IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., ***Plaintiff*,** ***v.*** **BIONPHARMA INC.,** ***Defendant*.**	**Civil Action** **Nos. 21-cv-1286, 21-cv-1455**

MEMORANDUM OPINION

Goldberg, J.[1] **January 11, 2023**

These cases comprise what the parties refer to as the "Third Wave" in an ongoing patent infringement dispute between Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity") and Defendant Bionpharma Inc. ("Bionpharma"). The parties' dispute revolves around Bionpharma's generic enalapril oral liquid. Bionpharma's counterclaims assert antitrust "sham litigation" claims under the Sherman Act, 15 U.S.C. §§ 2, 15, and 26, alleging that Azurity brought these and other lawsuits in bad faith to stifle competition. Bionpharma claims that these lawsuits were objectively baseless and brought only to force Bionpharma to incur litigation costs and delay market entry for the duration of the 30-month stay applicable to Hatch-Waxman litigation.

Before me is Azurity's motion to dismiss the antitrust counterclaims. For the reasons that follow, Azurity's motion will be denied.

[1] Pursuant to 28 U.S.C. § 292(b), I have been designated to serve as a visiting judge for the District of Delaware to handle this matter and other District of Delaware cases.

I. FACTUAL AND PROCEDURAL BACKGROUND

The following facts are taken from Bionpharma's Answer and Counterclaims, and, where appropriate, matters of public record regrading the litigation history between Azurity and Bionpharma. These facts will be viewed in the light most favorable to Bionpharma. See Burtch v. Millberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011).

A. Azurity's EPANED Product and Related Patents

Azurity's brand product EPANED is an oral liquid formulation of the blood pressure medicine enalapril. (Answer[2] ¶ 9; Counterclaims ¶¶ 13, 34-35.) EPANED "is the only ready-to-use oral solution of enalapril, which caters to specific populations of patients that have trouble swallowing solid oral dosage forms." (Counterclaims ¶ 38.)

From March 2016 to April 2021, Azurity filed nine patent applications for enalapril liquids, each a continuation of a prior application, and each with a priority date of March 18, 2016.[3] The precise claim limitations differ from patent to patent, but the essence of each is a stable mixture of water, enalapril, and other ingredients such as buffers, preservatives, and sweeteners. The following claims from two of those patents are illustrative:

> A stable oral liquid formulation, comprising:
>
> (i) about 1 mg/ml enalapril maleate;
> (ii) a buffer comprising about 1.82 mg/ml citric acid and about 0.15 mg/mL sodium citrate dihydrate;
> (iii) about 1 mg/ml of a preservative that is sodium benzoate; and
> (iv) water;

[2] Paragraph citations to "Answer" refer to Docket Entry 26 in 21-cv-1455. Paragraph citations to "Counterclaims" refer to paragraphs beginning on page 10 of that document.

[3] These applications issued as U.S. Patent Nos. 9,669,008 (the '008 patent), 11,040,023 (the '023 patent), 11,141,405 (the '405 patent), 9,808,442 (the '442 patent), 10,786,482 (the '482 patent), 10,918,621 (the '621 patent), 10,039,745 (the '745 patent), 10,772,868 (the '868 patent), and 10,154,987 (the '987 patent).

> wherein the pH of the formulation is less than about 3.5; . . .
>
> wherein the formulation is stable at about 5 ± 3° C. for at least 12 months; [and]
>
> wherein the stable oral liquid formulation has about 95% or greater of the initial enalapril amount and about 5% w/w or less total impurities or related substances at the end of the given storage period.

(Claim 1 of the '008 patent.)

> A stable oral liquid formulation, comprising:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
> (ii) a buffer comprising about 0.8 to about 3.5 mg/ml citric acid and about 0.1 to about 0.8 mg/ml sodium citrate;
> (iii) about 0.7 to about 1.2 mg/ml sodium benzoate; and
> (iv) water;
>
> wherein the formulation is stable at about 5 ± 3° C. for at least 12 months; and
>
> wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

(Claim 1 of the '745 patent.)

B. Bionpharma's ANDA

In August 2018, Bionpharma filed an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) for a generic oral enalapril liquid. (Counterclaims ¶¶ 14, 63.) Bionpharma alleges that its ANDA differs from Azurity's EPANED product in that it does not contain a buffer and uses a preservative consisting of parabens rather than sodium benzoate. (Counterclaims ¶ 61.) Bionpharma alleges it made these alterations to "design . . . around" Azurity's patents. (Id.)

To date, Azurity has filed seven lawsuits in three separate courts regarding Bionpharma's generic enalapril liquid—five against Bionpharma and two against Bionpharma's contract manu-

facturer, CoreRx.[4]

C. Bionpharma's Paragraph IV Notice to Azurity

When a generic manufacturer files an ANDA, it must send a notice (a "Paragraph IV Notice") to patentholders listed for the brand drug in the FDA's "Orange Book." See 21 U.S.C. § 355(j)(2)(B). In October 2018, Bionpharma sent a Paragraph IV Notice to Azurity regarding the '008, '442, and '745 patents. (Counterclaims ¶ 64.)

Bionpharma's Paragraph IV Notice offered to provide Azurity with confidential access to Bionpharma's ANDA, under terms similar to those used in prior litigation between Azurity and Bionpharma. (Counterclaims ¶ 65.) Bionpharma requested that Azurity agree not to share information with its patent prosecution counsel (an agreement called a "patent prosecution bar") because Azurity had patent prosecution open for enalapril liquids and Bionpharma was concerned that Azurity could file new applications targeted to Bionpharma's ANDA. (Counterclaims ¶ 68.) Azurity declined the offer of confidential access, and Bionpharma alleges that Azurity did so because Azurity was indifferent to the merits of its infringement position. (Counterclaims ¶¶ 65, 70-71.)

[4] For reference, Azurity's seven lawsuits over Bionpharma's ANDA are summarized in the table below:

Docket No.	Defendant	Filed In	Filed On	Patents
D. Del. 18-1962	Bionpharma	D. Del.	12/12/2018	'008, '442, '745
D. Del. 19-1067	Bionpharma	D. Del.	6/7/2019	'987
D. Del. 20-1256	Bionpharma	D. Del.	9/18/2020	'868, '482, '621
D. Del. 21-1286	Bionpharma	D.N.J.	6/22/2021	'023
D. Del. 21-1455	Bionpharma	D. Del.	10/15/2021	'405
M.D. Fla. 21-2515	CoreRx	M.D. Fla.	10/26/2021	'023, '405
D. Del. 21-1522	CoreRx	D. Del.	10/27/2021	'023, '405

D. Azurity's Lawsuits Against Bionpharma

From December 12, 2018 to October 15, 2021, Azurity filed five lawsuits against Bionpharma only over Bionpharma's generic enalapril liquid. Collectively, these lawsuits involve all nine of Azurity's patents for enalapril liquids. The parties refer to groups of these lawsuits as the the "First Wave," "Second Wave," and "Third Wave."

The First Wave (Nos. 18-cv-1962 and 19-cv-1067) involved the '008, '442, '745, and '987 patents. In February 2021, the Honorable Leonard Stark held a bench trial on these patents and on April 27, 2021 entered judgment for Bionpharma, finding that:

(1) Prosecution history estoppel precluded Azurity from claiming that the active ingredient in Bionpharma's ANDA, enalapril maleate, was equivalent to the citrate buffer limitation in the asserted claims;

(2) Azurity failed to prove that enalapril maleate acted as a buffer; and

(3) Azurity could not claim parabens as equivalent to the claimed preservative sodium benzoate because parabens were disclosed in the specification but not claimed.

(See No. 19-1067, Docket Entry 244.) The Court of Appeals for the Federal Circuit affirmed Judge Stark's findings without an opinion. See Azurity Pharmaceuticals, Inc. v. Bionpharma Inc., No. 2021-1926 (Fed. Cir. March 9, 2022).

The Second Wave lawsuit (No. 20-cv-1256) involved the '868, '482, and '621 patents. After the Federal Circuit's affirmance became final in the First Wave suits, Azurity stipulated to dismissal of the Second Wave lawsuit.

The Third Wave lawsuits (Nos. 21-cv-1286 and 21-cv-1455), which are ongoing, involve the '023 and '405 patents. One of these lawsuits (No. 21-cv-1286) was originally filed in the District of New Jersey and transferred to this Court on Bionpharma's motion.

All of these lawsuits were reassigned to me on March 2, 2022.

E. Azurity's Acquisition of and Lawsuits Against CoreRx

Bionpharma contracted with a third party, CoreRx, Inc. ("CoreRx") to develop and manufacturer the enalapril oral liquid that became Bionpharma's ANDA. (Counterclaims ¶ 13.) In January 2021, Azurity's corporate parent, NovaQuest Capital Management ("NovaQuest") acquired a controlling interest in CoreRx. (Counterclaims ¶ 17.) As of February 2022, Azurity and CoreRx had several directors in common on their respective corporate boards. (Counterclaims ¶¶ 19-22.)

After NovaQuest acquired CoreRx, Azurity sued its new corporate sister twice, in two different courts, for infringing Azurity's patents by manufacturing Bionpharma's ANDA. See Azurity Pharmaceuticals, Inc. v. CoreRx, Inc., No. 21-cv-2515 (M.D. Fla. filed October 26, 2021); Azurity Pharmaceuticals, Inc. v. CoreRx, Inc., No. 21-cv-1522 (D. Del. filed October 27, 2021). Bionpharma alleges that Azurity and CoreRx were not genuinely adverse parties in these lawsuits because their common parent, NovaQuest, could have simply "direct[ed] CoreRx to cease manufacturing for Bionpharma without involving the courts." (Counterclaims ¶ 157.) Bionpharma moved to intervene in the Florida CoreRx lawsuit, allegedly "in order to protect itself against the feigned threat of an injunction against CoreRx's performance of its contractual obligation to supply Bionpharma with Bionpharma's ANDA product." (Counterclaims ¶ 162.) Azurity then settled with CoreRx, wherein CoreRx agreed to stop supplying the generic enalapril oral liquid to Bionpharma. (Counterclaims ¶ 164.)

Based on all the allegations set forth above, Bionpharma claims that Azurity sought to improperly maintain a monopoly in enalapril liquids by punishing generic competition through burdensome and costly litigation. Bionpharma also contends that Azurity brought the First Wave suits solely to obtain the Hatch-Waxman 30-month stay even though Azurity had no expectation of succeeding on the merits. Azurity has moved to dismiss these antitrust counterclaims.

II. LEGAL STANDARD

To survive a motion to dismiss pursuant to Rule 12(b)(6), 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 Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Conclusory allegations do not suffice. Id. Twombly and Iqbal's plausibility standard requires more than a "sheer possibility that a defendant has acted unlawfully." Id. Plausibility requires "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements of a claim." Phillips v. County. Of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008).

To determine the sufficiency of a complaint under Twombly and Iqbal, a court must (1) "tak[e] note of the elements a plaintiff must plead to state a claim"; (2) identify the allegations that are not entitled to the assumption of truth because they are no more than conclusions; and (3) "where there are well-pleaded factual allegations, . . . assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." Burtch v. Millberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011). Courts must construe the allegations in a complaint "in the light most favorable to the plaintiff." Id. at 220.

When deciding a motion to dismiss, "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014).

III. DISCUSSION

Azurity contends that Bionpharma's antitrust claims should be dismissed for six separate reasons, each of which is addressed below.

A. Compulsory Counterclaims

Azurity first argues that Bionpharma's antitrust claims should be barred because they were compulsory counterclaims that Bionpharma should have asserted when the First Wave suits were filed.

A counterclaim is compulsory if it "bears a logical relationship" to the primary claim. Xerox Corp. v. SCM Corp., 576 F.2d 1057, 1059 (3d Cir. 1978). A logical relationship, in turn, depends on whether the two claims "involve many of the same factual issues, or the same factual and legal issues, or where they are offshoots of the same basic controversy between the parties." Id. Under this standard, Azurity argues that the First Wave suits were for patent infringement and that Bionpharma's antitrust claims in the present lawsuit include allegations that bear a logical relationship to the First Wave suits.

"Whether a Sherman Act antitrust claim is a compulsory counterclaim in a patent infringement action is a question of considerable debate." P & M Services, Inc. v. Gubb, No. 07-cv-12816, 2008 WL 4185903, at *3 (E.D. Mich. Sept. 8, 2008). The closest binding precedent on this issue is the Supreme Court's decision in Mercoid Corp. v. Mid-Continent Investment Co., 320 U.S. 661 (1944). There, with little discussion regarding the compulsory counterclaim test, the Supreme Court appeared to assume that an antitrust claim alleging that the patentee had attempted to expand its patent to cover an unpatented component of the invention by suing a user of such a component was not a compulsory counterclaim to the infringement suit. See id. at 671. In a clearer pronouncement, the Ninth Circuit has interpreted Mercoid as holding that a claim of "predatory patent litigation" is not a compulsory counterclaim to a claim of infringement. Hydranautics v. FilmTec Corp., 70 F.3d 533, 536-37 (9th Cir. 1995) ("Mercoid leaves open the possibility of raising antitrust claims . . . in a separate and subsequent action.").

The Second Circuit, by contrast, views Mercoid as an "exception" to the compulsory counterclaim rule that has been "subject to serious criticism" and has opined that Mercoid should be "limited to [its] facts." Critical-Vac Filtration Corp. v. Minuteman International, Inc., 233 F.3d 697, 701, 702 n.6 (2d Cir. 2000). However, for claims alleging patent misuse (as opposed to misconduct before the Patent and Trademark Office), the Second Circuit acknowledged that Mercoid is binding and thus permits such claims to be raised in a subsequent litigation. Id. at 704; see also Rohm & Haas Co. v. Brotech Corp., 770 F. Supp. 928, 932 (D. Del. 1991) (recognizing a similar distinction).

The Second and Ninth Circuits also agree that it is relevant that, when antitrust claims are brought as counterclaims in an infringement action, courts often bifurcate the antitrust claims. This common practice weighs against viewing the antitrust claims as compulsory counterclaims:

> If patent infringement claims are frequently bifurcated from antitrust counterclaims and tried separately under Rule 42(b), it would seem that the same underlying logic would apply equally to Rule 13(a). In other words, if judicial economy is promoted by severing two claims and trying them separately, it would seem inappropriate and illogical to regard either claim as a compulsory counterclaim to the other and require consolidation.

Critical-Vac, 233 F.3d at 703 (quoting Teague I. Donahey, Antitrust Counterclaims in Patent Infringement Litigation: Clarifying the Supreme Court's Enigmatic Mercoid Decision, 39 IDEA: J.L. & Tech. 225, 249-50 (1999)); Hydranautics, 70 F.3d at 536.

An additional reason for not treating antitrust counterclaims as compulsory is that they resemble traditional malicious prosecution claims, which are generally not considered compulsory. Hydranautics, 70 F.3d at 536-37; see also T.C.R. Realty, Inc. v. Cox, 372 A.2d 721, 728 (Pa. 1977). A malicious prosecution claim, like a sham litigation claim, "arises from the [allegedly wrongful] legal proceeding, not from the same transactions or occurrences from which [that proceeding]

arose." T.C.R. Realty, 372 A.2d at 728.

Also instructive is the accrual rule for antitrust damages. "[F]uture damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative or their amount and nature unprovable." Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 339 (1971). "In these instances, the cause of action for future damages, if they ever occur, will accrue only on the date they are suffered[.]" Id.

At this juncture, it is unnecessary for me to resolve the disagreement between Azurity and Bionpharma over whether Bionpharma's antitrust counterclaims actually accrued when the First Wave suits were filed. The possibility that antitrust claims might not accrue until sometime after Hatch-Waxman infringement litigation plays out suggests that they do not "bear[] a logical relationship" to that infringement suit. Xerox Corp., 576 F.2d at 1059. When Bionpharma filed its answer to the First Wave suits, there was no guarantee that the FDA would ever approve Bionpharma's ANDA. It was thus arguably unknown at the time whether the First Wave lawsuits would ever suppress competition, even if they were brought in bad faith. Cf. AstraZeneca AB v. Glenmark Generics, Ltd., No. 14-cv-665, 2014 WL 5366050, at *1 n.1 (D. Del. Oct. 9, 2014) (finding no antitrust claim where generic was unable to enter the market). And, if Azurity had prevailed in the First or Second Wave suits, Bionpharma could not allege it suffered an antitrust injury because Azurity would have lawfully kept Bionpharma off the market. It would not serve "fairness and considerations of convenience and of economy" to require Bionpharma to plead, speculatively, upon being sued in the First Wave, that it would someday have a viable, noninfringing product. Xerox Corp., 576 F.2d at 1059.

Azurity relies on U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592 (Fed. Cir. 1995), for the proposition that "the place to challenge litigation as sham is in the asserted sham litigation,"

but Philips involved highly unusual facts that are distinguishable from the case before me. In Philips, the antitrust claimant (Izumi) was a defendant in two simultaneous infringement suits in two different courts. See id. at 593. In the first suit, a codefendant raised antitrust counterclaims, which were tried together with the patent claims at Izumi's insistence. Id. When Izumi attempted to assert similar antitrust counterclaims in the second lawsuit, the court denied that request but invited Izumi to assert those claims in the first lawsuit. Id. The Federal Circuit affirmed the refusal to let Izumi litigate its antitrust counterclaims in the second lawsuit, reasoning that because Izumi had successfully argued in the first lawsuit that the antitrust and infringement claims must be tried together, it was judicially estopped from splitting those claims in the second lawsuit. Id. at 596-97. In short, Philips dealt with parallel, simultaneous lawsuits and judicial estoppel. That case is thus inapplicable to the situation before me, and, moreover, the Federal Circuit expressly disavowed holding that a sham litigation claim was " 'compulsory' in the technical definition of this term." Id. at 595.

Given all of the above, I find the Ninth's Circuit's reasoning in Hydranautics persuasive, and conclude that in viewing the present allegations as true, Bionpharma's antitrust claims were not compulsory counterclaims in the First Wave suits.

B. Antitrust Injury

Azurity next argues that Bionpharma cannot show antitrust injury because Azurity's lawsuits failed to keep Bionpharma's generic product off the market. In Azurity's view, even if those lawsuits harmed Bionpharma by forcing Bionpharma to incur litigation costs, the antitrust laws only protect competition, not individual competitors. See Atlantic Richfield Co. v. USA Petroleum Co. 495 U.S. 328, 344 (1990). Therefore, Azurity reasons, Bionpharma cannot show that there

was harm to competition in the enalapril liquid market, and Bionpharma's antitrust claims should be dismissed.

The Federal Circuit addressed this situation in TransWeb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295 (Fed. Cir. 2016). In that patent infringement lawsuit, the alleged infringer brought an antitrust counterclaim alleging that the patent was fraudulently obtained (a so-called "Walker Process claim"). Id. at 1306. The infringement suit was unsuccessful but the antitrust claim succeeded, with the district court awarding attorneys' fees as antitrust damages. Id. In affirming the damages award, the Federal Circuit held that those attorneys' fees constituted "an antitrust injury" even though "[the patentee] fail[ed] to prevail in [its] lawsuit" and thus failed to keep the accused product off the market. Id. at 1308-12. TransWeb therefore directly addressed and rejected the argument Azurity makes here.

Azurity relies on Otsuka Pharmaceutical Co. v. Torrent Pharmaceuticals Limited, 187 F. Supp. 3d 483 (D.N.J. 2016), which distinguished TransWeb on the ground that "TransWeb, LLC addressed itself to the issue of recoverable antitrust damages" as opposed to whether there had been an antitrust injury at all. Otsuka, 187 F. Supp. 3d at 486 n.6 (emphasis in original). Aside from the fact that I am not bound by Otsuka, TransWeb did in fact hold that attorneys' fees were an "an antitrust injury." 812 F.3d at 1299.

C. Causation

Azurity also challenges Bionpharma's allegation that the First Wave suits delayed the entry of Bionpharma's generic enalapril liquid to market. Specifically, Bionpharma alleges that the automatic 30-month stay that applies in Hatch-Waxman litigation, and which remained in effect from the First Wave suits until April 30, 2021, delayed Bionpharma's ability to market its enalapril

liquid until August 17, 2021. (Counterclaims ¶¶ 193, 201.) Azurity responds that because there was a three-and-a-half-month gap between the expiration of the 30-month stay and Bionpharma's market entry, it cannot be inferred that Bionpharma could have entered the market sooner but for the stay.

Bionpharma's allegation that the 30-month stay delayed its entry must be accepted as true at the pleadings stage. Iqbal, 556 U.S. at 678. It is also plausible under the Twombly standard that a legal prohibition on the FDA granting final approval would delay launch of the product. Azurity's counterargument implicates a factual dispute that is not appropriate for resolution at this stage of the litigation.

Azurity also asserts that its lawsuits could not have harmed competition because it had an alternative way to keep Bionpharma's generic enalapril liquid off the market. Namely, Azurity's parent NovaQuest could have simply asked Azurity's corporate sister CoreRx to stop manufacturing the product for Bionpharma. (See Azurity's Brief at 18 ("[Bionpharma's] but-for world is the same as the real world[.]").) This is an unusual argument that appears to suggest that because Azurity could have suppressed competition some other way, it should not be held liable for the method it in fact chose. Unsurprisingly, Azurity cites no authority for this argument.

D. Noerr-Pennington Part 1: Objective Baselessness

Azurity's next argument for dismissal is that its lawsuits were protected under the Noerr-Pennington doctrine. "The filing of a lawsuit carries significant constitutional protections, implicating the First Amendment right to petition the government for redress of grievances, and the right of access to courts." Hoeber v. Local 30, United Slate, Tile & Composition Roofers, Damp & Waterproof Workers Ass'n, 939 F.2d 118, 126 (3d Cir. 1991). Under the Noerr-Pennington doc-

trine, such lawsuits "are generally immune from antitrust liability" unless certain exceptions are met. FTC v. AbbVie Inc., 976 F.3d 327, 359-60 (3d Cir. 2020). To overcome Noerr-Pennington immunity, an antitrust plaintiff must show that: (1) "the lawsuit [was] objectively baseless in the sense that no reasonable litigant could [have] realistically expect[ed] success on the merits"; and (2) "the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." Id. at 360.

Azurity contends that certain events that occurred in the First Wave show that those lawsuits were not objectively baseless. According to Azurity, those events are: (1) Judge Stark denying leave to file a motion for judgment on the pleadings; (2) Judge Stark hearing five days of testimony and authoring a 70-page opinion; (3) Bionpharma not seeking leave to file a motion for summary judgment; and (4) the Federal Circuit granting oral argument in the appeal from the First Wave suits. Whether these events show that Azurity's lawsuits were not objectively baseless is a factual question that cannot be resolved on a motion to dismiss.

Azurity also takes issue with the substance of Bionpharma's reasons for calling Azurity's seven lawsuits objectively baseless. Bionpharma alleges that Azurity's lawsuits were objectively baseless for numerous reasons, involving issues of infringement, validity, licensing, and jurisdiction. At this stage of the litigation, it is not necessary to analyze all of Bionpharma's allegations that Azurity's lawsuits were objectively baseless. Instead, because two of these allegations involve all seven lawsuits, for purposes of a motion to dismiss analysis it is sufficient to examine two of these allegations, which claim: (1) that the First and Second Wave suits were objectively baseless because Bionpharma's ANDA does not contain an equivalent to a citrate buffer; and (2) that the Third Wave and CoreRx suits were objectively baseless because the Third Wave patents'

specification does not describe liquids without buffers.

Before analyzing the substance of these allegations, it is necessary to make two preliminary points. First, while Judge Stark entered judgment in Bionpharma's favor as to some of Bionpharma's allegations, the mere fact that Azurity lost on these grounds does not mean that its position was objectively baseless from the start. Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc. (PRE), 508 U.S. 49, 60 n.5 (1993). Indeed, Azurity contends that the positions it took in the First Wave were colorable even if Judge Stark did not ultimately agree with them.

Second, although it is sometimes possible to decide whether a lawsuit was objectively baseless "as a matter of law," PRE, 508 U.S. at 63, not all of the facts underlying Bionpharma's antitrust allegations are undisputed. For example, it is a factual question whether Azurity had a basis to believe that certain ingredients in Bionpharma's ANDA could act as a buffer. In addition, while legal issues underlying Bionpharma's allegations might be resolvable at the pleadings stage, Azurity's motion contains only a cursory analysis of those issues, which is inadequate for me to conclude, at this juncture, that Bionpharma's allegations necessarily fail as a matter of law.

With those points in mind, I consider whether two of Bionpharma's allegations plausibly give rise to an inference that the First Wave, Second Wave, Third Wave, and CoreRx suits were objectively baseless.

1. Lack of Claimed Buffer in Bionpharma's ANDA

The patents asserted in the First Wave suits claimed buffers made from citric acid and sodium citrate. As to some of those claims, the language was amended during the prosecution history to add sodium citrate. Bionpharma argued in the First Wave suits that the amendment

triggered amendment-based prosecution history estoppel—such that Azurity could not claim solutions lacking sodium citrate. Bionpharma alleges that Azurity's position that it could overcome this defense was objectively baseless, such that Noerr-Pennington immunity does not apply.

In its present motion, Azurity asserts it "believed the amendment was made for clarification purposes and was not a narrowing amendment," but Azurity does not explain why the pleadings compel the conclusion that this belief was objectively colorable. It therefore remains a factual dispute whether Azurity had an objective basis for alleging that Bionpharma's ANDA infringed the First Wave patents, and I thus decline to dismiss Bionpharma's counterclaims as to this ground.

2. Lack of Written Description Supporting Liquids Without Buffers

The Third Wave patents differ from the First Wave patents in that the Third Wave patents claim formulations that lack buffers. Bionpharma alleges that the specification does not support formulations without buffers and that, therefore, the Third Wave patents are invalid for lack of written description. And Bionpharma asserts that it was objectively baseless for Azurity to claim that it could overcome this invalidity defense.

Azurity responds only that there is a presumption that an issued patent is valid and does not address the substance of Bionpharma's argument. I therefore cannot conclude, at this stage, that Azurity necessarily had an objective basis to assert the Third Wave patents against Bionpharma's ANDA.

For these reasons, Bionpharma has plausibly alleged the first prong of the exception to Noerr-Pennington immunity by alleging that Azurity's seven lawsuits were objectively baseless. Whether these lawsuits were in fact objectively baseless remains an issue for factual development.

E. Noerr-Pennington Part 2: Subjective Motivation

Azurity next contends that Bionpharma has not adequately pled the subjective component necessary to overcome Noerr-Pennington immunity. "Under the subjective motivation prong, a plaintiff must show the defendant brought baseless claims in an attempt to thwart competition (i.e., in bad faith)." FTC v. AbbVie, 976 F.3d at 360 (quotation marks omitted).

Bionpharma alleges several facts that it argues raise a plausible inference that Azurity intended to thwart competition:

First, Bionpharma alleges that Azurity turned down an opportunity to view Bionpharma's ANDA before filing the First Wave suits, suggesting that Azurity was disinterested in learning whether those suits were viable. See FTC v. AbbVie, 976 F.3d at 360 (a relevant factor is "whether the defendant was indifferent to the outcome on the merits of the suit" (alterations and quotation marks omitted)).

Second, Bionpharma points to the number of lawsuits—seven across three courts—and reasons that Azurity's nine patents on enalapril liquids enabled it to file new lawsuits as patents were issued. Bionpharma notes that the FDA has raised concerns that "the practice of filing 'continuation' patent applications . . . can allow companies to create 'patent thickets' by obtaining multiple patents on different aspects of the same product within a patent application," a practice which "increases litigation burdens and potentially delays the approval of generics . . . ." See September 10, 2021 Letter from Acting Commissioner Woodcock to the USPTO at 3, https://www.fda.gov/media/152086/download.

Third, Bionpharma alleges that because Azurity's lawsuits were baseless, an experienced litigant like Azurity would only bring them for a reason other than eventual success on the merits. See FTC v. AbbVie, 976 F.3d at 369 ("Evidence that a defendant knew its claims were meritless

may help a plaintiff to show a defendant was indifferent to the outcome on the merits of the suit and decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." (alterations and quotation marks omitted)).

Azurity responds to these allegations primarily by identifying contrary facts that it claims show a proper motivation for filing suit, such as that it spent time and resources litigating an appeal. Azurity also notes that the Hatch-Waxman Act gives a patentholder a short window to decide whether to file a lawsuit and states that it had a legitimate, unspecified reason to turn down Bionpharma's offer of confidential access. Whether these countervailing reasons will ultimately demonstrate that Azurity's lawsuits were brought in good faith is a factual question that cannot be resolved at this stage.

Azurity also objects to consideration of the number of lawsuits it filed, citing authority that an accusation of "serial petitioning" is inapplicable to Hatch-Waxman lawsuits because Congressional policy favors prompt resolution of property rights. See In re Wellbutrin XL Antitrust Litigation, 868 F.3d 132, 157-58 (3d Cir. 2017). But Azurity's cited authority is addressed to the situation where a brand manufacturer sues multiple different generic competitors, as Hatch-Waxman requires it to. See id.; Kaiser Foundation Health Plan, Inc. v. Abbott Labs., Inc., 552 F.3d 1033, 1047 (9th Cir. 2009) (finding repeated Hatch-Waxman lawsuits were not sham litigations because "the volume of [the patentee's] suits was dependent on the number of generic companies attempting to enter the . . . marketplace, a matter over which [the patentee] had no control"). Here, Azurity filed seven lawsuits over the same generic product and has not pointed to anything in the Hatch-Waxman Act that endorses such a practice.

For these reasons, Bionpharma has plausibly alleged that Azurity filed its seven lawsuits to interfere with competition in enalapril liquids through means other than eventual success on the

merits. Whether that was Azurity's actual motivation remains an issue for factual development.

F. Intent to Monopolize

Lastly, and somewhat cursorily, Azurity asserts that Bionpharma "fails to sufficiently allege a specific intent to monopolize." Azurity also states that Bionpharma's "allegations amount to, at most, an intent to exclude infringing products, which is insufficient."

Largely for the reasons set out in the previous section, Bionpharma's allegations raise a plausible inference that Azurity "ha[d] the specific intent to . . . monopolize the [enalapril liquid] Market." (Counterclaims ¶ 257.) Whether Bionpharma's product was infringing such that Azurity could legitimately exclude it is a subject of ongoing dispute that cannot be resolved at this time.

IV. CONCLUSION

For the reasons set out above, Azurity's motion to dismiss will be denied.

An appropriate order follows.