UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY D/B/A/ BLUE CROSS AND BLUE SHIELD OF LOUISIANA, AND HMO LOUISIANA, INC., ET AL. ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, **Plaintiffs,** **v.** **JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and BTG INTERNATIONAL LIMITED,** **Defendants.**	Civ. No. 19-cv-14146 (KM) (ESK) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

To extend its exclusivity as the sole seller of profitable prostate cancer drug, Zytiga, Janssen Biotech ("Janssen"), along with BTG International Limited ("BTG"), obtained a follow-on combination therapy patent that was later invalidated. Now, Louisiana Health Service & Indemnity Company ("BCBSLA") brings this antitrust action, in which it seeks to represent a class of indirect purchasers of Zytiga who allegedly overpaid for the drug during the period in which Janssen's[1] infringement litigation delayed the entrance of generic versions of Zytiga into the market. Defendants move to dismiss the currently operative complaint. (DE 155.)[2] For the following reasons, defendants' motion to dismiss (DE 155) is **GRANTED**.

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[1] The defendants in this action were plaintiffs in the earlier patent infringement litigation. For convenience, I refer to them together as "Janssen."

[2] Certain citations to the record are abbreviated as follows:

DE = docket entry in this case

I. BACKGROUND

In 1997, BTG obtained a patent (U.S. Patent No. 5,604,213, the "'213 patent") on a therapeutic compound called abiraterone acetate. (SCCAC ¶ 3, 113.) BTG licensed this patent to Cougar Biotechnology in 2004, and Cougar was purchased by Janssen in 2009. (*Id.* ¶ 114.) Abiraterone acetate is the key ingredient in Janssen's drug Zytiga, which in 2011 was approved by the FDA as a treatment for prostate cancer. (*Id.* ¶ 127.) Zytiga was widely prescribed for prostate cancer and earned Janssen billions of dollars in sales revenue. (*Id.* ¶ 130.) The original '213 patent, however, was set to expire in 2016. (*Id.* ¶ 3, 151.) Anticipating generic competition and lower profits, Janssen sought to parlay its patent protection by (to simplify a bit) patenting a combined therapy. Its initial attempts to obtain a new patent on the combined use of abiraterone and a steroid, prednisone, were repeatedly rejected by the United States Patent and Trademark Office ("PTO") as obvious. (*Id.* ¶ 115–25, 131–148.) In 2013, however, Janssen did obtain a new patent for combined abiraterone acetate/prednisone therapy (United States Patent No. 8,822,438, the "'438 patent"), relying substantially on the argument that obviousness was rebutted by the prior commercial success of Zytiga. (*Id.* at ¶ 152–67.) Janssen, however, allegedly never disclosed to the PTO that Zytiga's commercial success was attributable to the '213 "blocking patent," dating back to 1997, which had blocked any other company from manufacturing and selling any drug that contained abiraterone acetate. (*Id.* at ¶ 166.)[3]

Infringement Action DE = Docket Entry in *BTG Int'l Ltd., et al., v. Amneal Pharmaceuticals LLC, et al.*, 15-cv-5909 (D.N.J.)

SCCAC= Second Consolidated Class Action Complaint (DE 147)

Mot. = Defendants' brief in support of their motion to dismiss (DE 155-1)

Opp. = Plaintiffs' brief in opposition to the motion to dismiss (DE 158)

Reply = Defendants' reply in support of motion to dismiss (DE 160)

[3] Janssen contests this (Opp. at 5), but at this stage I take all well-pleaded allegations as true. *Morrow v. Balaski*, 719 F.3d 160, 165 (3d Cir. 2013) (en banc).

In 2015, a number of generic companies filed Abbreviated New Drug Applications ("ANDAs") with the FDA, claiming that Janssen's new '438 patent was invalid and that they should be permitted to sell generic versions of Zytiga when the first, '213, patent expired in 2016. (*Id.* ¶ 168–69.) Janssen, exercising its rights under the Hatch-Waxman Act, then filed an action (the "infringement action", 15cv5909 (D.N.J.)), against the generic manufacturers, triggering a 30-month stay of the approval of the ANDAs. (*Id.* ¶ 170.)[4] The infringement action and its appeals lasted for more than four years. In that action, Janssen filed a complaint and two amended complaints, and was denied leave to file a third amended complaint. (Infringement Action DE 279.) The parties briefed numerous motions, including three motions in limine and a motion for summary judgment. (Infringement Action DE 364–66, 369, 387, 389, 408.) Oral argument was held on summary judgment. (Infringement Action DE 420.) The motion for summary judgment was administratively terminated, however, and an 8-day bench trial took place (Infringement Action DE 483, 522–31.) As it happened, both the Patent Trial and Appeal Board ("PTAB") and this Court ultimately determined that Janssen's second patent was invalid for obviousness. (SCCAC ¶ 203–35.)[5] Janssen made every effort to enjoin generic competition, but the Federal Circuit and the Supreme Court denied those attempts and generic competition began on November 21, 2018 (*Id.* ¶ 238–43.) In May 2019, the Federal Circuit upheld the decision of the PTAB, a ruling which required it also to dismiss the appeal from this Court. (*Id.* ¶¶ 247–50).[6]

By engaging in this extended litigation, Janssen allegedly delayed the entrance of generics onto the market. (*Id.* ¶ 251–53.) And as a result of that delay, indirect purchasers paid much more for Zytiga in the interim than they would have paid for a generic substitute. (*Id.* ¶ 11.) In this action, Plaintiffs

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[4] The suit was *BTG Int'l Ltd., et al., v. Amneal Pharmaceuticals LLC, et al.*, 15-cv-5909 (D.N.J.).

[5] *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352 (D.N.J. 2018).

[6] *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063 (Fed. Cir. 2019).

allege that by bringing "sham litigation," Janssen violated the Sherman Act, 15 U.S.C. § 2, as well as a number of state antitrust and consumer protection laws. They seek to represent a class of indirect purchasers of Zytiga.

BCBSLA initially filed this suit in the United States District Court for the Eastern District of Virginia on April 18, 2019. (DE 1.) On May 24, 2019, Janssen moved to change venue to this court. (DE 30.) On May 31, 2019, BCBSLA moved to consolidate this case and to appoint interim class counsel. (DE 35, 37.) On June 21, 2019, the Eastern District of Virginia transferred the case to this court, which granted the motion to consolidate and appoint interim co-lead class counsel. (DE 54.) On August 20, 2019, Self-Insured Schools of California, the plaintiff in a related case, moved to consolidate cases. (DE 92.)[7] This second motion to consolidate was granted on September 27, 2019. (DE 108.) On February 10, 2021, I granted BCBSLA's motion to appoint class counsel. (DE 146.)

On February 22, 2021, plaintiffs filed their Second Consolidated Class Action Complaint. (DE 147.) On April 6, 2021, Janssen moved to dismiss. (DE 155.) Plaintiffs filed a brief in opposition (DE 158) and Janssen filed a reply (DE 160). This motion is fully briefed and ripe for decision.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8(a) does not require that a pleading contain detailed factual allegations, but it must assert "more than labels and conclusions." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The allegations must raise a claimant's right to relief above a speculative level, so that a claim is "plausible on its face." *Id.* at 570. That standard is met when "factual content [] allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rule 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim. The defendant bears the burden to show that no claim has been stated. *Davis v. Wells Fargo*, 824 F.3d 333, 349 (3d Cir. 2016). I accept facts in

[7] *Self-Insured Schools of California v. Janssen Biotech, Inc.,* 19-cv-14291 (D.N.J).

the complaint as true and draw reasonable inferences in the plaintiffs' favor. *Morrow v. Balaski*, 719 F.3d 160, 165 (3d Cir. 2013) (en banc).

III. DISCUSSION

a. Standing

Plaintiffs bring 58 numbered claims, all essentially based on the allegation that Janssen engaged in "sham litigation." (SCCAC ¶ 287–823.)[8] Count 58 is a federal claim under the Sherman Act, 15 U.S.C. § 2. (*Id.* ¶ 803–23.). Counts 1–29 bring claims under the antitrust laws of a number of states, plus the District of Columbia and Puerto Rico. (*Id.* ¶ 287–488.) Counts 29–56 bring claims under many jurisdictions' consumer protection laws. (*Id.* ¶ 489–755.) Finally, count 57 asserts unjust enrichment claims under the laws of 41 jurisdictions. (*Id.* ¶ 756–801.) The named plaintiffs, however, allege that they purchased or were reimbursed for Zytiga in only 22 states. (*Id.* ¶ 20–24.) Janssen does not contest that plaintiffs have standing to bring their own federal claims, and may assert claims under the laws of states where they purchased or reimbursed insurance policy holders for Zytiga. Janssen argues, however, that plaintiffs lack standing to assert state-law claims under the laws of states where the named plaintiffs did not purchase Zytiga. (Mot. at 39–44.)

After first outlining the law of standing in putative class actions, I rule that plaintiffs' claims should not be dismissed on standing grounds.

Class actions, governed in federal court by Federal Rule of Civil Procedure 23, are a form of representative litigation. One or more class representatives litigate on behalf of absent class members and, if a class is certified, both the named plaintiffs and the absent class members will be bound by the court's decision.

A named class representative, like any federal-court plaintiff, must establish personal standing under the relevant constitutional standard. *See*

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[8] Unjust enrichment claims under the laws of 39 states, Puerto Rico, and Washington, D.C. are grouped under count 57. (SCCAC ¶ 130–46.)

Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).[9] Thus it is not enough that absent class members suffered injuries; rather, "the representative herself must have standing." William B. Rubenstein, 1 Newberg on Class Actions § 2:3 (5th ed.); *see also Simon v. E. Kentucky Welfare Rts. Org.*, 426 U.S. 26, 40 n.20 (1976). Here, there is no question that the plaintiffs properly alleged personal standing, in that they were themselves allegedly overcharged for Zytiga.

Next comes the murky issue of so-called "class standing," invoked by defendants here. Plaintiffs argue that their claims under the laws of states in which they did not purchase Zytiga should not be dismissed, because they have personal standing and there is no separate "class standing" requirement. (Opp. at 36–37 (quoting *In re Prudential Ins. Co. Am. Sales Prac. Litig. Agent Actions*, 148 F.3d 283, 306 (3d Cir. 1998).) It is true that once the class representative demonstrates that he or she possesses standing, for him or her "there remains no further separate class standing requirement in the constitutional sense." *Prudential Ins. Co.*, 148 F.3d at 306–07. Nor are absent class members required to prove that they independently have standing. Such a requirement would defeat the purpose of representative litigation. *See Parko v. Shell Oil Co.*, 739 F.3d 1083, 1084–85 (7th Cir. 2014). Rather, once the class representative has shown he or she has standing, "the issue [becomes] one of compliance with the provisions of Rule 23, not one of Article III standing." *Prudential Ins. Co.*, 148 F.3d at 307 (quoting *Goodman v. Lukens Steel Co.*, 777 F.2d 113, 122 (3d Cir.1985), *aff'd*, 482 U.S. 656 (1987)).[10]

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[9] Standing requires "(1) an injury-in-fact, which is an invasion of a legally protected interest that is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of; and (3) that it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007).

[10] A related problem that has spurred a great deal of debate, but is not relevant here, is the issue of class members who have not suffered an injury. For more on that debate, *see* 1 Newberg on Class Actions § 2.3; *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 461–62 (2016).

Janssen, however, is making a different point. Janssen argues that named plaintiffs—not absent class members—lack standing because in a suit with multiple claims "at least one named class representative must have standing with respect to each claim." 1 Newberg on Class Actions § 2.5; *Long v. SEPTA*, 903 F.3d 312, 323 (3d Cir. 2018) ("A plaintiff must demonstrate standing for each claim [he or she] seeks to press."). If, for example, no named plaintiff alleges that it purchased Zytiga in California, Janssen maintains that all California law counts must be dismissed. (Mot. at 40.) This argument, however, misunderstands the meaning of "claim" in this context and, if accepted, would undermine the ability of plaintiffs to bring nationwide class actions.[11]

The cases cited by Janssen concern different issues, and personal standing. In *Long v. SEPTA*, for example, the issue was the named plaintiff's individual standing to bring federal claims under the Fair Credit Reporting Act ("FCRA"). The Third Circuit held that the named plaintiff had standing to bring an FCRA claim related to SEPTA's failure to provide him and the absent class members with copies of their consumer reports. He did not have standing, however, to bring an FCRA claim related to SEPTA's failure to provide him and the absent class members with notice of their rights under the FCRA, because that was a "bare procedural violation, divorced from any concrete harm." *Long v. SEPTA*, 903 F.3d at 325 (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016), as revised (May 24, 2016)). In short, as to that second issue, no one had standing; it was not a matter of divergent statutory claims, or named plaintiffs vs. absent class members.

Having standing with respect to "each claim" relates to the facts underlying the claim of injury and whether they rise to the Constitutional standing threshold, not the label of each cause of action. One court has glossed

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[11] Janssen cites a number of cases holding that named plaintiffs cannot rely on injuries of absent class members to establish their own standing. (Mot. 39-41.) As explained above, however, these standing issues are conceptually distinct.

this requirement as follows: "So long as the class representatives have constitutional standing to raise a particular *issue* before the court, no further constitutional standing requirements exist for the remainder of the class." *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 246 (D. Del. 2002), aff'd, 391 F.3d 516 (3d Cir. 2004) (emphasis added). Here, there is, factually, one issue and thus one claim: Janssen engaged in sham litigation to delay generic competition and overcharge for Zytiga.[12] Plaintiffs unquestionably have standing to bring that claim and the standing inquiry, at this stage, stops there.

To illustrate this principle, imagine a product defect class action involving two allegedly defective products (products A and B), but where the sole named plaintiff has only purchased product A. The named plaintiff then, would not have standing to bring claims regarding product B, because her alleged injury relates only to product A. Thus, all claims related to product B would be dismissed. She could, however, bring a nationwide class action that makes claims regarding product A's defects under the laws of any state where absent class members purchased product A. Because she was allegedly injured by product A, the question is no longer one of standing. Rather the question is whether it is appropriate for the named plaintiff to represent a nationwide class, despite the differences in state law. In this case, the class comprises indirect purchasers of Zytiga under state antitrust and consumer protection laws. Once plaintiffs are found to have standing, the issue becomes a Rule 23 issue. "As long as the named plaintiffs have standing to sue the named defendants, any concern about whether it is proper for a class to include out-of-state, nonparty class members with claims subject to different state laws is a question of predominance under Rule 23(b)(3)." *Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 93 (2d Cir. 2018).[13]

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[12] The fact that there is one claim means that the whole case rises and falls together, as discussed below.

[13] Although *Langan* is the clearest statement of this rule, many other courts have reached the same conclusion. *See, e.g.*, *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d

What may really be at issue here, as plaintiffs acknowledge, is the *timing* of the standing inquiry. (Reply at 17–18.) In *Amchem Products, Inc. v. Windsor*, the Supreme Court held that it may be appropriate to handle class certification issues in advance of standing issues when certification is "logically antecedent to the existence of any Article III issues." 521 U.S. 591, 612 (1997). The named plaintiffs, as noted, surely cannot be dismissed from the case for lack of standing, because they do possess standing in their own right. Now it is true that the named plaintiffs may *also* end up representing absent plaintiffs from other states—*if* the class is certified in the manner requested.[14] At the motion to dismiss stage, however, such standing issues are speculative and contingent. It might be found, for example, that common issues do not predominate.[15] Thus, it is appropriate to defer standing issues until class certification and consider them as part of the broader Rule 23 analysis. *See In*

516, 529 (3d Cir. 2004) (upholding the certification of a nation-wide antitrust class that brought claims under the laws of all fifty states and finding that the issues of different state laws was one of predominance); *Morrison v. YTB Int'l, Inc.*, 649 F.3d 533, 536 (7th Cir. 2011) (stating that whether plaintiff could represent a class of out of state plaintiffs based on different state laws "has nothing to do with *standing,* though it may affect whether a class should be certified") (emphasis in original); *Ramirez v. STi Prepaid LLC*, 644 F. Supp. 2d 496, 505 (D.N.J. 2009) (stating that once plaintiff has established individual standing, "the fact that the named Plaintiffs may not have individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants' calling cards is immaterial. The issue Defendants raise is one of predominance" not of standing.); *In re Grand Theft Auto Video Game Consumer Litig. (No. II)*, 2006 WL 3039993, at *3 (S.D.N.Y. Oct. 25, 2006) (stating that where named plaintiffs have established individual standing, the relevant question is not "whether the Named Plaintiffs have standing to sue Defendants… but whether their injuries are sufficiently similar to those of the purported Class to justify the prosecution of a nationwide class action" and thus should be dealt with at the class certification stage).

[14] And if it is later revealed, for example, that no class *member* purchased or was reimbursed for Zytiga in Wyoming, the Wyoming law counts will be dismissed.

[15] Or, for that matter, that a class action is not a superior means of adjudicating the conflict, that plaintiffs' claims are not typical, that plaintiffs are not appropriate representatives, or that the action does not meet any of the other Rule 23 requirements.

re Remicade Antitrust Litig., 345 F. Supp. 3d 566, 585 (E.D. Pa. 2018); *In re FieldTurf Artificial Turf Mktg. & Sales Pracs. Litig.*, 2018 WL 4188459, at *8 (D.N.J. Aug. 31, 2018); *In re Grand Theft Auto Video Game Consumer Litig. (No. II)*, 2006 WL 3039993, at *2 (S.D.N.Y. Oct. 25, 2006) (stating that it is better "to treat class certification as logically antecedent to standing where class certification is the source of the potential standing problems"); *Langan*, 897 F.3d at 96.

Because plaintiffs themselves have standing, which is enough to justify the action's going forward, I deny the motion to dismiss plaintiffs' claims on standing grounds, without prejudice to consideration of how these and related issues may be altered in light of the class certification process.

b. *Illinois Brick* and Indirect Purchasers

Plaintiffs' Sherman Act claim must be dismissed because it runs afoul of the *Illinois Brick* direct purchaser rule. *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). That is a judge-made, bright-line rule that limits the class of potential plaintiffs in an antitrust action.

In *Illinois Brick*, the Supreme Court limited antitrust actions "to suits brought by parties that are the direct purchasers of the product." *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011) (citing *Illinois Brick*, 431 U.S. 720)). The Supreme Court reasoned that allowing indirect purchaser suits would expose defendants to the risk of multiple liability and raise intractable questions as to how much of an overcharge had been passed down the distribution chain. More generally, the Court made a policy determination that antitrust laws would be more effectively enforced by direct purchasers. *Illinois Brick*, 431 U.S. 730–34.[16] In the aftermath of *Illinois Brick*, however, many

[16] The *Illinois Brick* direct purchaser rule has been interpreted as a standing doctrine. *See McCarthy v. Recordex Service, Inc.*, 80 F.3d 842, 847–48 (3d Cir. 1996) ("[T]he Supreme Court articulated the so-called 'direct purchaser' rule, an antitrust standing doctrine that barred downstream indirect purchasers from bringing an antitrust claim.") The short of it is that indirect purchasers cannot maintain an action under the Sherman Act unless they fall into one of the exceptions to *Illinois Brick*.

states amended their own antitrust laws to allow indirect purchaser suits. *See, e.g.*, Cal. Bus. & Prof. Code § 16750(a); Haw. Rev. Stat. § 480-3.

In a footnote to *Illinois Brick*, the Supreme Court acknowledged an exception to the direct purchaser rule, which applies "where the direct purchaser is owned or controlled by its customer." 431 U.S. at 736 n.16. The logic of this exception, known as the "control exception," is that if the initial sale is from a parent to a subsidiary, and then the subsidiary sells to the plaintiff, the plaintiff is, in essence, a direct purchaser. *Jewish Hosp. Ass'n of Louisville, Ky. v. Stewart Mech. Enters.*, 628 F.2d 971, 975 (6th Cir. 1980) (stating that the exception applies when "there effectively has been only one sale"). The Third Circuit has applied this exception only when the initial seller actually owned the initial purchaser. *Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 371 (3d Cir. 2005). Other circuits have found the exception to apply outside of the parent/subsidiary context when there is a relationship of "fundamental economic or other unity" between the seller and the initial purchaser. *Jewish Hosp. Ass'n*, 628 F.2d at 975; *see also Fisher v. Wattles*, 639 F. Supp. 7, 9 (M.D. Pa. 1985) (to fall within the control exception, plaintiffs must show "such significant control" that the two companies are "virtually the same entity"). Examples of such unity include "interlocking directorates, minority stock ownership, loan agreements that subject the wholesalers to the manufacturers' operating control, [or] trust agreements." *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 605 (7th Cir. 1997); *see also In re G-Fees Antitrust Litig.*, 584 F. Supp. 2d 26, 33 (D.D.C. 2008). One court in this district has gone so far as to extend the rationale of the control exception to an agency relationship. *In re Mercedes-Benz Anti-Trust Litig.*, 157 F. Supp. 2d 355, 366 (D.N.J. 2001). Still, the control exception, though well-established, remains narrow and is not generously construed. *Sun Microsystems Inc. v. Hynix Semiconductor Inc.*, 608 F. Supp. 2d 1166, 1180 (N.D. Cal. 2009) (observing "there are few authoritative cases that clearly define the legal showing required to justify application of the control exception"); *In re*

G-Fees, 584 F. Supp. 2d at 33 (stating that the "control exception is construed narrowly"); *see also* 6 Newberg on Class Actions § 20:8.

Here, plaintiffs claim that this case falls within the control exception by virtue of Janssen's close relationship with the pharmacies that purchased Zytiga from Janssen and then resold it to the members of the putative indirect-purchaser class here.[17] (Opp. at 23–27.) Plaintiffs allege that these were "specialty" pharmacies whose economic interests aligned with Janssen's to such a degree that they were Janssen's "agents," were controlled by Janssen, and would have no ability or incentive to assert antitrust claims against Janssen on their own account. (*Id.* at 25.) The pharmacies at issue included CVS/Caremark, and Alliance/Walgreens. (SCCAC ¶ 822.)

This argument falls short. Plaintiffs do not sufficiently allege that Janssen controlled the specialty pharmacies to such a degree that there was in essence only one sale, *i.e.*, the sale from the pharmacies to their customers. Aligned incentives are not enough. The exception, only grudgingly extended, applies only when the original seller had a degree of control over a buyer analogous to that of a parent corporation over a subsidiary. Plaintiffs do not, and perhaps cannot, allege that Janssen and the pharmacies functioned as an economic unit. They do not allege that the business relationship between Janssen and, for example, CVS/Caremark is anything akin to a parent/subsidiary relationship. Nor have they alleged that these entities were so intertwined that a transaction between them should not count as a true purchase/sale for purposes of *Illinois Brick*. Absent plausible allegations of

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[17] Plaintiffs analogize to *Albers v. Mercedes-Benz USA, LLC*, 2020 WL 1466359 (D.N.J. Mar. 25, 2020) in an attempt to fit their claim into the control exception. In *Albers*, I declined to apply the analogous RICO direct purchaser rule to dismiss claims against Robert Bosch GmbH by purchasers of Mercedes cars with Bosch-made engines. I determined, however, that the close relationship between Mercedes and Bosch in creating the automobiles, as well as Bosch's substantial control over the engines, meant that plaintiffs established a "sufficiently direct relationship" between Bosch and their RICO injury. *Albers*, 2020 WL 1466359 at *7.

such control, plaintiffs remain indirect purchasers, and they lack the capacity to bring claims under the Sherman Act.

Plaintiffs also argue that the control exception applies because the relationship between Janssen and the pharmacies was that of principal and agent. Even assuming *arguendo* that an agency relationship would invoke the exception, *see supra*, the complaint does not allege the key requisites of an agency relationship: that "the agent shall act on the principal's behalf and subject to the principal's control". Restatement (Third) Of Agency § 1.01 (2006).[18] Plaintiffs allege only that the business relationship between Janssen and the pharmacies was profitable and that the pharmacies thus "will not bite the hand that feeds them."[19] (Opp. at 26.) A mutually profitable business relationship is a far cry from the "fundamental economic … unity" required for plaintiffs to fall into this narrow exception to *Illinois Brick*'s direct purchaser rule. *Jewish Hosp. Ass'n*, 628 F.2d at 975.

All that remains is plaintiffs' assertion that Janssen controlled the price at which Zytiga was sold by the pharmacies. (Opp. at 26; SCCAC ¶ 817–18.) Although plaintiffs specifically disclaim that their control argument is based on price-setting, I briefly address the issue. (*Id.* at 27.) Both the Supreme Court and the Third Circuit have rejected price-setting as the relevant criterion for determining whether the *Illinois Brick* direct purchaser rule applies. What matters is whose hands the products pass through on the way to the consumer. Only the first pair of hands are deemed to be those of a direct

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[18] Plaintiffs do allege generally that Janssen "controlled" the pharmacies. This language is conclusory in that it is not backed by facts sufficient to establish "control" within the specialized meaning of the *Illinois Brick* exception. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to survive a motion to dismiss. *Iqbal*, 556 U.S. at 678. (Opp. at 25–26.)

[19] As Janssen points out, this argument is undermined by the fact that one of the specialty pharmacies, KPH Healthcare Services, Inc., has indeed sued Janssen for antitrust violations related to Zytiga. (Mot. at 31 n.9.) KPH, albeit as the assignee of McKesson Corporation, brought a direct purchaser antitrust case against Janssen. *KPH Healthcare Services, Inc. v. Janssen Biotech, Inc.*, 2021 WL 4739601, at *2 (D.N.J. Oct. 12, 2021). (Mot. at 34.)

purchaser. *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1522 (2019); *In re Hypodermic Prod. Antitrust Litig.*, 484 F. App'x 669, 675 (3d Cir. 2012) (citing *Warren Gen. Hosp.*, 643 F.3d at 88).

Because plaintiffs do not allege that Janssen exercised such a degree of control over the pharmacies that there was an economic unity between them, the plaintiffs' Sherman Act claim must be dismissed under the *Illinois Brick* direct purchaser rule.

c. *Noerr-Pennington Doctrine*

Setting aside the *Illinois Brick* issue, defendants argue in the alternative that the *Noerr-Pennington* doctrine, rooted in the First Amendment, insulates Janssen's litigative efforts from antitrust scrutiny.

The *Noerr-Pennington* doctrine is a Constitutional defense to antitrust liability. *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999). Generally, a party that exercises its First Amendment right to petition the government for redress is shielded from antitrust liability based on such petitioning. *Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). That immunity extends to persons who petition all types of government entities, including courts. *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) ("The right of access to the courts is indeed but one aspect of the right of petition.") A court may decide the applicability of the *Noerr–Pennington* doctrine on a motion to dismiss under Fed. R. Civ. P. 12(b)(6) in the absence of factual issues. *Indivior Inc. v. Dr. Reddy's Lab'ys S.A.*, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020) (citing *Trustees of Univ. of Pa. v. St. Jude Children's Res. Hosp.*, 940 F. Supp. 2d 233, 242–43 (E.D. Pa. 2013)); *see also Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 63 (1993) ("*PRE*") ("Where, as here, there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause as a matter of law.")

So a company does not violate the Sherman Act if, for example, it exercises its First Amendment right to lobby an administrative agency to publish a rule that will injure a competing company. *See PRE*, 508 U.S. at 57–58 ("evidence of anticompetitive intent or purpose alone cannot transform otherwise legitimate activity into a sham"). In the Hatch-Waxman context, the doctrine means that antitrust liability will usually not attach to a patentee who sues generic manufacturers after receiving a Paragraph IV notice letter and thereby obtains the benefit of the automatic thirty-month stay on generic competition. 21 U.S.C. § 355 (j)(5)(iii). That is so even if the patentee harbors the anticompetitive motive to delay generic competition.

But *Noerr-Pennington* immunity, as applied to litigation, does have a limit. It does not apply to a lawsuit so lacking in merit that it is a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. Plaintiffs argue that Janssen's 2015 patent infringement action against generic manufacturers was such a "sham lawsuit." (SCCAC ¶ 823; Opp. at 10–23; *BTG Int'l Ltd., et al., v. Amneal Pharmaceuticals LLC, et al.*, 15-cv-5909 (D.N.J.).) To be considered sham litigation, a lawsuit must be both objectively and subjectively baseless. *PRE*, 508 U.S. at 60–61. "Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." *Id.* at 60. Because I find that the litigation was not objectively baseless, I do not examine Janssen's subjective motivation for filing suit.

The Supreme Court has held that a lawsuit is objectively baseless only if "no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized… and an antitrust claim premised on the sham exception must fail." *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. The Court went on to clarify that "probable cause," as used here, is not the concept familiar from

criminal law: "Probable cause to institute civil proceedings requires no more than a reasonable belief that there is a *chance* that a claim may be held valid upon adjudication.... [T]he existence of probable cause is an absolute defense." *Id.* at 62–63 (emphasis added); *see also Cheminor Drugs*, 168 F.3d at 122. If the plaintiff reasonably believes that there is a chance it could prevail in court, its bringing of a lawsuit is immunized under the *Noerr-Pennington* doctrine.

It is rightly difficult to prove that a lawsuit is a mere sham. The hurdle is higher still in ANDA cases, because the Hatch-Waxman Act deems it an act of infringement to submit an ANDA for a drug covered by a duly issued patent. "Since the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 149 (3d Cir. 2017).[20] In addition, the Third Circuit has recently stated that "we must not penalize a brand-name manufacturer whose litigiousness was a product of Hatch-Waxman" because "[d]oing so would punish behavior that Congress sought to encourage." *Fed. Trade Comm'n v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020), *cert. denied*, 141 S. Ct. 2838 (2021) (quoting *Wellbutrin*, 868 F.3d. at 158) (cleaned up).

To clear this doctrinal hurdle, plaintiffs argue that Janssen knew that its patent was invalid and had been granted only because the '213 blocking patent had not been revealed to the PTO. It follows, they say, that any reasonable litigant in Janssen's position would have known that it had absolutely no chance to prevail in its infringement action. (Opp. at 12–13.)[21] In plaintiffs'

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[20] In addition, the Third Circuit has stated that the serial petitioning exception to *Noerr-Pennington*, which derives from *California Motor*, 404 U.S. 508, does not apply in the Hatch-Waxman context. *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 361 (3d Cir. 2020), *cert. denied,* 141 S. Ct. 2838 (2021).

[21] Here the plaintiffs are walking a tightrope. The patent did issue, and they specifically disclaim a *Walker Process* theory that Janssen committed fraud on the

telling, Janssen knew that the second, '438, patent rested on an unstable foundation and was certain to be invalidated as soon as it faced an adversarial process. Yet Janssen filed suit anyway, unconcerned with the outcome, solely to obtain the benefit of the thirty-month stay. (*Id.* at 11–12.)

There is no straightforward test or bright line rule to determine whether a losing lawsuit was objectively baseless. (A winning lawsuit, of course, is not a sham.) The Supreme Court has warned against the "'understandable temptation to engage in *post hoc* reasoning by concluding' that an ultimately unsuccessful 'action must have been unreasonable or without foundation.'" *PRE*, 508 U.S. at 61 n.5 (quoting *Christiansburg Garment Co. v. EEOC*, 434 U.S. 412, 421–422 (1978)). There are numerous indicia that I can look at to determine whether a lawsuit was a sham, including my personal experience presiding over the first case and its bench trial. *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003).

I find that Janssen's infringement action, though unsuccessful, was not objectively baseless. Just to set up the issues required a 30-page *Markman* opinion construing the term "treatment." The case was a triable one, in my view, and was hard fought by both parties. After an eight-day bench trial, I found the patent invalid in a 70-page opinion setting forth findings of fact and conclusions of law. The obviousness issue required close analysis of multiple factors. One strand of that argument, commercial success, was undermined by the effect of the blocking patent. Although I wrote that "there can be no dispute that ZYTIGA® has yielded billions of dollars in sales," I recognized that the existence of the blocking patent "would have discouraged entry at the very time when the obviousness of combination therapy was manifesting itself." *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 386, 387 (D.N.J. 2018). Although Janssen claimed that it attempted to license the patent, I found that

PTO. (Opp. at 11.) *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

those efforts were "desultory," and further found that "the sales of ZYTIGA may not be wholly attributable to the patented combination therapy." *Id.* at 387.

On another strand, Janssen put forward a substantial if ultimately unavailing argument that the patent was not obvious from prior art. After analyzing the arguments and published research, I found that prior art had identified abiraterone as a cancer treatment and that it was superior to a similar compound ketoconazole. *Id.* at 384. I also analyzed a paper that, though flawed, found that prednisone was also an anti-cancer agent that reduced PSA levels. *Id.* I thus found that, based on the prior art and even considering potential side effects, there was "more than sufficient motivation for a [person of ordinary skill in the art] to combine abiraterone with prednisone." *Id.* at 385. In addition, I found that the professional-approval factor weighed in Janssen's favor. *Id.* at 389. Overall, Janssen presented a plausible case, if not a winning one. I did not doubt then and do not doubt now that it had probable cause to bring the case and a real, if not strong, chance of prevailing.[22]

Plaintiffs discuss a recent case in which the Third Circuit upheld a determination that a patent infringement suit was objectively baseless. (Opp. at 8, 13 (citing *AbbVie*, 976 F.3d at 360, 370).) If anything, however, the differences between that case and this one confirm that Janssen's infringement action was not objectively baseless. In *AbbVie*, the Third Circuit upheld the district court's finding that a lawsuit was objectively baseless because of prosecution history estoppel. After its first attempt to obtain a patent was denied, AbbVie amended its patent claim to include only one "penetration enhancer" chemical rather than the 24 it had included the first time. *AbbVie*, 976 F.3d at 366. The alleged infringer used a penetration enhancer chemical

[22] Plaintiffs cite a study showing that those challenging pharmaceutical patents under Hatch-Waxman prevail 76% of the time. (Opp. at 12.) Of course, success in a patent lawsuit is not a probabilistic event, like repeated tosses of a coin; it depends on the merits of the individual action. But even indulging the statistical approach, if Janssen reasonably believed it had a 24% chance of prevailing in the lawsuit, it could not have been a sham.

that was included among the original 24 chemicals, but which AbbVie had specifically *removed* from its second patent application. The alleged infringer pointed out in its Paragraph IV notice that it had used one of the penetration enhancers that was dropped from the second patent application, and that the prosecution history estopped AbbVie from asserting infringement based on that no-longer-claimed chemical.[23] *Id.* Thus, the court found, any reasonable litigant in AbbVie's position should have realized that it had literally no chance of prevailing in its infringement suit. *Id.* at 366–68. Here, there is no such clear-cut reason that Janssen should have been certain that its lawsuit would fail. Plaintiffs claim that with the blocking patent revealed, Janssen's patent would automatically have been invalidated for obviousness, but, as stated above, I find that the non-obviousness argument was plausible and not frivolous.

I find that Janssen had probable cause to bring its patent infringement action and that it was therefore not objectively baseless. Because that infringement action was not objectively baseless, the *Noerr-Pennington* doctrine immunizes Janssen from antitrust liability based on that action. Plaintiffs' Sherman Act claim based on "sham litigation" must be dismissed for this reason.

Dismissing the Sherman Act claim still leaves plaintiffs with 57 numbered state law counts. These, too, must be dismissed under the *Noerr-Pennington* doctrine. Plaintiffs allege no anti-competitive activity other than the infringement litigation, which I have determined was not a sham litigation. Their state law antitrust, consumer protection, and unjust enrichment claims rest on the same basis as their federal claim—and it is the merit, or not, of the prior federal infringement claim, not particulars of the state law claims now asserted, that controls the *Noerr-Pennington* issue. Because the *Noerr-Pennington* doctrine is a Constitutional doctrine based on the First Amendment

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[23] On the well-established law of prosecution history estoppel see *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366–67 (Fed. Cir. 2003).

right to petition, it bars Sherman Act and analogous state law claims alike.[24] Many state courts have so held. *See Coll v. First Am. Title Ins. Co.*, 642 F.3d 876, 896 n.18 (10th Cir. 2011) (collecting cases from 23 states). The Third Circuit, too, has acknowledged that the *Noerr-Pennington* bar is not limited to federal antitrust claims, but applies to state law claims as well. *Cheminor Drugs*, 168 F.3d at 128 (stating "we have been presented with no persuasive reason why these state tort claims, based on the same petitioning activity as the federal claims, would not be barred by the *Noerr–Pennington* doctrine" and applying the doctrine to dismiss tortious interference and unfair competition claims). A state cannot hold defendants liable, whether in antitrust, tort, or equity, for activities that are protected by the First Amendment.[25]

Thus, counts 1–57 must be dismissed along with plaintiffs' Sherman Act claim.

IV. CONCLUSION

For the reasons set forth above, defendants' motion to dismiss (DE 155) is GRANTED. A separate order will issue.

Dated: October 27, 2021

/s/ Kevin McNulty

Hon. Kevin McNulty
United States District Judge

[24] It has long been recognized, of course, that the First Amendment is incorporated as against the states *via* the due process clause of the Fourteenth Amendment. *E.g., Gitlow v. New York*, 268 U.S. 652 (1925).

[25] Because I find that the state claims must be dismissed under *Noerr-Pennington*, I do not address Janssen's arguments that the claims must also be dismissed under *Copperweld*, 467 U.S. 752 (1984), and for other, state-specific reasons. (Mot. at 36–65.)