UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS, INC., Plaintiff, v. TEVA PHARMACEUTICALS INDUSTRIES, LTD, *et al*., Defendants.	Civil Action No. 21-13087 (JXN)(JSA) **OPINION**

NEALS, District Judge

This is one of two pharmaceutical antitrust cases involving Copaxone, a drug used to treat multiple sclerosis.[1] In sum: Teva Pharmaceuticals Industries, Ltd. ("Teva") makes brand-name Copaxone. Mylan Pharmaceuticals, Inc. ("Mylan") makes generic Copaxone. Mylan sued Teva under Section 2 of the Sherman Act, alleging that Teva illegally protected Copaxone from generic competition.

Before the Court is Special Master Faith S. Hochberg's ("Special Master") Report and Recommendation ("R&R") (ECF No. 159) recommending that the Court partially grant Teva's motion to dismiss Mylan's Complaint. Mylan objected to portions of the R&R (ECF No. 163), and Teva replied (ECF No. 169). The Court has carefully considered the parties' submissions and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure[2] 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court **ADOPTS** the R&R (ECF No. 159).

[1] For the related case, *see In re Copaxone Antitrust Litig.*, No. 22-1232.

[2] "Rule" or "Rules" hereinafter refer to the Federal Rules of Civil Procedure.

I. BACKGROUND

A. Drug Regulations

To frame the antitrust issues in this case, the Court describes the relevant legal framework for approving and dispensing new drugs.

i. Approving New Drugs

The Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355 *et seq.*, commonly referred to as the Hatch-Waxman Act, governs the approval of new drugs. A drug manufacturer "wishing to market a new prescription drug" must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") "and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the FDA." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (quoting 21 U.S.C. § 355(b)(1)). After the FDA approves a new drug, whose active pharmaceutical ingredient has not been previously approved for any other drug, the manufacturer may exclusively make and sell that product for five years. 21 U.S.C. § 355(c)(3)(E)(ii).

"One of the goals of Hatch-Waxman is to increase competition between generic and brand-name drugs. To that end, the Act allows the manufacturers of generic drugs to obtain FDA approval without having to endure the gauntlet of procedures associated with NDAs." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 143 (3d Cir. 2017). So, after the FDA approves a brand-name drug, Hatch-Waxman permits a generic drug manufacturer to submit an Abbreviated New Drug Application ("ANDA") "specifying that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *Actavis*, 570 U.S. at 142 (quoting *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012)). Filing an ANDA allows "the generic to piggy-back" on the brand-name drug's NDA

approval, eliminating the need to undergo the same "costly and time-consuming studies" as the brand-name drug. *Id.* (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

Hatch-Waxman also "sets forth special procedures for identifying, and resolving, related patent disputes" between NDAs and ANDAs. *Id.* at 143. The Act requires the "brand-name manufacturer to list in its [NDA] the 'number and the expiration date' of any relevant patent." *Id.* (quoting 21 U.S.C. § 355(b)(1)). The FDA then publishes the approved NDA, along with its corresponding patent numbers and expiration dates, "in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products with Therapeutic Equivalence Evaluations)." *Caraco Pharm.*, 566 U.S. at 405–06.

Because the FDA "cannot authorize a generic drug that would infringe a patent," a generic drug company filing an ANDA "must assure the FDA that its proposed generic drug will not infringe the [brand drug's] patents." *Id.* The generic manufacturer "can provide this assurance in one of several ways." *Actavis*, 570 U.S. at 143. One option, relevant here, is called a "Paragraph IV Certification," wherein the generic manufacturer certifies that "any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the drug described in the [ANDA]." *Id.* (quoting 21 U.S.C. § 355(j)(2)(A)(vii)).

A Paragraph IV Certification "automatically counts as patent infringement." *Id.* "If the brand-name patentee brings an infringement suit within [forty-five] days, the FDA then must withhold approving the generic, usually for a [thirty]–month period, while the parties litigate patent validity (or infringement) in court." *Id.*; *see also* 21 U.S.C. § 355(j)(5)(B)(iii). "If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product." *Actavis*, 570 U.S. at 143 (2013) (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

ii. Dispensing New Drugs

Mylan notes that many states have "automatic substitution" laws. (Compl. ¶ 52, ECF No. 1.) Automatic substitution laws require pharmacies to substitute generic drugs for brand drugs "even if the prescription specifies the brand drug." (*Id.*) Mylan alleges that many automatic substitution laws do not require generic substitution where a prescription for a brand drug states, "Dispense as Written" ("DAW"). (*Id.* ¶ 53.)

B. Copaxone

Teva makes and sells Copaxone, an injectable drug used to treat multiple sclerosis. (*Id.* ¶ 68.) The active ingredient in Copaxone is glatiramer acetate ("GA"). (*Id.* ¶ 1.) The FDA first approved Copaxone in a 20mg vial on December 20, 1996. (*Id.* ¶ 73.) In its initial form, users would inject themselves with Copaxone. (*See id.*) The FDA then approved syringes pre-filled with 20mg of Copaxone for daily injectable use on February 12, 2002. (*Id.*) The patents for 20mg Copaxone expired in May 2014. (*Id.* ¶ 118.)

Sandoz filed an ANDA for generic 20mg GA in December 2007, which the FDA approved in April 2015. (*Id.* ¶ 75.)

In 2013, Teva filed a supplemental NDA ("sNDA") for 40mg Copaxone in a pre-filled syringe, to be injected three times a week. (*Id.* ¶¶ 74, 117.) The FDA approved Teva's sNDA in January 2014. (*Id.* ¶ 74.) The legal exclusivity for 40mg Copaxone expired on January 28, 2017. (*Id.*)

Mylan, meanwhile, filed an ANDA for generic 20mg GA in June 2009, and generic 40mg GA on February 12, 2014. (*Id.* ¶ 78.) The FDA approved both ANDAs on October 3, 2017. (*Id.* ¶ 79.) Mylan launched its generic 20mg and 40mg GA injections shortly thereafter. (*Id.* ¶ 80.)

C. The Alleged Scheme to Protect Copaxone

Mylan alleges Teva engaged in five kinds of anticompetitive conduct to protect Copaxone's market share from generic competitors like Mylan:

i. The "Dispense as Written" Campaign

Teva, like many pharmaceutical companies, employs sales representatives to promote its drugs to medical professionals. (*Id.* ¶ 131.) Mylan alleges that Teva, through its sales representatives, intentionally spread false information about Mylan and its generic GA medications. (*Id.* ¶ 132.) Specifically, Mylan alleges Teva sales representatives told medical professionals that "generic GA is only 80% or only 85% as effective as Copaxone" (*see id.* ¶¶ 135–41); "that Mylan does not provide copayment support for its generic GA" (*see id.* ¶¶ 142–46); and "that Mylan does not provide training and nursing support for its generic GA." (*see id.* ¶¶ 147–51). Teva's goal, according to Mylan, was to persuade doctors to write DAW prescriptions for Copaxone, so pharmacies would not automatically substitute Copaxone with Mylan's generic. (*Id.* ¶ 132.) And, according to Mylan, the DAW campaign succeeded—in October 2017, 13.5% of Copaxone prescriptions were DAW; less than a year later, that number rose to 77%. (*Id.* ¶ 161.)

ii. Exclusionary Agreements with PBMs

Pharmacy Benefit Managers ("PBMs") are middlemen between health insurance companies and consumers. (*Id.* ¶ 62.) They negotiate drug prices with manufacturers and reimbursements with pharmacies. (*Id.* ¶ 63.) Many PBMs also own specialty pharmacies. (*Id.*) PBMs create lists of prescription drugs (called formularies) "for which the health plan will reimburse pharmacies on behalf of the plan's members." (*Id.* ¶ 64.) If a drug is not on a formulary, the health insurance company generally does not cover it, and the patient must pay for it out-of-pocket. (*Id.*) Mylan alleges the PBM market is highly concentrated. (*Id.* ¶ 67.) And, in Mylan's

telling, "[b]rand manufacturers will compete for preferred and even exclusive placement on PBMs' formularies and may offer a host of concessions to obtain such placement, including price reductions, rebates, and temporal commitments." (*Id.* ¶ 66.)

Mylan alleges that Teva conditioned rebates to PBMs on the PBMs agreeing to exclude generic GA from their formularies. (*Id.* ¶¶ 163–65.) According to Mylan, if PBMs agreed to exclude generic GA from formularies, insurance would not cover generic GA. (*Id.* ¶ 164.) Mylan also claims Teva paid "PBM-owned specialty pharmacies to switch generic prescriptions with branded Copaxone." (*Id.* ¶ 166.) Mylan states these arrangements "subvert[ed] automatic substitution laws." (*Id.*)

iii. Teva's Regulatory and Judicial Conduct

Mylan alleges that, since at least 2008, Teva employed "a repetitive and continuous strategy to abuse regulatory and judicial processes to delay the launch of generic GA." (*Id.* ¶ 102.)

a. Regulatory Abuse

The Complaint alleges, without further elaboration, that Teva began abusing the regulatory process in 2008. (*Id.*) Mylan advanced more specific allegations of regulatory abuse in opposition to Teva's motion to dismiss and at oral argument before the Special Master on December 12, 2023. (*See* Mylan Opp'n, ECF No. 56; Dec. 12, 2023 Tr.) In opposition to Teva's motion to dismiss, Mylan alleged Teva "filed a series of eight functionally identical Citizen Petitions with the FDA, all which were rejected." (Mylan Opp'n at 10.) At oral argument, Mylan further alleged Teva filed the eight citizen petitions between 2008, and 2015, in connection with Sandoz's 20mg GA ANDA.[3] (Dec. 12, 2023 Tr. at 58:18–61:3, 72:13–16.) Mylan also alleges Teva interfered in the

[3] *See* Citizen Petition (Food & Drug Admin., Sept. 26, 2008), https://www.regulations.gov/document/FDA-2008-P-0529-0001 (First Petition); Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Nov. 19, 2009), https://www.regulations.gov/document/FDA-2009-P-0555-0001 (Second Petition); Citizen Petition Requesting That

regulatory processes of other countries to prevent the approval of generic GA medications. (Compl. ¶¶ 92–100.)

b. Teva's 2014 Suit Against the FDA

The Complaint makes passing reference to a suit Teva filed against the FDA to prevent the FDA from approving Sandoz's 20mg generic GA. (*See id.* ¶¶ 3, 9, 128, 187.) Though the Complaint itself pleads no facts about the lawsuit (*see id.*), Mylan argued in opposition and at oral argument that it partially formed the basis for its allegations about Teva's petitioning and litigation conduct. (*See* Mylan Opp'n at 10–11, Dec. 12, 2023 Tr. at 73:11–13.)

Mylan refers to *Teva Pharmaceutical Industries, Ltd. v. Sebelius*, No. 14-786 (D.D.C.). In that case, Teva challenged the FDA's denial of one of its citizen petitions and sought an injunction preventing the FDA from approving any ANDA referencing Copaxone that did not comply with the conditions Teva requested. *See* Compl. at 33, *Sebelius*, No. 14-786 (D.D.C. May 9, 2014). Teva filed the lawsuit on May 9, 2014. *See id.* Five days later, on May 14, 2014, the court denied the request for an injunction and dismissed the complaint. *See* Order, *Sebelius*, No. 14-786 (D.D.C. May 14, 2014).

FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Dec. 10, 2010), https://www.regulations.gov/document/FDA-2010-P-0642-0001 (Third Petition); Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., June 4, 2012), https://www.regulations.gov/document/FDA-2012-P-0555-0001 (Fourth Petition); Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Sept. 12, 2013), https://www.regulations.gov/document/FDA-2013-P-1128-0001 (Fifth Petition); Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Dec. 5, 2013), https://www.regulations.gov/document/FDA-2013-P-1641-0001 (Sixth Petition); Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., July 2, 2014), https://www.regulations.gov/document/FDA-2014-P-0933-0001 (Seventh Petition); Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., March 31, 2015), https://www.regulations.gov/document/FDA-2015-P-1050-0001 (Eighth Petition).

c. 20mg ANDA Litigation

At oral argument and in its opposition brief, Mylan discussed Teva's litigation involving Sandoz and Mylan's 20mg ANDAs. (*See* Mylan Opp'n at 7–9, 25; Dec. 12, 2023 Tr. at 57:18–69:25, 72:13–74:8.) The Complaint does not. (*See* Compl.)

The Court provides some background. After Sandoz and Mylan filed ANDAs for generic 20mg GA, Teva sued both companies for patent infringement. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 303 (S.D.N.Y. 2012), *aff'd in part, rev'd in part,* 723 F.3d 1363 (Fed. Cir. 2013), *vacated,* 574 U.S. 318 (2015). The District Court found Sandoz and Mylan's ANDAs infringed on Teva's Copaxone patents. *Id.* The Federal Circuit reversed as to one group of claims ("Group I claims") but affirmed as to another ("Group II claims"). *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1366 (Fed. Cir. 2013), *vacated,* 574 U.S. 318 (2015). Teva appealed to the Supreme Court as to the Group I claims. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015). The Supreme Court vacated and remanded to the Federal Circuit for further proceedings. *Id.* at 336. On remand, the Federal Circuit reached the same conclusion as before, reversing as to the Group I claims and affirming as to the Group II claims. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1337–38 (Fed. Cir. 2015). Because the Federal Circuit invalidated the Group I claims, Mylan argues the 20mg ANDA litigation was meritless and designed to delay approval of Mylan's generic. (Opp'n at 28.)

d. 40mg ANDA Litigation

The Complaint alleges that, after Teva learned Mylan filed an ANDA for generic 40mg GA, Teva sued Mylan for patent infringement, "which imposed an automatic 30-month stay on FDA approval of Mylan's application." (Compl. ¶ 104.) The District Court invalidated 40mg Copaxone patents for obviousness and the Federal Circuit affirmed. *In re Copaxone Consol. Cases*,

No. 14-1171, 2017 WL 401943 (D. Del. Jan. 30, 2017), *aff'd sub nom. In Re: Copaxone Consol. Cases*, 906 F.3d 1013 (Fed. Cir. 2018).

e. 2020 Reclassification Petition and Lawsuit

The Complaint alleges that Teva requested the FDA reclassify Copaxone as a biological product ("biologic") in February 2020. (Compl. ¶¶ 176, 181–87.) Mylan asserts that, while a brand drug can be substituted for a generic drug under automatic substitution laws, a brand biologic cannot be automatically substituted for a generic biologic (called a "biosimilar"). (*Id.* ¶¶ 54–56.) Mylan claims Teva argued before the FDA that "Copaxone was a protein or an 'analogous product' to a protein, and therefore should be reclassified as a biologic." (*Id.* ¶ 181.) Mylan asserts that Teva sought to reclassify Copaxone as a biologic for the sole purpose of stopping automatic substitution. (*Id.* ¶¶ 183–84.) On March 20, 2020, the FDA rejected Teva's request to classify Copaxone as a biologic. (*Id.* ¶ 182.) According to Mylan, Teva sued the FDA four days later. (*Id.* ¶ 183.) The District Court dismissed the lawsuit, concluding the FDA's "failure to reach Teva's preferred outcome does not, however, indicate that it acted unreasonably, arbitrarily, or capriciously." *Teva Pharm. USA, Inc. v. U.S. Food & Drug Admin.*, 514 F. Supp. 3d 66, 117 (D.D.C. 2020)

f. Non-Orange Book Patent Litigation

Mylan's opposition brief also referenced patent suits Teva filed against Mylan outside of Mylan's Paragraph IV certification (referred to as "non-Orange Book" patent litigation). (*See* Mylan Opp'n at 26–28.) Those actions, however, do not appear in the Complaint. (*See* Compl.)

iv. The "Market Shift"

Mylan alleges that, after Sandoz filed an ANDA for 20mg generic GA, Teva shifted the market from 20mg Copaxone to 40mg Copaxone. (*Id.* ¶¶ 103, 112–30.) Mylan claims that "[b]ecause a 20mg GA is not automatically substitutable for 40mg Copaxone, shifting the market

to 40mg would prevent the generic 20mg product from taking shares away from branded Copaxone in the manner ordinarily expected in a competitive market." (*Id.* ¶ 112.)

According to Mylan, Teva held clinical trials, beginning in at least 2003, to test the effectiveness of 40mg Copaxone taken once a day. (*Id.* ¶ 114.) After those clinical trials showed 40mg daily Copaxone was not more effective than 20mg daily Copaxone, Teva allegedly "pivot[ed] to exploring the 40mg dose as a less frequent and more convenient regimen." (*Id.*) However, Mylan claims Teva "previously rejected this less-frequent dosing regimen strategy as less profitable." (*Id.*) But, in Mylan's telling, Teva nonetheless chose this "less profitable course" to create a barrier to generic competition. (*Id.* ¶¶ 115–16.)

Teva launched 40mg Copaxone "just before the 20mg patents expired." (*Id.* ¶ 119.) To shift the market from 20mg Copaxone to 40mg Copaxone, Mylan alleges Teva employed "1) economically irrational pricing, 2) tying the rebates on the 20mg product to the purchase of the 40mg product, 3) anticompetitive agreements with other industry stakeholders, and 4) a marketing campaign targeted at doctors and patients." (*Id.*)

First, Teva priced 40mg Copaxone "lower than the weekly price of Copaxone 20mg," which Mylan claims was "economically irrational." (*Id.* ¶ 120.) Instead, Mylan alleges Teva charged less for 40mg Copaxone to preempt generic competition for 20mg GA products. (*Id.* ¶¶ 120–21.)

Second, Mylan alleges Teva "conditioned contractual rebates for Copaxone 20mg on the addition of Copaxone 40mg to the PBMs' formularies." (*Id.* ¶ 123.) Mylan claims "this tying tactic" succeeded in preventing PBMs from switching to generic 20mg GA, and instead forced PBMs to cover Copaxone 40mg. (*Id.* ¶ 124.)

Third, Mylan alleges Teva entered agreements with PBMs "to divert prescribers from" Copaxone 20mg to Copaxone 40mg. (*Id.* ¶ 125.) The goal, according to Mylan, was to convert as many patients from Copaxone 20mg to Copaxone 40mg as possible.(*Id.*)

Fourth, Mylan alleges Teva engaged in a marketing campaign "to encourage patients and physicians to switch to the 40mg product that continued even after generic GA 20mg had launched." (*Id.* ¶ 126.)

v. Charitable Donation Copay Assistance

Finally, relying on allegations from a 2020 lawsuit the Department of Justice ("DOJ") brought against Teva under 42 U.S.C. § 1320a-7b(b), the anti-kickback statute, Mylan claims Teva gave two third-party foundations[4] $300 million to cover Medicare copays for Copaxone patients. (*Id.* ¶¶ 170, 174.) Mylan alleges Teva disguised the money as a "donation," when really, it was an investment to drive Copaxone sales. (*Id.* ¶ 172.) Mylan asserts Teva "made payments only to these two foundations because 'it had assurance that its money would go to patients taking its drug, Copaxone,' rather than to patients taking other drugs." (*Id.* ¶ 173.) The goal, according to Mylan, was to "remove the patients' incentive to seek the more affordable generic GA," and induce them to stay on Copaxone. (*Id.* ¶ 171.)

vi. Effects

Mylan alleges that Teva's anticompetitive scheme to protect Copaxone worked and will continue to do so. (*Id.* ¶ 192.) Mylan asserts that Teva's conduct significantly delayed Mylan's launch of generic 20mg GA, cost Mylan additional sales, restricted Mylan's share of the GA product market, and spread mistrust of Mylan among consumers. (*Id.* ¶¶ 192–94.) Moreover, when

[4] The Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF")

Mylan entered the market with generic 40mg GA, Mylan claims it did not obtain "the degree of generic conversion normally expected in a competitive market." (*Id.* ¶ 195.)

D. The Instant Lawsuit

Mylan filed this action against Teva in June 2021. (*See generally id.*) The Complaint includes claims for: (1) monopolization and attempted monopolization, in violation of the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, §§ 15, 26 (Count I); (2) violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B) (Count II); (3) tortious interference (Count III); (4) unfair competition (Count IV); (5) trade libel (Count V); and violation of the New Jersey Antitrust Act, N.J.S.A. 56:9-4 (Count VI).

In March 2022, Teva moved to dismiss the Complaint and strike its allegations related to foreign regulatory processes. (Mot. to Dismiss, ECF No. 55.) Mylan opposed (Mylan Opp'n to MTD, ECF No. 56), and Teva replied (Teva Reply, ECF No. 57). In August 2023, the Court appointed a Special Master. (Order of Appointment, ECF No. 128.) The Special Master's duties include "making recommendations to the Court regarding . . . pretrial motions to dismiss." (*Id.* at 3–4.) Accordingly, the Court referred Teva's motion to dismiss to the Special Master. (Transfer Order, ECF No. 131.) The Special Master held oral argument on the motion on December 12, 2023, January 8, 2024, and March 1, 2024. (*See* R&R at 4.)

E. The R&R

On February 27, 2025, the Special Master issued a ninety-one-page R&R recommending the Court grant in part Teva's motion to dismiss. (*See* R&R.)

i. The Antitrust Claim (Count I)

The Special Master began with Mylan's antitrust claim. (*See* R&R at 20.) She noted that Mylan grouped five categories of anticompetitive conduct under a single cause of action.

Accordingly, the Special Master evaluated whether she could rule on the "sufficiency of each allegation of anticompetitive conduct separately," or whether "all allegations of such conduct, whether individually unlawful or not, are to be considered together as part of an alleged 'overall scheme' of anticompetitive conduct." (*Id.* at 22.)

After reviewing applicable Third Circuit caselaw, the Special Master concluded that:

> if one or more components [of an anticompetitive scheme] are plausibly alleged to be exclusionary, then other components that are not plausibly alleged to be individually unlawful can nonetheless be considered as part of an overall scheme only if the independently lawful acts are plausibly alleged to augment the exclusionary effect of the conduct that has been properly alleged to be exclusionary.

(*Id.* at 27.) Thus, the Special Master described her analytical approach as follows:

> [E]ach category of conduct alleged in the Complaint is analyzed both as to whether it is plausibly pled as unlawful on its own; and if the answer to that question is "no," the analysis proceeds to look at whether it is plausibly pled as having a synergistic role that exacerbates the exclusionary effect of the plausibly alleged exclusionary acts. If that answer is "yes", then it can be properly alleged as part of an "overall scheme."
>
> This test requires thoughtful analysis of the many component parts to determine first if some of them are plausibly alleged to be exclusionary, standing alone. It then considers the other components alleged to be part of the overall scheme, even if not plausibly pled as independently exclusionary, to determine whether they are plausibly pled to augment the exclusionary effect of the conduct properly pled as "exclusionary" under the antitrust laws. The analysis further requires that the combined conduct be plausibly pled as injurious to competition in the market as a whole, and not just to the plaintiff individually.

(*Id.* at 28.)

a. The DAW Campaign

Teva moved to dismiss the DAW campaign allegations, arguing that (1) false advertising claims "rarely rise to the level of an antitrust violation"; (2) Mylan did not allege reliance on any

false statements; (3) the DAW campaign was a legitimate form of competition, and (4) Mylan failed to allege the DAW campaign caused any form of anticompetitive harm. (*Id.* at 29.)

The Special Master rejected each argument. First, she found the "Third Circuit law does not hold that allegations of false statements can never be part of the alleged bases of a Sherman Act claim: rather, the law of this Circuit also looks at the scope and plausibility of the other alleged exclusionary conduct." (*Id.* at 30.) So, the mere fact that Mylan alleged false advertising, by and of itself, did not warrant dismissal.

Second, the Special Master found Mylan's "allegations sufficiently allege reliance by patients and medical professionals on the alleged false statements sufficient at this stage of the litigation." (*Id.* at 31.)

Third, the Special Master determined that, while DAW conduct, standing alone, "may not rise to the level of anticompetitive conduct, the allegations in the Complaint are coupled with allegations of false statements meant to induce the writing of these prescriptions, including several specifically alleged categories of false statements." (*Id.*) Those allegations, the Special Master found, were enough to survive a motion to dismiss.

Fourth, the Special Master explained that, while Teva's arguments about the anticompetitive effect of the DAW campaign "could prove to be a persuasive defense," the issue was "ill-suited to a ruling at the motion to dismiss stage." (*Id.* at 32.)

Consequently, the Special Master recommended the Court deny the motion to dismiss as to the DAW campaign allegations.

b. Exclusionary Agreements

Teva argued the agreements at issue were not anticompetitive as a matter of law. (*Id.* at 33.) However, as the Special Master noted, the parties disagreed about what test the Court should

apply in considering whether the exclusionary agreements were a form of "competition on the merits." (*Id.*) Teva argued the price-cost test should apply; Mylan argued the "rule of reason" test should apply.

Under the price-cost test, the only question is whether Teva sold Copaxone below cost. But, as the Special Master remarked, the price-cost test is inappropriate where "there is additional exclusionary conduct alleged beyond a price discount." (*Id.* at 34.) And, because the Complaint alleged exclusionary conduct beyond below-cost pricing, the Special Master concluded the price-cost test did not apply.

The Special Master then applied the "rule of reason" test to the allegedly exclusionary agreements. She explained that, under the rule of reason, "[t]he legality of an exclusive dealing arrangement depends on whether it will foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." (*Id.* at 38 (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012).) After surveying the Complaint, the Special Master concluded the pleading "alleged a set of facts from which to plausibly infer that the Rebate Agreements and Switch Agreements adversely affected competition," such that dismissal was unwarranted. (*Id.* at 40.) And, while the Special Master acknowledged the Complaint did not "robustly set forth" allegations of antitrust injury, she concluded such an issue was "more suited for decision after fact discovery is completed." (*Id.* at 43.)

Therefore, the Special Master recommended the Court deny the motion to dismiss as to the allegations of exclusionary agreements.

c. Petitioning and Litigation Conduct

Teva argued Mylan's allegations of petitioning and litigation conduct should be dismissed because (1) *Noerr-Pennington* immunity protected Teva's First Amendment right to file lawsuits

and regulatory petitions, and (2) Mylan failed to adequately allege Teva's petitioning and litigation conduct caused a delay in Mylan's generic approval. (*Id.* at 45.)

The Special Master started with *Noerr-Pennington* immunity. (*Id.* at 46.) She explained that *Noerr-Pennington* immunity shields those who "petition the government for redress." (*Id.* (quoting *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, No. 18-1994, 2021 WL 3144897, at *9 (D.N.J. July 26, 2021).) The Special Master then stated *Noerr-Pennington* immunity does not apply where petitioning is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with business relationships of a competitor." (*Id.* (quoting *E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).) However, the Special Master noted the parties disagreed over the appropriate test to determine whether petitioning conduct is a "mere sham." (*Id.*) Teva argued the "mere sham" exception applies where (1) the lawsuit or petition is "objectively baseless," meaning no reasonable litigant would believe they had a chance of winning; and (2) the lawsuit or petition was taken for the purpose of using the government process as an anticompetitive weapon. (*Id.* (citations omitted).) Mylan argued the more flexible "serial petitioning" test should apply. (*Id.*) The "serial petitioning" test looks at whether petitions were filed "without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." (*Id.* at 46–47 (quoting *Hanover 3201 Realty, LLC v. Vill. Supermarkets Inc.*, 806 F.3d 162, 180 (3d Cir. 2015).)

The Special Master, however, concluded that the Third Circuit considered the issue, "expressly declined to apply the 'serial petitioning' standard . . . in the Hatch-Waxman context," and instead applied the "objectively baseless" standard in Hatch-Waxman cases. (*Id.* at 47–48 (quoting *In re Wellbutrin*, 868 F.3d at 157–58.) Thus, to the extent the Complaint alleged Hatch-Waxman conduct, she applied the "objectively baseless" standard. (*Id.* at 48.)

The Special Master remarked that, even if she used the "serial petitioning" standard, the eight regulatory petitions Teva filed "would not be appropriately considered under that standard." (*Id.* at 50.) That is because, according to the Special Master, (1) under FDA rules, a citizens petition is automatically dismissed after 150 days if the FDA takes no action on it; (2) a citizens petition must be pending at the time when it approves an ANDA; (3) only the FDA knows when it will approve an ANDA; and (4) a brand company cannot file one petition to remain on file with the FDA until the FDA approves an ANDA. Taken together, the Special Master found Teva filed each citizens petition "after the FDA dismissed the prior petition as premature, and hence it was necessary to re-file it to preserve Teva's rights to have a petition on file at the time that the FDA decided to act." (*Id.* at 49.) In other words, "to be sure that a timely petition was on file whenever the FDA decided to approve Sandoz's ANDA, substantially the same petition making the same points needed to be re-filed multiple times." (*Id.*) Having reviewed the citizens petitions, the Special Master "determined that the petitions are factually to be considered as one single petition, refreshed as necessitated by the FDA regulations. Thus, the serial petitioning standard shall not apply based on the wording of the FDA regulations, even if that standard were applicable in this Circuit." (*Id.* at 50.)

Next, the Special Master considered whether the "objectively baseless" or "serial petitioning" standard applied to conduct outside the Hatch-Waxman context. The Special Master noted that the "serial petitioning" standard required plausible allegations that conduct constituted a "pattern of petitioning." (*Id.* at 51 (quoting *Hanover*, 806 F.3d at 180).) However, the Special Master concluded the "disparate non-Hatch-Waxman litigations" alleged in the Complaint were not a pattern of petitions—they involved "different targets and objectives, in terms of intent," and did not represent "a repeated attempt at the same action, but disparate events separated by years."

(*Id.*) Consequently, the Special Master reviewed the Complaint using the "objectively baseless" standard. (*Id.*)

1. 20mg Citizens Petitions

The Special Master dismissed with prejudice allegations concerning the 20mg Citizens Petitions. First, she determined that the Complaint lacked "any specific mention of the 20mg petitions, much less any non-conclusory allegations as to why the 20mg petitions were objectively baseless." (*Id.* at 54.)

Next, the Special Master concluded that Mylan could not plausibly allege that the 20mg petitions delayed approval of Mylan's generic. (*Id.* at 56.) She noted the Complaint only vaguely alluded to the 20mg petitions. (*Id.* at 53 (quoting Compl. ¶ 102).) That allegation claimed Teva's "regulatory abuse" started in 2008 (Compl. ¶ 102), which is when Sandoz filed an ANDA for generic GA. (*Id.* ¶ 75). Thus, the Special Master explained that,

> [w]hile Mylan's allegations of regulatory abuse do not explicitly reference Teva's FDA petitions about Sandoz's ANDA, the "regulatory abuse" averment in the Complaint, combined with references to these petitions in both parties' Motion to Dismiss briefs and oral arguments, leads to the inference that the term "regulatory abuse" does in fact refer to these citizens petitions directed at Sandoz's ANDA.

(R&R at 53.)

The Special Master, however, concluded "there are no facts stated in the Complaint that even remotely plausibly connect the petitioning activity prior to the Sandoz 20mg generic FDA approval, and the two-year gap in agency action approving the Mylan generic." (*Id.* at 55.) She also noted the Third Circuit held that "where FDA approval of the generic occurred a year after the alleged unlawful antitrust delay had ended, there was no plausible factual basis that the alleged wrongful activity caused the harm claimed, i.e. the later FDA approval date." (*Id.* (quoting *In re Wellbutrin*, 868 F.3d 132 at 152–53).)

The Special Master further determined Mylan could not amend its way out of this defect because (a) the 20mg petitions were "only about the Sandoz 20mg generic," and (b) the parties did not dispute "the dates of the citizens petitions, the final disposition in 2015 when Sandoz's generic GA was approved, and the additional two-year hiatus until Mylan's FDA approval in 2017." (*Id.* at 56.) The Special Master also stated that

> Despite the vague and generalized language of the Complaint on its face, the voluminous facts and law argued to the Special Master during multiple oral argument days have fully aired any theory that could be premised on the Sandoz 20mg petitioning activity as the causal element in this case regarding the Mylan approval date.

(*Id.* at 57 n.20.) Thus, the Special Master recommended the Court dismiss the 20mg petition allegations with prejudice.

2. 20mg ANDA Lawsuit

Next, the Special Master recommended the Court dismiss the 20mg ANDA lawsuit allegations with prejudice. The Special Master remarked that the Complaint alleged "no facts" as to how the 20mg ANDA lawsuit was "objectively baseless," nor could it. (*Id.* at 57.) That is because Teva initially *won* the 20mg ANDA lawsuit. (*Id.*) Mylan appealed, and the Federal Circuit reversed as to the Group I claims, finding them indefinite; Teva appealed the Federal Circuit's reversal to the Supreme Court; the Supreme Court remanded; and the Federal Circuit again concluded the Group I claims were indefinite. (*Id.* at 57–58.) Though Mylan argued that the lawsuit was baseless because the Group I claims were found indefinite, "[l]osing a case after extensive rounds of litigation, going all the way up the Supreme Court and remanded to the Federal Circuit, does not remotely suggest that it was objectively baseless to initiate." (*Id.* at 58.) Similarly, the Special Master concluded the Complaint lacked any plausible allegation that the 20mg ANDA lawsuit caused delay in Mylan's generic approval, because the FDA did not approve Mylan's

ANDA "until three-and-a-half years after the District Court's injunction ended." (*Id.*) The facts of the 20mg ANDA litigation were "judicially noticeable," meaning no additional facts could plausibly connect the 20mg ANDA litigation to a delay in Mylan's ANDA approval. (*Id.* at 60.) The Special Master, accordingly, determined that "Mylan not be granted leave to amend its Complaint to include allegations concerning this patent litigation as a basis for its Sherman Act count alleging sham litigation." (*Id.*)

3. 2014 FDA Lawsuit

The Special Master recommended the Court dismiss allegations about the 2014 FDA Lawsuit with prejudice. (*Id.* at 60–61.) In that case, the district court "denied Teva's motion for preliminary injunction and granted the FDA's motion to dismiss a mere five days after the case was filed by Teva." (*Id.*) The Special Master concluded "[t]here is no plausible basis from which to infer that Mylan, or competition, was harmed by this five-day lawsuit in 2014, directed at the Sandoz ANDA, and filed nearly three years before Mylan received FDA approval for its 20mg and 40mg products in 2017." (*Id.* at 61.)

4. 40mg ANDA Lawsuit

The Special Master recommended the Court dismiss Mylan's allegations about the 40mg ANDA lawsuit with prejudice. There, Teva sued Mylan for infringing Teva's patent for 40mg Copaxone. (*Id.*) Teva lost before the district court and the Patent and Trademark Board ("PTAB"). (*Id.* at 61–62.) The Special Master, however, remarked that "[m]erely losing a case, or a court's portrayal of the basis for the loss in a negative light, is not sufficient to allege that the case was a mere sham." (*Id.* at 62.) According to the Special Master, "[t]he outcome of this case is not atypical

for patent litigation in the ANDA context, and it cannot plausibly be alleged that no reasonable litigant could have expected to prevail in this Hatch-Waxman case." (*Id.*)

Likewise, the Special Master found Mylan did not and could not allege the 40mg ANDA lawsuit delayed FDA approval. (*Id.* at 62–63.) She reasoned that Teva's three-year exclusivity period for 40mg Copaxone could not be part of an anticompetitive scheme because it is a statutory right. (*Id.* at 63.) And, even if the 40mg ANDA litigation was objectively baseless, the district court's thirty month stay "ended two days after the three-year exclusivity period ended. In other words, the [thirty]-month judicial stay only could have stopped Mylan from getting approval for two days." (*Id.*) And, after those two days, the FDA still took eight months to approve Mylan's 40mg generic. (*Id.*)

5. Non-Orange Book Patent Litigation

The Special Master recommended the Court exclude Mylan's non-Orange Book patent litigation allegations. She explained Mylan raised non-Orange Book patent litigation for the first time in its opposition to Teva's motion to dismiss; Mylan did not identify any of those non-Orange Book cases; and the Complaint alleges no facts about how those lawsuits harmed competition or caused delay. (*Id.* at 64.) As the non-Orange Book patent lawsuits were "not allegations in the Complaint," the Special Master concluded "there is nothing to dismiss, nor anything to seek to amend." (*Id.*)

6. 2020 Petition for Reclassification and Related Lawsuit

The Special Master concluded Mylan's allegations about Teva's petition to reclassify Copaxone as a biologic, and its related lawsuit, were pled with "sufficient particularity to plausibly allege that this petition and subsequent litigation regarding reclassification were objectively baseless, to meet the first prong of the sham litigation exception." (*Id.* at 64.) As the Special Master

remarked, "[t]he detailed allegations about this biological drug petition and lawsuit stand in stark contrast to the sparse and conclusory allegations in the Complaint—or entire lack of allegations—that do not meet the standard with respect to other litigation or petitioning conduct discussed above." (*Id.* at 65.)

The Special Master then observed the Complaint was "less robust as to whether it can be plausibly inferred that this conduct caused antitrust injury to the market for GA, or even caused harm to Mylan." (*Id.*) Mylan argued the legal fees it incurred in defending the 2020 Reclassification Lawsuit were an antitrust injury. (*Id.* at 66.) After examining the caselaw, the Special Master concluded "the only Federal Circuit case cited by the parties on this issue finds that attorneys' fees can in certain cases constitute antitrust injury." (*Id.* at 67.) Thus, The Special Master recommended the Court deny the motion to dismiss as to Mylan's allegations about the 2020 Reclassification Petition and Lawsuit. (*Id.*)

7. The Overall Scheme

Though the Special Master recommended dismissing most of the petitioning and litigation allegations from the Complaint, Mylan sought to retain those allegations as part of an "overall antitrust scheme." (*Id.* at 68.) Teva argued those inadequately pled petitioning and litigation allegations could not remain as part of the "overall scheme." (*Id.*) Following oral argument and supplemental briefings from the parties, the Special Master found that "immunized petitioning/litigation needs a very strong causal connection to the claimed unlawfully exclusionary activity to lose its cloak of immunity." (*Id.* at 70.)

The Special Master then noted that none of the petitioning and litigation conduct within the sweep of *Noerr-Pennington* immunity had any connection to other allegedly exclusionary

activity: most of the conduct was directed at Sandoz, a non-party and all of it predated the FDA's approval of Mylan's generic. (*Id.* at 71.)

Thus, the Special Master concluded

> that, other than the plausibly pled 2020 petition and lawsuit against the FDA, the remaining petitioning/litigation allegations be removed from Mylan's Complaint. These allegations relate to First Amendment protected speech, and their inclusion that would confuse the real issues in dispute and impermissibly lead to inferences from immunized litigation that cannot plausibly have delayed Mylan's entry into the generic marketplace for GA, nor had any effect in suppressing generic uptake after 2017. In short, the recommendation is to tailor and confine this case to its proper scope. There is enough there to be fertile ground to develop the case and the defenses

(*Id.* at 72.)

d. Market Shift

The Special Master recommended the Court dismiss with prejudice Mylan's allegations about Teva shifting the market from 20mg to 40mg Copaxone. (*Id.* at 78.) The Special Master noted that all the events surrounding the purported market shift occurred more than two years before Mylan had FDA approval to sell any GA product. (*Id.* at 75.) Thus, the Special Master observed that when Teva allegedly shifted the market from 20mg to 40mg Copaxone, Mylan "could not lawfully market either a 20mg or 40mg dose." (*Id.* at 76.) So, the market shift, even if successful, could not have harmed Mylan. (*Id.*) The Complaint, moreover, offered no allegations showing the market shift supercharged the anticompetitive effects of the DAW Campaign or exclusionary agreements. (*Id.* at 77.) Accordingly, the Special Master found "[t]he alleged market

shift is too disparate in its nature and its timing to be plausibly alleged to have harmed Mylan as part of the same overarching scheme." (*Id.*)

e. Copay Assistance

The Special Master recommended the Court dismiss Mylan's allegations about copay assistance. She remarked that "Mylan essentially seeks to morph the DOJ's allegations against Teva alleging violations of the [Anti-Kickback Statute] and restate them as a Sherman Act violation." (*Id.* at 78–79.) Teva argued that (1) the Anti-Kickback Statute has "no private right of action," meaning Mylan cannot repurpose an Anti-Kickback Statute violation into a Sherman Act violation, and (2) Mylan failed to allege the conduct was exclusionary or caused antitrust injury to Mylan. (*Id.* at 79.)

Analyzing these arguments, the Special Master noted "[t]he essence of Mylan's allegation is that Teva's price assistance to patients was anticompetitive because Teva reduced their costs in a manner that violated the [Anti-Kickback Statute]." (*Id.* at 81.) She observed the Anti-Kickback Statute does not have a private right of action, and, in any event, "Mylan does not allege that it could not have discounted its own prices, nor that the discounts brought the price below Teva's costs, nor that Mylan lost any sales as a result." (*Id.*) Moreover, the Special Master determined Mylan's copay assistance allegations had "a major timing flaw," as Teva's copay assistance program was in place for years before the FDA approved any generic GA products. (*Id.*) Correspondingly, the Special Master found the copay assistance campaign could not have enhanced the exclusionary effect of the DAW Campaign or exclusionary agreements, because that conduct was found to plausibly allege harm to Mylan only after it began marketing generic GA. (*Id.* at 82–83.)

ii. Lanham Act Violation (Count II)

Mylan alleges that Teva, in carrying out the DAW Campaign, violated the Lanham Act's prohibition on making false statements as part of a commercial advertising or promotion. (*Id.* at 83–84.) Teva argued the statements it made during the DAW Campaign were "a handful of isolated statements," not an advertising campaign. (*Id.* at 83.) The Special Master concluded the Complaint adequately alleged the statements were false or misleading and disseminated to doctors. Accordingly, the Special Master recommended the Court deny Teva's motion to dismiss as to Count II. (*Id.* at 86.).

iii. The State Law Claims (Counts III to VI)

Teva argued that, if the Court dismissed Mylan's federal antitrust claim, it should decline supplemental jurisdiction over Mylan's state law claims. (*Id.*) But, because the R&R recommended the Court allow significant portions of Mylan's Sherman Act claim to proceed, the Special Master recommended the Court not dismiss the state claims. (*Id.* at 86–87.)

iv. The Motion to Strike Mylan's Foreign Allegations

Teva also moved to strike Mylan's allegations about foreign regulatory processes. (*See id.* at 87.) The Special Master recommended the Court grant Teva's motion to strike, as the "foreign allegations—some dating back ten years or more, and all premised on non-US laws or non-US competition regulations—will not tend to prove or disprove the claims that will proceed in the case." (*Id.* at 88.) Likewise, the Special Master found Mylan did not show a sufficient basis to

"delve into foreign discovery," which would "lead to information of dubious relevance to the issues in this case that could eventually be decided by a jury applying U.S. law." (*Id.*)

F. Mylan's Objections

Mylan timely objected to the R&R. (*See* Mylan Objs., ECF No. 163.) Mylan argued that the Special Master (1) should have applied the "serial petitioning" standard to Teva's 20mg petitions; (2) incorrectly concluded that the 20mg petitions and 2014 FDA Lawsuit could not have delayed Mylan's approval; (3) should have retained the 20mg petition allegations for evidence of an overall anticompetitive scheme; and (4) improperly dismissed the Complaint's regulatory and petitioning allegations with prejudice, and struck the foreign allegations. (*See generally id.*) Teva opposed. (*See* Teva Opp'n, ECF No. 169.)

II. LEGAL STANDARD

A. Special Masters

Rule 53(a) allows the Court to appoint a special master to "address pretrial and posttrial matters." The Court reviews objections to a special master's findings of fact and conclusions of law *de novo*. Fed. R. Civ. P. 53(f)(3)–(4). *De novo* review requires "an independent determination of a controversy that accords no deference to any prior resolution of the same controversy." *United States v. Raddatz*, 447 U.S. 667, 690 (1980) (Stewart, J., dissenting) (citation omitted).

B. Motion to Dismiss

Rule 12(b)(6) governs motions to dismiss for "failure to state a claim upon which relief can be granted." A complaint must contain "sufficient factual matter, accepted as true, 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)). A claim is facially plausible "when the

plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

The Court conducts a three-step inquiry in evaluating a motion to dismiss under Rule 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). First, the Court identifies "the elements a plaintiff must plead to state a claim." *Iqbal*, 556 U.S. at 675. Second, the Court accepts all plaintiff's well-pleaded factual allegations as true and "construe[s] the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). But the Court disregards "legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements." *Davis v. Wells Fargo*, 824 F.3d 333, 341 (3d Cir. 2016). Third, the Court considers "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679).

C. Motion to Strike

A court may, upon motion or *sua sponte*, strike from the pleadings "any redundant, immaterial, impertinent, or scandalous matter. Fed. R. Civ. P. 12(f). Granting a motion to strike "is discretionary." *Newborn Bros. Co. v. Albion Eng'g Co.*, 299 F.R.D. 90, 94 (D.N.J. 2014) (quoting *F.T.C. v. Hope Now Modifications, LLC*, No. 09-1204, 2011 WL 883202, at *1 (D.N.J. Mar. 10, 2011)). Nevertheless, a motion to strike is "highly disfavored" because it is often "a dilatory tactic." *Hope Now*, 2011 WL 883202, at *1 (quoting *Waste Mgmt. Holdings v. Gilmore*, 252 F.3d 316, 347 (4th Cir. 2001)).

"The purpose of a motion to strike is to simplify the pleadings and save time and expense by excising from a plaintiff's complaint 'any redundant, immaterial, impertinent, or scandalous matter' which will not have any possible bearing on the outcome of the litigation." *Garlanger v.*

Verbeke, 223 F. Supp. 2d 596, 609 (D.N.J. 2002). Even so, "a motion to strike should not be granted unless the presence of the surplusage will prejudice the adverse party." *Newborn Bros.*, 299 F.R.D. at 94 (quoting *Hope Now*, 2011 WL 883202, at *1). Thus, courts usually deny motions to strike "unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues." *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 619 (D.N.J. 2000) (quoting *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F.Supp. 200, 217 (D.N.J. 1993)). "A motion to strike should not be used as a vehicle to determine disputed and substantial questions of law or fact." *Id.* (citing *Glenside W. Corp. v. Exxon Co., U.S.A.*, 761 F. Supp. 1100, 1115 (D.N.J. 1991)).

A motion to strike is "construed strictly against striking portions of pleading on grounds of immateriality and if the motion is granted at all, the complaint should be pruned with care." *Morgan Home Fashions, Inc. v. UTI, U.S., Inc.*, No. 03-772, 2004 WL 1950370, at *8 (D.N.J. Feb. 9, 2004). "If there is any doubt as to whether a matter in a pleading should be stricken, the doubt should be resolved in favor of the pleading." *United States v. Bos. Sci. Neuromodulation Corp.*, No. 11-1210, 2014 WL 4402118, at *3 (D.N.J. Sept. 4, 2014).

III. DISCUSSION

A. The Sherman Act

i. Prima Facie Claim

Section 2 of the Sherman Act "makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007) (citing 15 U.S.C. § 2). To state a monopolization claim, the plaintiff must plausibly allege (1) the defendant has "monopoly power in the relevant market" and (2) defendant willfully acquired or maintained monopoly power, "as distinguished from growth or

development as a consequence of a superior product, business acumen, or historic accident." *Id.* at 307 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). To state an attempted monopolization claim, the plaintiff must show "(1) that the defendant has a specific intent to monopolize, and (2) that the defendant has engaged in anticompetitive conduct that, taken as a whole, creates (3) a dangerous probability of achieving monopoly power." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 108 (3d Cir. 2010) (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993)).

"Monopoly power is the ability to control prices and exclude competition in a given market." *Broadcom*, 501 F.3d at 307. Yet simply having monopoly power, by itself, is not unlawful. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). "The opportunity to charge monopoly prices—at least for a short period—is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth." *Id.* "To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." *Id.*

Anticompetitive conduct is "generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits." *Broadcom*, 501 F.3d at 308 (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003)). "Conduct that impairs the opportunities of rivals and either does not further competition on the merits or does so in an unnecessarily restrictive way may be deemed anticompetitive." *Id.* (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 604–05, 605 n.32 (1985)).

"To establish an actionable antitrust violation, [the plaintiff] must show both that [the defendant] engaged in anticompetitive conduct and that [the plaintiff] suffered antitrust injury as a result." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir. 2016). An antitrust

injury is: "(1) harm of the type the antitrust laws were intended to prevent; and (2) an injury to the plaintiff which flows from that which makes defendant's acts unlawful." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 281 (3d Cir. 2012) (quoting *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010)). Antitrust laws protect "*competition*, not *competitors*." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). So, an antitrust plaintiff must show that (1) the complained-of anticompetitive conduct harmed "the competitive process itself," *Broadcom*, 501 F.3d at 308, and (2) the plaintiff suffered an injury "stem[ming] from a competition-*reducing* aspect or effect of the defendant's behavior," *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990).

ii. Overall Scheme Liability

Mylan alleges Teva engaged in five kinds of anticompetitive behavior as part of one overarching anticompetitive scheme. "It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful." *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946). If lawful acts "are part of the sum of the acts which are relied upon to effectuate the conspiracy which the statute forbids, they come within its prohibition." *Id.* The Court, therefore, considers "the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003). That includes conduct that would, on its own, not violate Section 2. However, for the Court to consider legal conduct as part of an anticompetitive scheme, the plaintiff must plausibly allege the legal conduct contributed to the scheme's anticompetitive effect. *Id.* (examining legal conduct as part of anticompetitive scheme where legal conduct "reinforced the exclusionary effect of" illegal conduct). Moreover, an antitrust complaint cannot be "devoid of allegations of truly

anticompetitive conduct." *Phila. Taxi Ass'n, Inc v. Uber Techs., Inc.*, 886 F.3d 332, 341 (3d Cir. 2018) (affirming dismissal of Section 2 claim where none of the conduct alleged in overall scheme was anticompetitive).

Taken together, if some conduct, on its own, would not violate Section 2, the Court may nonetheless consider it as part of an overall anticompetitive scheme if (a) the scheme contains at least *some* conduct that would, on its own, violate Section 2, and (b) plaintiff alleges the legal conduct contributed to the overall scheme's anticompetitive effect.

iii. Noerr-Pennington Immunity

a. Overview

Noerr-Pennington immunity provides that "[t]hose who petition government for redress are generally immune from antitrust liability." *Prof'l Real Est. Inv'rs, Inc. v. Columbia Pictures Indus., Inc.* (*PRE*), 508 U.S. 49, 56 (1993); *E. R. R. Presidents Conf. v. Noerr Motor Freight, Inc.* (*Noerr*), 365 U.S. 127, 138 (1961) ("[T]he Sherman Act does not apply to the . . . mere solicitation of governmental action with respect to the passage and enforcement of laws."); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). The right to petition "extends to all departments of the Government," including administrative agencies and courts. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). Consequently, *Noerr-Pennington* immunity shields those who "use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-a-vis their competitors." *Id.* at 511. And, because petitioning conduct "is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act," the Court may not consider it as part of an overall monopolistic

scheme. *Pennington*, 381 U.S. at 670; *see also In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 360 (D.N.J. 2009) ("Conduct protected by *Noerr–Pennington* immunity cannot be properly included within the scope of the monopolization scheme at issue."); *Schenley Indus., Inc. v. N.J. Wine & Spirit Wholesalers Ass'n*, 272 F. Supp. 872, 886 (D.N.J. 1967) ("Since no claim for relief may be predicated on the allegations that defendant Wholesalers sought to influence governmental action, such allegations should be stricken from the complaint."); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) ("No provision is made for liability predicated on immune litigation as part of an alleged overall scheme to violate antitrust laws.").

b. The Sham Exception

Noerr-Pennington immunity does not, however, protect "sham" petitioning conduct. *PRE*, 508 U.S. at 56. The sham exception applies where protected conduct is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor," and to which "the application of the Sherman Act would be justified." *Noerr*, 365 U.S. at 144. The party invoking the sham exception has the burden of proving the petitioning or litigation is a sham. *See In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 311 (E.D. Pa. 2011) ("Under *PRE,* the burden falls on the party invoking the sham exception . . . to show that the conduct at issue constitutes a sham.").

The parties, however, disagree about what constitutes a sham. Teva argued that the Court should apply the two-part "objective baselessness" test the Supreme Court set forth in *PRE*, 508 U.S. at 60–61. (R&R at 46.) Under the objective baselessness test, the plaintiff must show (1) the litigation or petition is "objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits," and (2) that the defendant subjectively intended to "use the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive

weapon." *PRE*, 508 U.S. at 60–61 (quoting *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991)). Moreover, to state an antitrust claim for anticompetitive petitioning or litigation, the plaintiff must show not only that the petitioning or "litigation was a sham, but also that it caused an antitrust injury by delaying generic competition." *In re Wellbutrin*, 868 F.3d at 151.

Mylan argued that the Court should apply the "serial petitioning" standard. (R&R at 46–47.) This is "more flexible" than the "objective baselessness" test. *Hanover*, 806 F.3d at 180. The "serial petitioning" test "asks whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id.* The question "is not whether any one of [the petitions] has merit—some may turn out to, just as a matter of chance—but whether they are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival." *Id.* (quoting *USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO*, 31 F.3d 800, 811 (9th Cir. 1994)). The "best way" to choose between the "objective baselessness" and "serial petitioning" tests "depends on whether there is a single filing or a series of filings." *Id.* The "serial petitioning" test is generally "appropriate when dealing with a pattern of petitioning." *Id.*

The Third Circuit, however, has noted the "serial petitioning" test is "particularly inapt" where the defendant's "actions were consistent with the design and intent of Hatch-Waxman." *In re Wellbutrin*, 868 F.3d at 157–58 (applying objectively baseless standard to ANDA lawsuits and citizen petition); *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 361 (3d Cir. 2020) ("[W]e have declined to apply a related exception to *Noerr-Pennington* immunity—serial petitioning—in the Hatch-Waxman context."). Hatch-Waxman sets forth a special system of litigation and

"incentivizes brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to [thirty] months if they do so." *In re Wellbutrin*, 868 F.3d at 157–58 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). Penalizing "a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman' . . . . would punish behavior that Congress sought to encourage." *Id.* at 158 (quoting *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009)). The Court, therefore, applies the "objective baselessness" test to actions "consistent with the design and intent of Hatch-Waxman." *Id.* at 157.[5] As for non-Hatch-Waxman conduct, the Court considers whether it is a "pattern of petitioning." *Hanover*, 806 F.3d at 180.

Despite the breadth and complexity of the R&R, Mylan's objections are narrow. It argues the Special Master erred in concluding (1) that *Noerr-Pennington* immunity attached to the 20mg Citizen Petitions, (2) that the 20mg Citizen Petitions and 2014 FDA Lawsuit could not have

[5] Mylan briefly argues, in a footnote, that the Third Circuit has not categorically declined to apply the serial petitioning standard to Hatch-Waxman conduct. (*See* Mylan Objs. at 8 n.6.) And, according to Mylan, *AbbVie* and *Wellbutrin* are inapposite because here, Teva filed lawsuits and petitions against a competitor.

These arguments fall flat. In both *AbbVie* and *Wellbutrin*, the Third Circuit has clearly and unequivocally declined to apply the "serial petitioning" standard to Hatch-Waxman conduct. *See AbbVie*, 976 F.3d at 361; *In re Wellbutrin*, 868 F.3d at 157. While the Third Circuit has the power to clarify or limit its holdings in *Wellbutrin* and *AbbVie*, this Court does not. *See United States v. Kennedy*, 682 F.3d 244, 252 (3d Cir. 2012) (noting that district courts have "no power or authority to deviate from the mandate issued by an appellate court." (citation omitted)). This Court simply applies what the Third Circuit held.

Moreover, Mylan, as the party with the burden of showing the sham exception applies, has not persuasively explained why this case falls outside the holdings in *AbbVie* or *Wellbutrin*. To the contrary, this case, like *AbbVie* and *Wellbutrin*, involves a combination of petitions and lawsuits. *See AbbVie*, 976 F.3d at 341–46; *In re Wellbutrin*, 868 F.3d at 145–47.

Mylan also cites a District of Vermont case where a court considered *AbbVie* and *Wellbutrin* but nonetheless applied the "serial petitioning" standard to Hatch-Waxman conduct. *See Blue Cross & Blue Shield of Vt. v. Teva Pharm. Indus., Ltd.*, 712 F. Supp. 3d 499, 528–30 (D. Vt. 2024). That case is not instructive here. The *BCBS* court is neither within the Third Circuit, nor did it apply Third Circuit law.

delayed Mylan's approval, and (3) that the foreign allegations should be struck from the Complaint. The Court considers each point in turn.[6]

B. The 20mg Citizen Petitions

Mylan argues (1) the Special Master should have applied the "serial petitioning" standard to the 20mg Citizen Petitions, (2) the Special Master should not have resolved the question of *Noerr-Pennington* immunity on a motion to dismiss, and (3) the Special Master incorrectly concluded that the 20mg Citizens Petitions could not have delayed Mylan's approval.

i. The "Objectively Baseless" Standard Applies

The 20mg Citizen Petitions fall within the ambit of *Noerr-Pennington* immunity. They are, after all, petitions for redress from the government. *Trucking Unlimited*, 404 U.S. at 510–11. The question is whether the Court should apply the "objectively baseless" or "serial petitioning" standard in determining whether the 20mg Citizens Petitions are shams.

The "objectively baseless" standard applies. Each of the 20mg Citizen Petitions requested the FDA not grant or accept any ANDA application until certain requirements were met.[7] Teva

[6] For the avoidance of any doubt, the Court has also reviewed the unobjected-to portions of the R&R *de novo* and affirms the R&R as to those portions.

[7] Mylan notes that citizen petitioning "is not inherently or exclusively a part of the Hatch-Waxman paradigm." (Mylan Objs. at 8 n.6.) Abstractly, that might be true. But Teva's citizen petitions *in this case* requested that the FDA not approve or accept any ANDA referencing Copaxone until certain conditions were met. *See* Citizen Petition (Food & Drug Admin., Sept. 26, 2008), https://www.regulations.gov/document/FDA-2008-P-0529-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Nov. 19, 2009), https://www.regulations.gov/document/FDA-2009-P-0555-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Dec. 10, 2010), https://www.regulations.gov/document/FDA-2010-P-0642-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., June 4, 2012), https://www.regulations.gov/document/FDA-2012-P-0555-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Sept. 12, 2013), https://www.regulations.gov/document/FDA-2013-P-1128-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., Dec. 5, 2013), https://www.regulations.gov/document/FDA-2013-P-1641-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., July 2, 2014), https://www.regulations.gov/document/FDA-2014-P-0933-0001; Citizen Petition Requesting That FDA Not Approve An ANDA Referencing Copaxone Until Certain Conditions Are Met (Food & Drug Admin., March 31, 2015), https://www.regulations.gov/document/FDA-2015-P-1050-0001.

filed the petitions pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(q)(1). Thus, the petitions related directly to ANDA approval and the Hatch-Waxman process. Because the "serial petitioning" standard is "particularly inapt" for Hatch-Waxman conduct, the "objectively baseless" standard applies instead. *In re Wellbutrin*, 868 F.3d at 157.

ii. The Court Can Make a Sham Determination

Next, Mylan argues the Special Master could not make a sham determination at the motion to dismiss stage. Not so.

To be sure, *Noerr-Pennington* immunity is a fact sensitive issue, "generally not suitable for resolution at the pleading stage." *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-7106, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020). But that does not mean a court may *never* decide the issue on a 12(b)(6) motion. To the contrary, where "there is no dispute over the predicate facts of the underlying legal proceeding," *PRE*, 508 U.S. at 63, and the only issue is whether those facts are "sufficient to establish probable cause for the objective baselessness inquiry," *In re Wellbutrin*, 868 F.3d at 151, the Court faces "a legal question, not a factual one," *id.*, which it may properly resolve on a motion to dismiss. *See Indivior*, 2020 WL 4932547, at *8 ("A court may decide the applicability of the *Noerr–Pennington* doctrine on a motion to dismiss under Fed. R. Civ. P. 12(b)(6) if no factual issues are present."); *ADP, LLC v. Ultimate Software Grp., Inc.*, No. 16-8664, 2018 WL 1151713, at *3 n.3 (D.N.J. Mar. 5, 2018) (same); *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606 (D.N.J. 2000) (granting motion to dismiss on *Noerr-Pennington*

The Court may properly consider the 20mg Citizens Petitions on a motion to dismiss. "A court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice." *Bond v. Solvay Specialty Polymers, USA, LLC*, 583 F. Supp. 3d 643, 649 (D.N.J. 2022) (quoting *S. Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999)). Teva's citizen petitions and the FDA's responses are matters of public record and are, therefore, capable of judicial notice. *See* Fed. R. Evid. 201; *Novartis Pharm., Corp. v. Wockhardt USA LLC*, No. 12-3967, 2013 WL 5770539, at *5 (D.N.J. Oct. 23, 2013) (taking judicial notice of FDA citizen petition).

immunity); *Trs. of Univ. of Pa v. St. Jude Child.'s Rsch. Hosp.*, 940 F. Supp. 2d 233 (E.D. Pa. 2013) (same).

Here, there is no dispute over the predicate facts of the underlying proceedings. The 20mg Citizens Petitions and the FDA's responses[8] are matters of public record the Court may consider on a motion to dismiss. *See Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). So, the Court may resolve the purely legal question of whether the 20mg Citizens Petitions were objectively baseless at this juncture.

iii. Mylan Failed to Show the Petitions Were Objectively Baseless

A petition or lawsuit is objectively baseless if "no reasonable [party] could realistically expect success on the merits." *PRE*, 508 U.S. at 60. "The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." *Id.* at 62. Probable cause "requires no more than a 'reasonable belief that there is a chance that a claim may be held valid upon adjudication.'" *Id.* at 62–63 (cleaned up) (quoting *Hubbard v. Beatty & Hyde, Inc.*, 343 Mass. 258, 262 (1961)). Even "when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit." *Id.* at 61 n.5 (quoting *Christiansburg Garment Co. v. Equal Emp. Opportunity Comm'n*, 434 U.S. 412, 422 (1978)). If "an antitrust defendant claiming *Noerr* immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit." *Id.* at 63. "In other words, the essential question is not whether the suit succeeds, but whether the suit was a sham at the time it

[8] *See* FDA Response to Teva Citizen Petition, Dkt. No. FDA-2008-P-0529 (Mar. 25, 2008); FDA Response to Teva Citizen Petition, Dkt. No. FDA-2009-P-0555 (May 11, 2010); FDA Response to Teva Citizen Petition, Dkt. No. FDA-2010-P-0642 (Jun. 8, 2011); FDA Response to Teva Citizen Petition, Dkt. No. FDA-2012-P-0555 (Nov. 30, 2012); FDA Response to Teva Citizen Petition, Dkt. No. FDA-2013-P-1641 (May 2, 2014); FDA Response to Teva Citizen Petition, Dkt. No. FDA-2014-P-0933 (Nov. 26, 2014); FDA Response to Teva Citizen Petition, Dkt. No. FDA-2015-P-1050 (Apr. 16, 2015).

was filed." *In re Wellbutrin*, 868 F.3d at 148. A finding of probable cause "irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to *Noerr* immunity." *PRE*, 508 U.S. at 63.

Having reviewed the 20mg Citizen Petitions and the FDA's responses, the Court is satisfied Teva had probable cause to file the 20mg Citizens Petitions. In each petition, Teva requested the FDA not approve or accept any ANDA referencing Copaxone 20mg until certain requirements were met. *See* FDA Response to Teva Citizen Petition at 1–2, Dkt. No. FDA-2015-P-1050 (Apr. 16, 2015). The FDA recognized 21 U.S.C § 355(q)(1)(F) required the FDA to take final action on a petition within 150 days. *Id.* at 2. Yet the FDA denied six of the first seven petitions[9] as "premature," because, at the time, the "FDA had made no final determination about whether, or on what basis, to approve or not approve any ANDA for [GA] injection." *Id.* at 2. At that time, the FDA did not "definitively opine" on the specific requests in the Petitions. FDA Response to Teva Citizen Petition at 7, Dkt. No. FDA-2014-P-0933 (Nov. 26, 2014).

As the Special Master explained and Mylan does not dispute: (1) only the FDA knows when it will approve or not approve an ANDA; (2) Teva's petitions expired after 150 days; (3) Teva had to re-file a petition every 150 days; (4) the FDA is deemed to have taken a final agency action if it "makes a final decision" on the petition or fails to respond, 21 U.S.C. § 355(q)(2)(A); and (5) if Teva sued the FDA "with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition . . . , the court shall dismiss without prejudice the action for failure to exhaust administrative remedies," 21 U.S.C. § 355(q)(2)(B). In other words, a reasonable litigant in Teva's position: (1) could expect some chance of success on the merits of

[9] Teva withdrew the fifth petition before the FDA could rule on it. *See* FDA Response to Teva Citizen Petition at 2 n.2, Dkt. No. FDA-2015-P-1050 (Apr. 16, 2015).

each petition, if the FDA was considering an ANDA referencing Copaxone; and (2) would understand that not having a petition pending at the time of ANDA approval could foreclose their ability to file an action against the FDA. Accordingly, Teva's first seven citizen petitions were not objectively unreasonable.

When the FDA denied the Eighth Petition, it approved an ANDA and substantively analyzed Teva's requests. FDA Response to Teva Citizen Petition, Dkt. No. FDA-2015-P-1050 (Apr. 16, 2015). The FDA concluded:

> We do not find it necessary for an ANDA applicant seeking approval of generic glatiramer acetate injection to submit the information you describe. *Nonetheless, we recognize that approval of ANDAs for glatiramer acetate injection raises complicated scientific and regulatory issues, which we have carefully considered*.

Id. at 3 (emphasis added). Simply put, the FDA denied six of seven petitions as premature—not meritless—and carefully considered the eighth before rejecting it on thorough, substantive grounds. Thus, the Court is satisfied that, based on the undisputed facts in the petitions, a reasonable petitioner would believe "there [was] a chance" it would succeed on any of the eight petitions. *PRE*, 508 U.S. at 62–63 (cleaned up) (quoting *Hubbard*, 343 Mass. at 262).

As discussed previously, the party invoking the sham exception—in this case, Mylan—has the burden of proving the petitioning conduct is a sham. *See In re Flonase*, 795 F. Supp. 2d at 311. Here, the facts underlying the petitions are undisputed. Consequently, the Court may decide whether the petitions are objectively baseless as a matter of law. Mylan, however, has failed to meet its burden of showing that no reasonable petitioner would believe the petitions would succeed. And the Court concludes Teva had probable cause to file them. Because the 20mg Citizens Petitions were not "objectively baseless," *Noerr-Pennington* immunity applies, and the

Special Master did not err in dismissing allegations about the 20mg Citizens Petitions from the Complaint.[10]

iv. Dismissal is With Prejudice

Finally, Mylan argues the Special Master should have dismissed without prejudice the 20mg Citizens Petitions allegations. The Court disagrees.

To be sure, "if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." *Phillips*, 515 F.3d at 236. Amendment is futile if it is "frivolous or advances a claim that is legally insufficient on its face." *Pharm. Sales & Consulting Corp. v. J.W.S. Delavau Co.*, 106 F. Supp. 2d 761, 764 (D.N.J. 2000). Put differently, "leave to amend generally must be granted unless the amendment would not cure the deficiency." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000).

Amendment cannot cure the deficiencies in the Complaint's 20mg Citizens Petitions allegations. The "predicate facts" of the 20mg Citizens Petitions are not in dispute. *PRE*, 508 U.S. at 63. The only question is whether the content in the petitions "was sufficient to establish probable cause for the objective baselessness inquiry." *In re Wellbutrin*, 868 F.3d at 151. This is "a legal question, not a factual one." *Id.* Consequently, the deficiency here is legal, not factual. An amended

[10] The Court also notes that, even if Mylan had shown the 20mg Citizens Petitions were a sham, it would then have to prove the petitions "caused an antitrust injury by delaying generic competition." *In re Wellbutrin*, 868 F.3d at 151. Mylan failed to do so.

It is undisputed that: (1) when Teva filed its first 20mg Citizens Petition in 2008, only Sandoz had filed an ANDA for 20mg GA; (2) the FDA denied Teva's last 20mg Citizens Petition and approved Sandoz's ANDA for 20mg GA in April 2015; and (3) the FDA approved Mylan's ANDA for 20mg GA over two years later, in October 2017. The Complaint offers no plausible allegations to bridge the twenty-seven-month gap between the FDA's rejection of Teva's last citizen petition and simultaneous approval of Sandoz's ANDA in 2015, and the FDA's approval of Mylan's ANDA in 2017. *See In re Wellbutrin*, 868 F.3d at 152 n.24 (dismissing sham litigation claim where there was "no evidence in the record indicating that any delay can be linked to [the] period of time" where the defendant engaged in sham litigation). In its objections, Mylan argues that citizens petitions can delay ANDA approval, especially where the FDA fears litigation and diverts resources from the approval process to answer a petition. (Mylan Opp'n at 16.) The problem is that no such allegations appear in the Complaint.

pleading would still advance a somewhat more detailed but still legally insufficient claim. Thus, the Special Master did not err in dismissing with prejudice the 20mg Citizens Petitions allegations.

C. The 2014 FDA Lawsuit

Mylan argues the Special Master incorrectly determined that Teva's 2014 lawsuit against the FDA could not have plausibly delayed approval of Mylan's 20mg generic. The Court disagrees.

Noerr-Pennington immunity attaches to lawsuits, including this one. *Trucking Unlimited*, 404 U.S. at 510. To overcome *Noerr-Pennington* immunity and state a Section 2 claim, Mylan would have to show (1) the 2014 FDA Lawsuit "was a sham," and (2) "it caused an antitrust injury by delaying generic competition." *In re Wellbutrin*, 868 F.3d at 151.

Even if Mylan could show the 2014 FDA Lawsuit was a sham, Mylan fails to allege the litigation caused the FDA to delay approval of its generic. Mylan would have to show "that at least some delay can be attributed to" the period during which Teva participated in the litigation. *Id.* at 152 n.24. Mylan fails to do so. Teva's lawsuit against the FDA lasted five days. The FDA approved Mylan's 20mg ANDA nearly three years later. Mylan offers no facts plausibly alleging that a five-day-long lawsuit in 2014 caused (or even contributed to) the FDA approving Mylan's 20mg ANDA in 2017, especially considering that the FDA approved Sandoz's 20mg ANDA *two years earlier*. Nor has Mylan plausibly alleged that the 2014 FDA Lawsuit enhanced the anticompetitive effect of an overall monopolistic scheme. Simply put, Mylan does not and cannot plausibly link a five-day-long lawsuit in 2014 to the FDA's 2017 approval or a broader monopolistic scheme. The Special Master, accordingly, did not err in dismissing with prejudice allegations about the 2014 FDA Lawsuit.

D. The Foreign Allegations

Finally, Mylan argues the Special Master erred in striking allegations of Teva's foreign litigation conduct from the Complaint. The Court disagrees.

As discussed above, the Court will deny a motion to strike "unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues." *IVAX*, 77 F. Supp. 2d at 619 (quoting *Tonka*, 836 F.Supp. at 217).

Mylan's foreign allegations do not relate to this case. Nor can they. The Sherman Act does not apply to "conduct involving trade or commerce . . . with foreign nations" unless the conduct (1) "has a direct, substantial, and reasonably foreseeable effect" on American domestic, import, or certain export commerce, and (2) gives rise to a Sherman Act claim. *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 162 (2004) (quoting 15 U.S.C. §§ 6a(1)–(2)). The Complaint alleges Teva "implemented a worldwide scheme consistent with its U.S. strategies to insulate *even those foreign sales from competition*." (Compl. ¶ 92.) Mylan claims Teva used the same dilatory playbook against Mylan in Europe "to prevent generic entry" of GA *in the European market*. (*Id.* ¶¶ 93–100.) There is no allegation that any of that conduct has "a direct, substantial, and reasonably foreseeable effect" on American commerce. At most, Mylan claims Teva sought an injunction in Ireland compelling Mylan to destroy its stock of generic GA for export to the United States. (*Id.* ¶¶ 93–94.) But Teva *lost that lawsuit*. (*Id.* ¶ 94.) So, even if Mylan alleged that Teva's foreign conduct was directed at the United States, the Complaint does not allege that conduct had anticompetitive effect in the United States, nor that it had any synergistic effect on Teva's overall scheme. Thus, Mylan's foreign lawsuit allegations have no bearing on the merits of Mylan's antitrust claim.

Mylan's foreign allegations would prejudice Teva. As the Special Master correctly concluded, foreign discovery would be burdensome, inappropriate, expensive, and minimally probative at best. Moreover, foreign evidence of foreign regulators applying foreign laws would likely confuse a jury tasked with applying American law to an antitrust case covering an American market. Such discovery would also confuse the issues, because the Sherman Act does not cover Teva's foreign conduct. Accordingly, the Special Master did not err in striking the foreign allegations from the Complaint.

IV. CONCLUSION

For the foregoing reasons, the Court **ADOPTS** the Special Master Faith S. Hochberg's Report and Recommendation recommending that the Court partially grant Teva's motion to dismiss Mylan's Complaint. (ECF No. 159). An appropriate Order accompanies this Opinion.

DATED: 4/13/2026

JULIEN XAVIER NEALS
United States District Judge