the previous ones. "Because the FDA has addressed those assertions

[6] In addition, in 2016, the FDA issued amendments to its draft guidance and Allergan submitted comments on those amendments.

in its responses to the previous citizen petitions, it does not address them again here," the response explained. It continued:

> To the extent this Petition requests actions different from those requested in Allergan's previous citizen petitions that might have implications regarding the nature of the data and information necessary to support approval of an ANDA for cyclosporine ophthalmic emulsion, we deny those requests without comment. We will consider any issues related to such requests in the context of our review of specific applications and the record for the Draft Cyclosporine [Bioequivalance] Guidance.

2. Defrauding the USPTO into Issuing Second-Wave Patents

Meanwhile, in August of 2013, Allergan had filed six additional applications for patents with the USPTO. The applications are substantially identical to Allergan's prior, failed applications to obtain a patent specifically covering the Restasis® formulation, which Allergan had conceded was obvious in light of the Ding I patent.

Under patent law, "where there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations." *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. Dec. 11, 2013).[7] This was the issue facing Allergan: their own prior art patent disclosed a finite range, and prior studies showed that there was motivation to select the Restasis® formulation from that range. Therefore, to escape the conclusion of obviousness, Allergan would have to show an "unexpected result."

[7] Though this opinion had yet to issue at the time of Allergan's applications to the USPTO, the principle that unexpected results can overcome a prima facie case of obviousness in light of prior art was already established. *See, e.g., Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

Allergan purported to do just that. In its August 2013 filings, Allergan represented that, since its 2009 concession of obviousness, it had "collected evidence that supports the patentability of the pending claims." Specifically, Allergan told the USPTO that the Restasis® formulation of .05% cyclosporine to 1.25% castor oil performed far better than would be expected as compared to the .1% cyclosporine to 1.25% castor oil formulation. Allergan claimed that the Phase 2 trial revealed that the .1% cyclosporine formulation outperformed the .05% cyclosporine formulation, while the Phase 3 study revealed that the .05% formulation outperformed the .1% formulation. Thus, according to Allergan, the results of the Phase 3 trial were unexpected in light of the Phase 2 results.

These representations were false. The Phase 2 and Phase 3 trials were published in 2000, not "since 2009." Additionally, as described above, in neither Phase 2 nor Phase 3 did either of the formulations outperform the other. On October 17, 2013, the patent examiner rejected the second-wave patent applications.

A week later, on October 23, 2013, Allergan submitted to the patent examiner a declaration from Dr. Rhett Schiffman in an effort to overcome the rejection. Dr. Schiffman claimed that the Phase 3 results for Restasis® were surprising because it performed significantly better than the .05 cyclosporine/.625 castor oil formula, which was tested in Phase 2 and disclosed as an example in the Ding I patent. Dr. Schiffman said this result was unexpected because the Phase 2 trial had suggested that the .1% cyclosporine formulation was superior to the .05% formulation. Plaintiffs allege, relying on the decision in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2017 WL 4803941, at *38–39 (E.D. Tex. Oct. 16, 2017), that the Schiffman declaration was false and misleading for four separate reasons:

1. It relied on statistically insignificant data, and concealed the fact that the data was statistically insignificant from the USPTO.

2. It did not compare like test results; it compared the Schirmer tear tests performed with anesthetic to Schirmer tear tests conducted without anesthetic. Such a comparison has no scientific value.[8]

3. It used data manipulation techniques to amplify small differences between test results, giving the false impression that Dr. Schiffman had actually obtained significant results, and

4. It did not mention that Dr. Schiffman lifted the data he presented from the Phase 3 paper, published in 2000, more than a decade earlier. Thus, the data was prior art to the second-wave patents, and it could not support Allergan's patent application.[9]

The Schiffman declaration led the USPTO to reverse course. On November 21, 2013, the USPTO authorized the second-wave patents for which Allergan had applied. The decision to issue the patents explicitly relied on the representations made in the Schiffman declaration. In fact, in the Eastern District of Texas trial, Dr. Schiffman conceded that his declaration was instrumental in persuading the USPTO to grant the applications. The patents were issued one at a time. Five issued between January and April of 2014, and the sixth issued in February of 2016. Plaintiffs allege that Allergan procured these patents through knowing and intentional fraud on the USPTO.

3. Wrongfully Listing the Second-Wave Patents in the Orange Book

Under the Hatch-Waxman Act, a new drug applicant must submit to the FDA information on each patent that covers the drug or methods-of-use described in the NDA for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA then publishes this information in a digest titled *Approved Drug Products with Therapeutic Equivalence*

[8] A Schirmer tear test is a commonly used device to diagnose and measure dry eyes. It involves placing a strip of filter paper under a patient's eyelid and recording how many millimeters of the paper are wetted by the patient's tears.

[9] The Eastern District of Texas's decision is discussed in greater detail *infra* at pp. 20–21, in the section on Allergan's patent infringement lawsuits against the generic manufacturers.

Evaluations, which is known as the Orange Book. The purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug. If, as here, a drug patent is issued after the drug has already been approved by the FDA, the drug sponsor must file that patent information with the FDA no later than 30 days after the date the new patent is issued. *Id.* § 355(c)(2).

Allergan listed each of the five second-wave Restasis® patents that issued between January and April of 2014 in the Orange Book shortly after they were issued. Plaintiffs allege that these listings were improper because Allergan knew it had obtained the patents through fraud and that a claim of patent infringement could not reasonably be asserted based on them. Put another way, Allergan knew that it could not realistically expect to prevail on the merits of any patent infringement suit it brought, since it knew the claims in the second-wave patents were obvious in light of Ding I, and it was aware of the fraud it perpetrated through the Schiffman declaration.

The Orange Book listing has regulatory consequences with the FDA, two of which are significant here. First, a generic drug manufacturer, when it submits an ANDA, must include in its application one of the following four certifications with respect to the patents covering the branded drug it seeks to produce:

1. That such patent information has been not filed [in the Orange Book] (a "Paragraph I certification");

2. That such patent has expired (a "Paragraph II certification");

3. The date on which such patent will expire (a "Paragraph III certification"); or

4. That such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted (a "Paragraph IV certification").

21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(IV).

By listing the second-wave patents in the Orange Book, Allergan required any potential generic Restasis® manufacturer to submit a Paragraph IV certification with its ANDA. When an application containing a Paragraph IV certification is received by the FDA for substantive review, the ANDA must also provide the patent owner with notice of the Paragraph IV certification, which includes a description of the factual and legal basis for the ANDA's assertion that the patent is invalid. *Id.* § 355(j)(2)(B)(iv)(II). After receiving a Paragraph IV certification, a patent holder such as Allergan can initiate a patent infringement action against the company filing the ANDA. *Id.* § 355(j)(5)(B)(iii). If it does so within 45 days of receiving the Paragraph IV certification, the suit will result in an automatic stay of the FDA's approval of the ANDA for 30 months, or such period as the court hearing the patent infringement action might order. *Id.* The FDA can grant tentative, but not final, approval to ANDAs during such a stay. 21 C.F.R. § 314.105(a). As discussed more fully below, Allergan did file patent infringement suits against generic manufacturers who submitted ANDAs and did trigger a stay of the FDA's approval process for generic Restasis®.

Plaintiffs allege that the first generic manufacturer to file an ANDA with a Paragraph IV certification undertakes a substantial risk of patent infringement litigation. In order to incentivize generic manufacturers to file ANDAs with Paragraph IV certifications—as opposed to waiting to free-ride off of another generic manufacturer that assumes the risk of challenging the patent—the Hatch-Waxman Act provides that the first applicant to submit a substantially complete application containing a Paragraph IV certification will have a 180-day exclusivity period as the only generic on the market. 21 U.S.C. § 355(j)(5)(B)(iv). Subsequent ANDAs that contain Paragraph IV certifications cannot be approved until after this exclusivity period runs, unless the first applicant forfeits the exclusivity. *Id.* § 355(j)(5)(D).

Allergan's listing of the second-wave Restasis® patents, therefore, allowed it not only to trigger a 30-month stay of FDA approval for the first generic Restasis® application; it also prevented all other generic applications from being approved for an additional six months after the first application would have been approved. In effect, it allowed Allergan to extend its monopoly for the duration of the stay and potentially to limit the competition to only one generic competitor for an additional six months.

4. Filing a Series of Sham Patent Infringement Lawsuits

In June of 2015, the FDA acknowledged the receipt of several ANDAs containing Paragraph IV certifications for generic Restasis®. This triggered the ANDA applicants' obligation to serve notice of their Paragraph IV certifications on Allergan, which, starting in July of 2015, the generic manufacturers Apotex, Akorn, Mylan, and Teva did. Several more generic manufacturers would eventually do the same. On August 24, 2015, Allergan filed suit against Apotex, Akorn, Mylan, and Teva in the Eastern District of Texas, alleging infringement of the second-wave Restasis® patents. Allergan brought four more suits—against InnoPharma, Famy Care Pharma, Twi Pharmaceuticals, and Deva Holdings—in 2015 and 2016, after Allergan received those Paragraph IV certifications.

According to plaintiffs, knowing, as Allergan did, that the patents were procured through fraud, Allergan could not have had a reasonable expectation of prevailing on the merits in any of these suits. Rather, the purpose of the suits was to trigger the 30-month stay of FDA approval of the generics. Plaintiffs rely on the opinion of Federal Circuit Judge William C. Bryson, sitting by designation in the Eastern District of Texas, rendered after a bench trial, which found that the Restasis® formulation was obvious in light of the Ding I patent and that the subsequent patents issued only because Allergan had "painted a false picture" of the relevant data. *Allergan, Inc.*,

2017 WL 4803941, at *39. Allergan has appealed this decision, and that appeal is pending before the Federal Circuit.

5. Attempting to Avoid Invalidation of the Second-Wave Patents via Sale to the Saint Regis Mohawk Tribe

In June of 2015, generic manufacturer Apotex petitioned the USPTO to initiate an *inter partes* review of the second-wave patents. *Inter partes* review is a process by which private parties may challenge previously issued patent claims in an adversarial process before the USPTO. *SAS Institute Inc. v. Iancu*, 584 U.S. __, 138 S.Ct. 1348, 1352 (2018); 35 U.S.C. §§ 311–19. The process is initiated by the filing of a petition. 35 U.S.C. § 311(a). The petition may request cancellation of one or more claims of the patent on the grounds that the claims are obvious or not novel, and it must identify the grounds for the challenge and the evidence supporting the challenge. *Id.* §§ 311(b), 312(a)(3). The patent owner may submit a preliminary response to the petition explaining why *inter partes* review should not be instituted. *Id.* § 313. The Patent Trial and Appeals Board ("PTAB"), on behalf of the Director of the USPTO, then decides whether to institute an *inter partes* review. *Id.* § 314; 37 C.F.R. § 42.4(a). The PTAB does so if it finds that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). If the Board institutes review, the parties conduct discovery, brief issues, and present evidence at an oral hearing. *Iancu*, 138 S.Ct. at 1354. The parties may also settle their differences and seek to end the review. 35 U.S.C. § 317. If the review is not dismissed, the Board "shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner." *Id.* § 318(a).

In December of 2015, with a Board ruling expected shortly, Allergan settled the Apotex *inter partes* proceeding on undisclosed terms. By that point, however, other ANDA applicants, including Mylan and Teva, had also petitioned the Board for *inter partes* review. Those petitions

were granted in December of 2016, and the Board instituted *inter partes* review against all six second-wave patents.

In an effort to save the patents from invalidation, on September 8, 2017, Allergan conveyed ownership of the patents to the Saint Regis Mohawk Tribe, which in turn gave Allergan an exclusive license for all FDA approved uses of Restasis® in the United States. In addition to conveying the patents to them, Allergan paid the Mohawk Tribe $13.5 million, plus up to $15 million in annual royalties. In "consideration" for the patents, the initial payment, and the royalties, the Mohawk Tribe gave Allergan only one thing—a promise not to waive its sovereign immunity with respect to any *inter partes* review or other administrative action in the USPTO relating to the second-wave patents. After the transfer, on September 22, 2017, Allergan and the Mohawk Tribe petitioned the Board to dismiss the pending *inter partes* review proceeding based on tribal sovereign immunity. That motion was denied by the PTAB, whose decision was recently affirmed by the Federal Circuit. *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 2018 WL 3484448, at *1–2 (Fed. Cir. July 20, 2018) ("We hold that tribal sovereign immunity cannot be asserted in IPRs."). The Federal Circuit had stayed *the inter partes* review proceeding while the appeal was pending.

Allergan's Chief Executive Officer, Brent Saunders, explicitly acknowledged that the purpose of the Mohawk transfer was to disrupt the ongoing proceedings that may invalidate the patents—the *inter partes* review proceedings and the federal patent infringement lawsuit that Allergan itself had initiated against the generic manufacturers. Plaintiffs allege that no reasonable litigant could expect these obstructionist tactics to succeed and that Allergan undertook this sham transfer only to further delay the inevitable invalidation of its patents.

III. LEGAL STANDARDS

Defendant moves to dismiss the Consolidated Complaints pursuant to Federal Rule of Civil Procedure 12(b)(6). When considering such a motion, the court must accept as true all well-pleaded factual allegations and must draw all reasonable inferences in plaintiffs' favor. *Swiatkowski v. Citibank*, 446 Fed. Appx. 360, 360–61 (2d Cir. 2011). To survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Facial plausibility exists when a plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

When deciding a Rule 12(b)(6) motion, "courts must consider the complaint in its entirety, as well as . . . documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Allergan asks me to take judicial notice of the contents of its three citizen petitions to the FDA and the FDA's responses thereto, which are referenced in the complaints and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Ev. 201(b)(2). Plaintiffs do not oppose this request, and offer additional documents for judicial notice which are publicly available through U.S. government-operated websites, including the FDA's June 20, 2013 Draft Guidance on Cyclosporine, its revised February 16, 2016 Draft Guidance, and its revised October 5, 2016 Draft Guidance, as well as Allergan's comments on all three of them. As all of the documents are referenced in the complaints and publicly available from sources whose accuracy cannot reasonably be questioned, I do take judicial notice of them.

"Causation in fact is, of course, a necessary element of any claim for relief." *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017). "An antitrust plaintiff must show that

a defendant's anticompetitive act was a 'material' and 'but-for' cause of plaintiff's injury, although not necessarily the sole cause." *Id.* When a plaintiff alleges that a defendant excluded generic competition from the market, the plaintiff must plead facts giving rise to a plausible inference that, but for the challenged conduct, at least one generic manufacturer could and would have entered the market on an earlier date. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 149 (3d Cir. 2017); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *9 (D. Mass. Sept. 16, 2015). A plaintiff "need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury." *Actos*, 848 F.3d at 97–98 (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969)).

IV. ANALYSIS

For purposes of this motion, Allergan does not challenge the allegations of its misconduct: that it defrauded the USPTO into issuing it second-wave patents, used those patents to effect a 30-month stay of FDA approval of competitors to Restasis®, and filed a series of citizen petitions with the FDA attacking its guidelines for the approval of generic Restasis®; and when it appeared as though its patents would be invalidated by a federal court and/or the USPTO, Allergan conveyed them to the Saint Regis Mohawk Tribe and spent millions of dollars in an attempt to frustrate those proceedings by "renting" the Tribe's sovereign immunity.

Allergan argues only that these actions were harmless and caused no injury. It relies on a series of inferences leading to the conclusion that, Allergan's behavior aside, the FDA was nevertheless not ready to approve any of the generics. Allergan asks me to find, as a matter of law, that this conclusion is the only plausible one and therefore none of its alleged actions—which were taken with the sole objective of delaying market entry of competitors to Restasis®—could have been successful in causing any such delay.

A. Are the Citizen Petitions Protected by *Noerr-Pennington*?

As an initial matter, I must determine whether Allergan's citizen petitions are protected by the First Amendment and therefore immune from antitrust liability pursuant to the *Noerr-Pennington* doctrine. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965). The *Noerr-Pennington* doctrine shields citizen petitions that are not "wholly baseless" from liability. *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 62 n.7 (2d Cir. 2016). "Sham" petitions, *i.e.*, those that are "not genuinely aimed at procuring favorable government action," are unprotected. *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500 n.4 (1988). For petitions that are "essentially nothing more than an attempt to smother competition," "the First Amendment protections are lost and the Sherman Act applies." *Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 812–13 (2d Cir. 1983).

In *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 60 (1993), the Supreme Court set forth a two-pronged test to determine whether a party's conduct is a sham and thus is not entitled to immunity (the "PRE test"). First, plaintiffs must show that the petition was "objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits." *Id.* If such a showing is made, plaintiff must then establish that the subjective intent of the petitioning party was to inhibit competition, rather than to petition the government for redress. *Id.* at 60–61.[10]

[10] The Second Circuit has adopted an alternative test that applies in a subset of cases in which the petitioning party has engaged in a pattern or practice of filing successive petitions. *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92, 101–02 (2d Cir. 2000). That test asks only whether plaintiffs have alleged that the filings were made, "not out of a genuine interest in redressing grievances, but as a pattern or practice of successive filings undertaken essentially for purposes of harassment." *Id.* at 101. The parties dispute whether this test applies here, because it applies only where the number of filings is "voluminous." Allergan contends it filed only three citizen petitions,

In its motion, Allergan does not address the second (subjective) prong of the PRE test. In view of plaintiffs' allegations in the complaints, it is easily established that Allergan's subjective intent in filing citizen petitions was to frustrate generic competition of Restasis®. Plaintiffs allege that Allergan chose not to appeal any of the denials of its petitions to a federal court, knowing that it was unlikely to win an appeal and preferring instead to file successive petitions because that would be more disruptive to the FDA approval process. No other inference is offered by defendant as to why it did not appeal the denials. Plaintiffs also allege that Allergan made scientific misrepresentations to the USPTO to obtain the patents, filed frivolous litigation to delay the generics, and engaged in bad-faith dealings with the Mohawk Tribe to circumvent the invalidation of their patents. It is highly plausible that a company willing to engage in such conduct was intending to delay the entry of generics into the market, rather than seeking to protect the public health, when it filed its citizen petitions.

Allergan does, on the other hand, contend that plaintiffs' allegations do not satisfy the first prong of the PRE test—that the citizen petitions were objectively baseless. Allergan exclusively relies on the FDA's responses to its petitions to argue that they were not shams.[11] It claims that, because the FDA partially granted the first two petitions, these petitions cannot be deemed

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which is not enough. *See In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 309 n.10 (E.D. Pa. 2011) (declining to apply the test to a series of five petitions and collecting cases in which courts declined to apply the test to as many as nine petitions). Plaintiffs argue that I should consider the amendments to the three citizen petitions, as well as the comments on the draft guidance, bringing the total to 11 petitions. Because I find that plaintiffs have met their burden even under the stricter PRE test, it is not necessary to resolve whether this test applies.

[11] Defendant also suggests in its reply brief that its citizen petitions warrant First Amendment protection because the FDA solicited comments on the draft guidance and its petitions were responding to those requests. If I were to accept this argument, it would eliminate the sham exception to the *Noerr-Pennington* doctrine. In the face of overwhelming precedent, I decline to do so. *See, e.g.*, *PRE*, 508 U.S. at 51.

baseless. It further argues that the FDA's responses to all three petitions show that Allergan's submissions prompted the agency to consider revisions to, and actually to revise, its draft guidance as well as to alter its approach towards its review of ANDAs.

Objective baselessness is assessed at the time of filing. *See, e.g.*, *In re Wellbutrin XL*, 868 F.3d at 148–49. "[P]ost-petition events," such as those relied on by Allergan here, are relevant only "to the limited extent that they may shed light on the objective reasonableness of [defendant's] petition at the time it was filed." *In re Prograf Antitrust Litig.*, 2014 WL 4745954, at *10 n.10 (D. Mass. June 10, 2014). As a result, a grant or a denial of a citizen petition is rarely dispositive of whether the petition was baseless at the time it was submitted. If "the FDA's responses and post-petition developments *definitively* show that the petition was not a sham," a court may rely on that activity to find that the petition warrants First Amendment protection. *See id.* at *10 (emphasis added). Otherwise, as long as plaintiffs have plausibly alleged that defendant submitted "a sham petition not supported by science," the petition's "scientific merit" is "unsuitable for resolution on a motion to dismiss." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 243, 273 (3d Cir. 2017). Thus, whether a citizen petition is a sham is generally a question of fact for the jury. *See, e.g.*, *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009); *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1347–48 (Fed. Cir. 2014); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 689 (E.D. Pa. 2014); *In re Flonase*, 795 F. Supp. 2d at 310.

Several cases illustrate the heavy burden placed on a defendant, like Allergan, seeking *Noerr-Pennington* immunity at this stage of the litigation. In *In re Lipitor*, the district court had concluded, on a motion to dismiss, that the defendant's citizen petition was entitled to *Noerr-Pennington* protection. 868 F.3d at 273. The court had reasoned that the petition was not

objectively baseless because it was supported by science and because the FDA had observed that the petition raised "complex issues" and had taken several years to reach a decision before ultimately issuing a denial. *Id.* at 243, 273–74. The Third Circuit reversed. *Id.* at 274. It explained that by "[e]quating delay in consideration of a petition or its complexity with the petition's underlying merits," the district court had "fail[ed] to draw inferences in [] plaintiffs' favor." *Id.* The Third Circuit found that the plaintiffs' claim was entitled to proceed since plaintiffs had plausibly alleged that the citizen petition was not supported by science and one could reasonably infer that the FDA's actions in response to the petition "reflected little about its actual merits." *Id.* at 273–74.

Using like reasoning, the district court in *In re Suboxone* held, on a motion to dismiss, that defendant's citizen petition was not entitled to *Noerr-Pennington* immunity as a matter of law. 64 F. Supp. 3d at 689–90. The court found that the plaintiffs had plausibly pleaded that the petition was objectively baseless, rejecting the defendant's argument that its petition could not have been a sham because the FDA took the full 150-day period to respond, the FDA partially granted its relief, a reasonable litigant would not have known that the FDA would have ultimately placed certain requirements on the defendant, and "the regulations that prohibited the FDA from granting [defendant's] request were being considered for amendment" when the petition was filed. *Id.* at 689; *see also In re DDAVP*, 585 F.3d at 694–65 (reversing district court's finding that a citizen petition was protected by the First Amendment where the complaint plausibly alleged that the petition was a sham); *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, 2008 WL 169362, at *5 (S.D.N.Y. Jan. 18, 2008) (rejecting defendant's argument, on a motion to dismiss, that its citizen petition was entitled to immunity where there were "triable issues of fact concerning the reasonability and viability" of the petition). Similarly, in *In re Prograf*, on a summary judgment

motion, the defendant had argued that its citizen petition had merit because the FDA had observed, in an interim response, that the petition raised "complex issues requiring extensive review and analysis;" an FDA official had told some of the defendant's employees that the petition was "excellent;" the agency had given substantial consideration to the defendant's requests in its final response; and scientific developments subsequent to the petition's denial showed that the relief requested in the petition was reasonable. 2014 WL 4745954, at *10. But the court nonetheless concluded that, because plaintiffs "persuasively" contested defendant's assertions and claimed that the FDA's action failed to show that the petition was not a sham, it was up to the jury to resolve the debate over the petition's merits. *Id.*; *see also In re Flonase,* 795 F. Supp. 2d at 311–17 (denying summary judgment where genuine issues of fact remained regarding the merits of defendant's citizen petitions, including the significance of the FDA's responses).

In this case, the FDA's responses fall far short of demonstrating that plaintiffs' allegations of objective baselessness are implausible. The FDA denied every substantive request made by Allergan in each of its three petitions. Allergan repeatedly requested that the FDA do away with *in vitro* testing for bioequivalency for Restasis®, and the agency emphatically rejected this request each time it was made. Of course, that the petitions were denied in all substantive respects, standing alone, is not necessarily enough to plausibly allege that they were objectively baseless. *Apotex*, 823 F.3d at 61–62. In *Apotex*, the Second Circuit affirmed the district court's conclusion that the plaintiff had failed to show that a citizen petition was objectively baseless where "the only fact Apotex ha[d] pled other than the timing of the FDA's decision on [defendant] Accorda's citizen petition is that Accorda's citizen petition was ultimately fruitless." *Id.* But, unlike in *Apotex*, plaintiffs here do not merely allege that the petitions were denied. Plaintiffs allege that, given the draft guidance's strict requirements for proving bioequivalence through *in vitro* studies, there

would be no reason to expect any difference in clinical results between Restasis® and the generic drug, and therefore, *in vivo* testing would have served no purpose.[12] In fact, plaintiffs allege that *in vivo* testing would have delayed the FDA approval process, been more costly, involved human testing, which the FDA endeavors to avoid, and most importantly, would have been less reliable, because Restasis® has only a modest clinical benefit and any differences between the brand and generic would have been small. Therefore, plaintiffs have sufficiently alleged that, at the time it filed its petitions, Allergan could have had no reasonable expectation that the FDA would agree to require *in vivo* studies to show bioequivalence.

Moreover, Allergan's second and third citizen petitions largely rehash the claims of the first and were denied on the same grounds. The FDA, in denying the second petition, stated that Allergan had "repeat[ed] many of the assertions" from the first petition, that its data were "misleading" and "insufficient," and that its arguments "lack legal support" and "rest on flawed logic." In response to the third petition, the FDA stated that, because it had "addressed [Allergan's] assertions in its responses to the previous citizen petitions, it does not address them again here." It then denied any non-repetitive requests "without comment." The second petition was filed on December 23, 2014, and the third in August of 2017. The plausibility of objective baselessness grows with each filing. *See California Motor Transp. Co. v. Trucking Unlimited,* 404 U.S. 508, 513 (1972) ("One claim, which a court or agency may think baseless, may go unnoticed; but a

[12] The FDA draft guidance permitted the use of *in vitro* studies to prove bioequivalence only where the proposed generic: (1) included the same ingredients as Restasis® in the same amounts; (2) had the same physiochemical properties as Restasis® on at least six separate metrics; and (3) had an acceptable comparative release rate (meaning that the same amount of cyclosporine would be delivered to the eye for absorption).

pattern of baseless, repetitive claims may emerge which leads the factfinder to conclude that the administrative and judicial processes have been abused.").

That Allergan's first two petitions were "granted in part" also fails to establish that they were not baseless as a matter of law. *See In re Suboxone*, 64 F. Supp. 3d at 689–90 (rejecting defendant's argument that a citizen petition was objectively baseless because "the FDA granted [it] partial relief"); *In re Prograf*, 2014 WL 4745954, at *7, *10–11 (finding that questions of fact exist as to whether a citizen petition was a sham, even though one of the petition's requests, regarding "an uncontroversial issue with no impact on existing FDA practice or policy," was granted).

Plaintiffs point out that the petitions were granted only to the extent that the FDA agreed to do that which it had already done or was otherwise required to do by law. In response to Allergan's first petition, the FDA granted only Allergan's requests for an opportunity to comment on its bioequivalence methodology for generic versions of Restasis® and for an explanation of the scientific foundations for its decision to allow ANDA applicants to use *in vitro* testing to demonstrate bioequivalence, which the response itself provided. The FDA granted Allergan's second petition solely by agreeing to provide Allergan with "a more specific response" concerning the results of Allergan's testing of nine experimental test emulsions and by agreeing to share more information about the *in vitro* bioequivalence methods the FDA planned to recommend to ANDA applicants. The FDA then indicated that the information it provided in its response fulfilled Allergan's requests. Put simply, in response to the petitions, the FDA agreed to exchange information with Allergan about its scientific methodology, but the agency denied every one of Allergan's requests that it change that methodology. At a minimum, plaintiffs' reading of the FDA's partial grants of Allergan's first and second petitions is plausible.

Finally, in the absence of any actual substantive grants of its requests, defendant argues that its citizen petitions influenced FDA policy. It notes that, on a few occasions in its response to Allergan's first petition, the FDA stated that it was considering revising its draft guidance. Allergan claims that its petition prompted the FDA to engage in such reconsideration. Allergan further argues that the agency's revisions to its draft guidance in February of 2016 were largely the result of Allergan's comments in its second petition. Finally, Allergan points out that, in response to the third petition, the FDA agreed to "consider" Allergan's non-repetitive requests when reviewing specific ANDAs and the draft bioequivalence guidance. It also argues that the FDA denied this petition only because the 150-day statutory deadline for it to respond was imminent.

Plaintiffs dispute Allergan's characterization of the FDA's responses. They argue that Allergan seeks to take credit for changes in the draft guidance that it never sought or that simply clarified concepts that the FDA had accepted from the beginning. Plaintiffs further disagree with Allergan's claim that its second petition was the catalyst for the FDA's decision to revise its draft guidance in February of 2016. Plaintiffs do not specifically address Allergan's argument regarding the FDA's assertion in its response to the third petition that it will "consider" some of Allergan's requests. But they do allege that the brevity of the FDA's response, which denied every one of Allergan's requests "without comment," demonstrated that the petition was repetitive and unsupported. Because the significance of the FDA's actions is in dispute, and the inferences plaintiffs ask me to draw are plausible, defendant's petitions are not entitled to *Noerr-Pennington* immunity at this stage of the litigation. *See In re Flonase*, 795 F. Supp. 2d at 315 n.16 (declining, on a summary judgment motion, to find that a petition was entitled to *Noerr-Pennington* immunity

based on defendant's argument that its submission "contributed to the debate" on bioequivalence compliance for the relevant drug category).

In sum, whether, on all of the evidence, a factfinder would find that the petitions were not baseless remains to be seen. Certainly, the inferences Allergan draws, considering the other possible inferences, are not sufficient to find as a matter of law that the First Amendment shields Allergan's citizen petitions from antitrust liability.

B. Is it Plausible that Allergan's Alleged Anticompetitive Actions Caused a Delay in the FDA Approval Process?

Allergan asserts that, even if the citizen petitions are not immune from antitrust liability, plaintiffs have failed to plausibly allege that the petitions delayed the FDA's approval of generic drugs. It points to 21 U.S.C. § 355(q)(1)(A), which provides that the FDA may not delay approval of an ANDA in order to address a citizen petition unless the FDA determines, "upon reviewing the petition, that a delay is necessary to protect the public health." From this statute, Allergan argues that its citizen petitions could not have delayed FDA approval of generic entry.

Allergan also argues that plaintiffs have not shown that the 30-month stay occasioned by the patent infringement lawsuits, and made possible through the fraudulently obtained patents and the wrongful Orange Book listing, delayed the market entry of generics. Allergan notes that the FDA did not grant tentative approval to ANDAs during this stay, even though it could have done so. *See Actos*, 848 F.3d at 99–100 (plaintiff successfully alleged causation, where it had been granted tentative approval by the FDA and the approval did not become final only because of defendant's false patent descriptions). Allergan also asks me to infer that the stay had no impact on the FDA approval process since an ANDA has still not been approved, even though the stay was lifted in November of 2017.

Allergan's arguments are not sufficient to overcome the plausibility of plaintiffs' claims. Plaintiffs allege that, despite the existence of 21 U.S.C. § 355(q)(1)(A), the FDA in practice does delay approval of generics while responding to citizen petitions, even when those petitions turn out to be baseless. Plaintiffs cite two reasons for the FDA's practice: (1) it fears litigation if it grants an ANDA without fully addressing the citizen petition; and (2) it has limited resources, and responding to a citizen petition takes time away from the approval process.[13] As other courts have recognized, the inferences drawn are plausible. *See In re Suboxone*, 64 F. Supp. 3d at 690–91 (finding plausible the allegation that, despite § 355(q), "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, regardless of whether the petition actually does or not, and regardless of whether the petition is [a] sham or not"); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 2013 WL 2181185, at *20 n.14 (E.D. Tenn. May 20, 2013) ("there is a factual dispute regarding the effectiveness of the changes brought by [§ 355(q)] that need not be resolved at this time").

It is also reasonable to infer, as plaintiffs ask me to do, that the stay resulting from the patent infringement litigation led the FDA to divert its resources away from the ANDAs at issue. The FDA may have prioritized reviewing applications for other generic drugs, because, even if tentative approval were granted to the ANDAs, a drug subject to a stay would not be able to enter the market for some time (possibly over a decade if the patent infringement suit were successful and the ANDA applicant had to wait until the patent expired). *See, e.g.*, *In re Loestrin 24 Fe*

[13] In support of this allegation, plaintiffs cite to the FDA's Eighth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2015 at 8 (July 29, 2016), *available at* www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM517279.pdf ("the FDA remains concerned about the resources required to respond to . . . petitions . . . at the expense of completing the other work of the agency").

Antitrust Litig., 261 F. Supp. 3d 307, 336 (D. R.I. 2017) (absent the anticompetitive conduct, the ANDA "may have been able to obtain FDA approval earlier"); *In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *12 (D. N.J. Aug. 28, 2009) ("Plaintiffs [are not] required [on a motion to dismiss] to adduce proofs discrediting all possible intervening causes of the delayed launch of generic products, such as the failure to obtain tentative generic approval from the FDA before the expiration of the 30–month stays at issue.").[14]

It also is plausible that Allergan's actions resulted in a delay in the approval process that continues to this day. The FDA may have slowed or halted its review of ANDAs to address the citizen petitions and to account for the stay so that, even if the review is now moving along unobstructed, the ANDAs would have been approved months or even years ago had the petitions not been filed. *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 628 (E.D. Pa. 2011) ("Even if an antitrust violation is not the material cause of an injury and the only material cause is some intervening conduct, courts have consistently found the causation requirement satisfied and the chain of causation intact where that intervening conduct was the foreseeable consequence of the original antitrust violation.").

Allergan may be correct that its actions had no effect on the FDA's approval process. That process undoubtedly will be the subject of discovery and expert testimony. But it is also plausible that Allergan's efforts, which plaintiffs allege were intended solely to impede generic entry into the market, worked. "The choice between two plausible inferences that may be drawn from factual

[14] In its reply brief and at oral argument, Allergan argued that plaintiffs did not allege that the 30-month stay caused the FDA to "backburner" its review of Restasis® and thus urged the court not to consider this argument. Plaintiffs, however, need not plead in their complaints a response to every potential argument raised by defendant in its motion to dismiss. The crux of these lawsuits is plaintiffs' claim that Allergan's numerous actions, including obtaining the 30-month stay, delayed the FDA's review of ANDAs. Thus, the complaints provided defendant with notice of this issue, and defendant's claim of surprise is unconvincing.

allegations is not a choice to be made by the court on a Rule 12(b)(6) motion." *Anderson News, LLC v. Am. Media*, 680 F.3d 162, 185 (2d Cir. 2012). Rather, all inferences must be drawn in plaintiffs' favor. Therefore, I cannot infer that Allergan's conduct as alleged in the complaints did not impact the FDA's review and approval of the generics' applications. That there may be cases, like *Actos*, with an even stronger showing of causation because the FDA had granted tentative approval, does not mean that plaintiffs have failed to allege causation here. *See In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2017 WL 4910673, at *13 (E.D. Pa. Oct. 30, 2017) (to succeed on a motion to dismiss, defendant must show that the FDA's conduct "was a purely independent cause fully accountable for the alleged antitrust injury"); *In re Neurontin*, 2009 WL 2751029, at *12-13 (courts have "regularly" found that plaintiffs adequately pleaded antitrust injury based on assertions that "absent [a drug company's] overarching scheme, generic manufacturers would have launched their products and purchasers would have had access to lower-priced drugs years earlier then they ultimately did").

Finally, the likelihood that Allergan's citizen petitions and its efforts to protect fraudulent patents resulted in plaintiffs' injury increases when these actions are viewed in the aggregate. Here, for example, the 30-month stay coincided with other events that plaintiffs allege caused delay—Allergan's filing of its fourth supplement to its second citizen petition, the FDA's response to the second citizen petition, and Allergan's filing of its third citizen petition. That the FDA was confronted with these events simultaneously makes it more plausible that the agency chose not to prioritize its review of the ANDAs during this time period. *In re Skelaxin*, 2013 WL 2181185, at *13 (assessing whether plaintiffs have adequately alleged an antitrust injury by "viewing the factual allegations as a whole").

V. CONCLUSION

In sum, Allergan, admitting for purposes of the motion it brings, that it deliberately and repeatedly attempted to obstruct the entry of generics into the marketplace for Restasis®, argues that plaintiffs have not plausibly alleged that Allergan's aggressive and persistent efforts had *any* effect on the timing of approval for its generic competitors to enter the market. Whether Allergan can convince a jury of this remains open. But its arguments that plaintiffs' allegations are implausible, and that the court should dismiss the case for failure to plead causation, are meritless. On the face of the Consolidated Complaints, the inferences plaintiffs draw—namely, that Allergan's efforts bore fruit in causing delay—are logical and amply support the plausibility requirement. Although defendant accuses plaintiffs of speculating, as the Second Circuit stated in *Actos*:

> It is [defendant], however, that is here engaging in gross speculation. While it is possible that one or more of these factors may turn out to be barriers to plaintiffs' causation theory at later stages of the litigation, they do not mandate dismissing the complaint now. Indeed, even at summary judgment, an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct is deemed wrongful because it is believed significantly to increase the risk of a particular injury and that injury occurred. If plaintiffs reach the summary judgment stage and make that showing, then it would be [defendant's] burden to show that some other factors, such as the ones identified above, are the "true" cause of the delay, and therefore the "true" cause of the artificially high drug prices plaintiffs paid. Dismissal at this early stage on the basis of speculation about possible and not inherently more plausible alternative causes would be premature.

848 F.3d at 101 (internal citations and quotation marks omitted).

Defendant's motion to dismiss the Consolidated Complaints for lack of causation is therefore denied. The court will address defendant's motion to dismiss various EPP state law claims for failure to state a claim by separate order.

SO ORDERED.

Dated: September 17, 2018
Brooklyn, New York

/s/ Nina Gershon
NINA GERSHON
United States District Judge