UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, *et. al.*, Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., *et. al.*, Defendants.	Civil Action No.: 18-1994 (FLW) **OPINION**

WOLFSON, United States District Judge:

This matter comes before the Court on the Motion of Plaintiffs Takeda Pharmaceutical Company Limited ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A."), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (cumulatively, "Plaintiffs" or "Takeda") to dismiss the antitrust claims of Defendants Zydus Pharmaceuticals Inc. ("Zydus") and Cadila Healthcare Limited's ("Cadilla") (cumulatively, "Defendants" or "Zydus"), pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, Plaintiffs' Motion is **DENIED**.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs are pharmaceutical companies which research, develop, as well as market pharmaceutical products, including lansoprazole orally digestible tablets. Plaintiffs own the following patents which claim the formulation for the drug Prevacid® SoluTab™: (a) U.S. Patent No. 6,328,994, (the "'994 Patent"); (b) U.S. Patent No. 7,431,942 (the "'942 Patent"); (c) U.S. Patent Number No. 7,875,292 (the "'292 Patent"); and (d) U.S. Patent No. 7,399,485 (the "'485 Patent") (collectively, the "patents-in-suit"). Defs.' Counterclaims ("Defs.' Countercl."), ¶¶ 18-

21, 33-36. Defendants are pharmaceutical companies which manufacture, sell, as well as market generic copies of pharmaceutical products throughout the United States, that seek to produce a generic version of Prevacid® SoluTab™. *Id*. ¶ 22.

On August 30, 2002, the Food & Drug Administration ("FDA") approved New Drug Application ("NDA") No 21-248 for lansoprazole orally digestible tablets ("ODT") that Takeda sells under the name Prevacid® SoluTab™. *Id*. ¶ 30. Prescription Lansoprazole ODT is used to treat gastroesophageal reflux disease ("GERD") "in a specific subset of patients for whom other treatments are not a practical option[]" and its ODT "formulation allows the tablet to disintegrate in a patient's mouth leaving behind thousands of coated granules, which are then swallowed and released into the bloodstream." *Id*. ¶ 30 As Zydus alleges, "[t]his feature distinguishes Prescription Lansoprazole ODT from other GERD treatments, including other products containing the active ingredient lansoprazole, and is especially important for patients who cannot easily swallow pills in tablet form." *Id*. ¶ 30.

In February 2010, Zydus filed an Abbreviated New Drug Application ("ANDA") No. 200816 with the FDA, seeking to obtain regulatory approval for a generic version of lansoprazole ODT. *Id*. ¶ 37. Zydus subsequently submitted a letter to Takeda, wherein it provided notice of ANDA No. 200816 and included a Paragraph IV Certification.[1] *Id*. ¶ 38.

[1] Generally, "where an ANDA applicant seeks approval to market a generic version of a drug claimed by a properly filed, timely filed, non-expired patent, the ANDA must include a Paragraph IV certification. An ANDA applicant making a Paragraph IV certification must also give ANDA Notice to the patent owner, setting forth the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed. . . . Without a Paragraph IV certification, the patent holder would not receive formal notice of the ANDA, and thus might not have any occasion to bring an infringement suit, or even be aware of the possibility of one, until the ANDA is approved and the generic drug hits the market. Thus, the Paragraph IV certification serves to protect the patent holder in that it enables notice of potential infringement. Moreover, a Paragraph IV certification triggers a 30-month stay of FDA approval of the ANDA if the patent holder, upon receiving ANDA Notice, files [an] infringement action within" the 45 day deadline.

Following its receipt, on April 5, 2010, Takeda filed suit in this District against Zydus, alleging infringement of the '994 Patent and '992 Patent. *Id*. ¶ 39; *see Takeda Pharm. Co. v. Zydus Pharms. USA Inc.*, No. 10-1723, 2011 U.S. Dist. LEXIS 56328 (D.N.J. May 25, 2011). Although, during the course of that separate litigation, Takeda amended its complaint to include the '292 Patent, it eventually dismissed all of its infringement claims against Zydus, with the exception of those relating to the '994 Patent. *Id*. ¶ 40-42.

Trial ensued, at which the parties disputed the proper claim construction of the term "fine granules," as defined in the '994 Patent. *Id*. ¶ 42. Ultimately, on appeal of the District Court's decision in favor of Takeda on claim construction, the Federal Circuit Court of Appeals construed that term to mean "fine granules having an average particle diameter of precisely 400 μm or less," as opposed to a deviation of ± 10%. *Id*.; *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014). In that regard, because Zydus's ANDA product was measured to have an average particle size of 412.28 μm, the Court of Appeals ruled that "there can be no dispute that Zydus' ANDA product does not literally infringe . . . the '994 patent," reversed the decision below, and judgment was entered in favor of Zydus. *Id*.

Subsequently, Zydus filed an amended ANDA No. 200816 with the FDA, which allegedly contains only one minor difference from the previously submitted ANDA No. 200816: "[an] immaterial addition of inactive substances ("excipients") to the formulation . . . added to address certain issues raised by the FDA regarding administration of the product." *Id*. ¶ 45. In that regard, the FDA allegedly "indicated to Zydus that it was prepared to approve Zydus's ANDA No. 200816, as amended," following which, on January 3, 2018, Zydus submitted a letter to Takeda notifying Takeda of the amended ANDA No. 200818. *Id*. ¶ 46. The letter included

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Eisai Co. v. Mut. Pharm. Co., No. 06-3613, 2007 U.S. Dist. LEXIS 93585, at *47 (D.N.J. Dec. 20, 2007) (citations omitted).

another Paragraph IV Certification and "detailed some of the reasons why there could be no infringement of the patents-in-suit," such as: "because Zydus' product has fine granules having an average particle diameter of *greater than* 400 μm, the basis for the Federal Circuit's determination that Zydus' product does not infringe applies with equal force to all four patents-in-suit." *Id*. ¶ 47 (emphasis in original).

Following the submission of its January 3, 2018 letter, Zydus allegedly attempted to provide Takeda with the amended ANDA for its review, "no less than eight times[.]"*Id.* ¶ 48. However, despite also making "[s]everal telephone calls[,]" Zydus's efforts were unsuccessful. *Id*.

On February 12, 2018, Takeda brought the instant action against Zydus, alleging that Zydus directly infringed the '994 Patent, '942 Patent, '292 Patent, and '485 Patent by filing amended ANDA No. 200818 with the FDA, which, according to Zydus, is alleged to be "in every material respect, identical to [the] 2012 Lawsuit[.]" *Id*. ¶ 50. On March 29, 2018, Zydus filed counterclaims against Takeda, alleging, among other things, violations of: (1) the Sherman Act, 15 U.S.C. § 2; and (2) the New Jersey Antitrust Act, N.J.S.A. § 56:9-1.[2] On July 26, 2018, this Court entered a Stipulation and Order of partial dismissal, pursuant to which Takeda voluntarily dismissed with prejudice all of its infringement claims against Zydus. The Stipulation and Order, however, did not dismiss Zydus's antitrust counterclaims.

[2] "The language of the New Jersey Antitrust Act is virtually identical to the antitrust provisions in the Sherman Act . . . [moreover], the New Jersey act specifically provides that it 'be construed in harmony with ruling judicial interpretations of comparable Federal antitrust statutes and to effectuate, insofar as practicable, a uniformity in the laws of those states which enact it." *St. Clair v. Citizens Fin. Group*, No. 08-1257, 2008 U.S. Dist. LEXIS 92135, at *16 (D.N.J. Nov. 12, 2008).

Currently, Takeda moves to dismiss those counterclaims pursuant to Federal Rule of Civil Procedure 12(b)(6), on the basis of *Noerr-Pennington* immunity.[3] Zydus opposes the motion.

II. DISCUSSION

A. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a claim "for failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss, courts must first separate the factual and legal elements of the claims, and accept all of the well-pleaded facts as true. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). All reasonable inferences must be made in the plaintiff's favor. *See In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir. 2010). In order to survive a motion to dismiss, the plaintiff must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). This standard requires the plaintiff to show "more than a sheer possibility that a defendant has acted unlawfully," but does not create as high of a standard as to be a "probability requirement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The Third Circuit has required a three-step analysis to meet the plausibility standard mandated by *Twombly* and *Iqbal*. First, the court should "outline the elements a plaintiff must plead to a state a claim for relief." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). Next, the court should "peel away" legal conclusions that are not entitled to the assumption of truth. *Id.*;

[3] Although Takeda has moved, in the alternative, to bifurcate and stay Zydus's anticompetitive counterclaims, this issue is moot. Indeed, on July 27, 2018, the Court entered a stipulation and order pursuant to which Takeda withdrew all of its patent infringement claims. As such, Zydus's anticompetitive counterclaims are the only ones which require resolution in this action.

see also Iqbal, 556 U.S. at 678-79 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). It is well-established that a proper complaint "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations and citations omitted). Finally, the court should assume the veracity of all well-pled factual allegations, and then "determine whether they plausibly give rise to an entitlement to relief." *Bistrian*, 696 F.3d at 365 (quoting *Iqbal*, 556 U.S. at 679). A claim is facially plausible when there is sufficient factual content to draw a "reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The third step of the analysis is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*. at 679.

B. ANALYSIS

i. *Noerr-Pennington* Immunity

In the context of antitrust litigation, the *Noerr-Pennington* doctrine "provides broad immunity from liability to those who petition the government, including administrative agencies and courts, for redress of their grievances." *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179 (3d Cir. 2015) (citation omitted). Nevertheless, immunity under *Noerr-Pennington* is not absolute; indeed, its protections do not extend to the activities of those who engage in "sham litigation." *Noerr-Pennington. Prof'l Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); *Hanover 3201 Realty, LLC*, 806 F.3d at 178; *Otsuka Pharm. Co*, 118 F. Supp. 3d 646, 656 (D.N.J. 2015).

The "sham litigation" exception under *Noerr-Pennington* requires a two-pronged showing: "first, 'the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits' . . . [s]econd, 'the baseless lawsuit [must]

conceal[] an attempt to interfere directly with the business relationships of a competitor,' rather than reflect a legitimate effort to obtain judicial review." *Otsuka Pharm. Co*, 118 F. Supp. at 656 (quoting *Noerr-Pennington. Prof'l Real Estate Investors*, 508 U.S. at 60-61); *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 272 (3d Cir. 2017). The latter inquiry, therefore, requires an examination of an alleged wrongdoer's "subjective intent." *ADP, LLC v. Ultimate Software Grp., Inc.*, No. 16-8664, 2018 U.S. Dist. LEXIS 35240, at *10 (D.N.J. March 5, 2018). A successful showing of both subjective and objective baselessness will preclude a party from invoking immunity under *Noerr-Pennington*.

Notably, district courts within this Circuit have routinely prohibited parties from invoking the protections of *Noerr-Pennington* at the dismissal stage of a case in the context of patent suits, at which time the factual record remains undeveloped and insufficient for the purpose of determining whether a "sham litigation" has been filed. *FTC v. Shire ViroPharma, Inc.*, No. 17-131, 2018 U.S. Dist. LEXIS 45727, at *18 (D. Del. March 20, 2018) ("[W]hether [the patent holder's] activity was in fact a sham under either standard is a factual inquiry, which cannot be resolved at the motion to dismiss stage."); *Otsuka Pharm Co.*, 118 F. Supp at 657 ("Moreover, even assuming the allegations proved insufficient, the inquiry into whether [the plaintiff-counter-defendant] maintains in this action 'objectively and subjectively baseless' infringement claims turns upon issues of reasonableness and intent—issues which are premature to consider upon the present record."); *S3 Graphics Co. v. ATI Techs. ULC*, No. 11-1298, 2014 U.S. Dist. LEXIS 16928, at *9 (D.N.J. Feb. 11, 2014) (holding that the issue of *Noerr-Pennington* immunity is "not proper before discovery"); *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 U.S. Dist. LEXIS 98547, at *6 (D. Del. Aug. 31, 2011) ("Whether the underlying litigation is baseless is a factual issue not to be determined on a motion to dismiss."); *In re Metoprolol Succinate*

Direct Purchaser Antitrust Litig., No. 06-52, 2010 U.S. Dist. LEXIS 36303, at *34 (D. Del. April 13, 2010) ("The court, however, cannot [determine whether *Noerr-Pennington* applies] at the motion to dismiss stage, because it is fact intensive"); *Hoffman La Roche Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 380 (D.N.J. 1999) ("Reasonableness is a question of fact, and the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss.").

ii. Objective and Subjective Baselessness

In the instant matter, Takeda argues that its decision to bring suit is *per se* reasonable, because it was filed in response to a paragraph IV certification. Memorandum of Law in Support of Motion to Dismiss Defendants' Antitrust Counterclaims, ("Pls.' Support Brief"), at 2. According to Takeda, Zydus's amended filing, in of itself, constitutes an act of infringement thereby providing Takeda with "a statutory right to sue." *Id*. at 18-19. Indeed, Takeda contends that Zydus's Paragraph IV Certification included an "assertion[] of noninfringement," to which a reasonable party could have disagreed. *Id*. at 20. Thus, because "Zydus's Paragraph IV Certification allowed Takeda to 'have perceived some likelihood' of success when it sued, the sham-litigation claim should be dismissed." *Id*. That possibility, Takeda argues, is sufficient for the purpose of invoking *Noerr-Pennington* immunity. *Id*. However, I disagree with Takeda's position, as the circumstances here are not different from the general practice of denying *Noerr-Pennington* immunity on a factually undeveloped record.

Takeda's arguments are confined to the issue of filing suit in response to a paragraph IV certification, the submission of which creates a "technical act of constructive infringement necessary" for a patent holder to bring an action for infringement. *Otsuka Pharm. Co.*, 118 F. Supp. at 656 n.10. Indeed, Takeda does not challenge the sufficiency of Zydus's allegations, in

of themselves, but instead maintains that the protections of *Noerr-Pennington* automatically extend to this case, because Takeda filed suit in response to Zydus's Paragraph IV Certification. Therefore, Takeda's request for relief on this motion rises and falls on that limited inquiry.

I note at the outset that, Takeda does not support its position with, nor is this Court aware of, any statutory authority or case law from which to find that an infringement action filed in response to a paragraph IV certification is *per se* reasonable, such that immunity automatically applies. To the contrary, Takeda's exact argument was rejected in *Otsuka Pharm Co.*, wherein the defendant asserted counterclaims against the plaintiff patent holder pursuant to the Sherman Act's prohibition of anticompetitive conduct. Specifically, the court, there, held that the defendant's submission of a paragraph IV certification did not automatically trigger the invocation of *Noerr-Pennington* immunity at the dismissal stage of litigation, reasoning:

> In its [p]aragraph IV certification, [the defendant] specifically certified that [its generic product] would 'not infringe any valid claim of the [patents in dispute].' In that respect, even though [the defendant's] certification provided the technical act of constructive infringement necessary to initiate an action under 35 U.S.C. § 271(e)(2)(A), nothing in a paragraph IV certification necessarily compels the institution of an infringement suit. Indeed, it is commonplace for NDA owners not to file suit after analyzing the contents of an ANDA filer's notice and certification, and the case law cited by [the plaintiff] provides little support for its position that the filing of a paragraph IV certification renders this litigation *per se* reasonable.

Otsuka Pharm Co., 118 F. Supp at 656 n.10. Moreover, the *Otsuka* court distinguished the same cases upon which Takeda relies here to invoke *Noerr-Pennington* immunity, including *AstraZeneca AB v. Mylan Labs., Inc.*, a non-binding out-of-circuit decision, and *Celgene Corp. v. Barr Labs., Inc*:

> Critically, in [*Celgene Corp. v. Barr Labs., Inc.*,] the Court considered the factual and legal basis of the litigation in the context of a request for sanctions under Federal Rule of Civil Procedure 11, not in connection with a *Noerr-Pennington* analysis. In [*AstraZeneca AB v. Mylan Labs., Inc.*,] a case that relied upon *Celgene*, then addressed the defendant's antitrust counterclaims and *Noerr-*

> *Pennington* immunity, following 'a 42-day bench trial' on the allegations of the plaintiff's claims and based, at least in part, upon the public records associated with that lengthy bench trial. . . . No such record has been developed in this instance.

Id.; *see also Shionogi Pharma, Inc*., 2011 U.S. Dist. LEXIS 98547, at *19 ("Thus, the procedural posture of *AstraZeneca* permitted the court to make factual findings that this Court cannot make here."). Accordingly, the plaintiff patent holder in *Otsuka* could not rely on the protections of *Noerr-Pennington* prior to the development of a factual record, even though the dispute stemmed from the submission of a paragraph IV certification, because the defendant's certifications with respect to the non-infringement of its ANDA product were sufficient for the purpose of alleging the sham litigation exception. This Court similarly finds that Zydus has adequately pled facts to state a claim for sham litigation.

Like *Otsuka*, the Court, here, lacks a factually developed record from which to conduct a sufficient *Noerr-Pennington* analysis, because this case remains in its procedural infancy. Furthermore, Zydus has sufficiently alleged facts to show that Takeda's "petition[ing]" activity constitutes sham litigation. *Hanover 3201 Realty, LLC*, 806 F.3d at 179. Indeed, Zydus's Paragraph IV Certification provided "Takeda with a detailed statement explaining why [its] amended ANDA and its lansoprazole [ODT] tablets do not infringe the patents-in-suit," in addition to a letter further articulating "numerous reasons why there could be no infringement, including how the ANDA changes . . . applied to *inactive* ingredients having nothing to do with the patents-in-suit[.]" Defendants' Opposition to Plaintiffs' Motion to Dismiss ("Defs.' Opp. Brief"), at 18-19; Countercls. ¶¶ 46, 63. While these allegations, standing alone, are sufficient to meet the sham litigation exception, Zydus also relies on the parties' prior litigation history to

demonstrate that Takeda is not entitled to invoke *Noerr-Pennington* immunity at this early stage of the proceedings.[4]

In that regard, the parties previously litigated the patents-in-suit in 2010, and the issue of infringement turned on the construction of the term "fine granules," as defined in the '994 Patent. *See Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014). The Federal Circuit, on appeal, applied ordinary principles of patent construction and ultimately ruled that the disputed claim term is "fine granules having an average particle diameter of *precisely* 400 µm or less," as opposed to a deviation of ± 10%. *Takeda Pharm. Co.*, 743 F.3d at 1365 (emphasis added). Significantly, under that patent construction, it was determined that Zydus's ANDA product could not literally infringe, because its fine granules had an average particular diameter of greater than 400 µm.

In addition to its submission of detailed letters explaining the basis for non-infringement, here, Zydus asserts that the contents of the amended ANDA support the allegation of a sham litigation because its generic drug does not literally infringe on Takeda's product. Countercls. ¶ 48. Indeed, the Federal Circuit already determined a "hard cut-off" of precisely 400 µm above which there can be no infringement, and Zydus alleges that its amended ANDA pertains only to "inactive substances" which do not relate to granule size. *Id*. ¶¶ 42, 45. In that regard, because the generic product was previously determined to have an average particle size of 412.28 µm, Zydus alleges that Takeda lacked a legitimate basis to bring suit, but, nevertheless, filed the

[4] Although the Court acknowledges that Takeda has previously dismissed suits against generic manufacturers after determining that their disputed ANDAs are non-infringing, the prior litigation history between the parties, here, serves to distinguish the instant action. Pls.' Brief, at 10-12. In any event, the manner in which Takeda conducted itself in various, separate legal disputes is insufficient for the purpose of dismissing Zydus's anticompetitive counterclaims, at least not before the development of a full factual record.

instant action wherein it asserts infringement claims which have already been "litigated and fully resolved in Zydus' favor by October 2014."[5] *Id*. ¶ 5. Moreover, while Zydus allegedly offered to provide Takeda with access to its amended ANDA on numerous occasions, from which Takeda could have confirmed that the ANDA product does not infringe, Zydus alleges that all of its efforts were ignored prior to the initiation of this action. Defs.' Opp. Brief, ¶ 19; Countercls. ¶¶ 46-49, 51-54.

Accordingly, I find that the allegations in Zydus's Counterclaims are sufficient to meet the sham litigation exception at this early juncture of the case. Indeed, the Court may infer that Takeda's decision to file this suit is objectively and subjectively baseless, as well as motivated by anticompetitive purposes. Moreover, although Takeda argues that it was proper to bring this action in response to Zydus's Paragraph IV Certification, that factual dispute must be resolved at a later stage of the litigation. Accordingly, Takeda's invocation of *Noerr-Pennington* fails.[6]

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[5] Takeda maintains that, notwithstanding the Federal Circuit's prior findings with respect to the patents-in-suit, the submission of an amended ANDA, in of itself, indicates that Zydus made "other than minor changes [to its] product formulation[.]" Pls.' Support Brief, at 20-21. That circumstance, according to Takeda, allowed it to reasonably infer that Zydus's amended ANDA infringed on the patents-in-suit, prior to its decision to file the instant action against Zydus. Pls.' Support Brief, at 20-21. However, Takeda's contentions are insufficient for the purpose of dismissing Zydus's anticompetitive counterclaims; as stated, Zydus has alleged that it provided Takeda with multiple correspondences wherein it articulated various grounds for non-infringement. These allegations, the Court finds, are sufficient to state a claim for sham litigation. *See*, *e.g.*, *Otsuka Pharm Co.*, 118 F. Supp. at 656 (anticompetitive counterclaim adequately pled where the defendant alleged that the plaintiff initiated litigation "despite [the defendant's] allegedly dispositive evidence of non-infringement'"); *Knoll Pharm. Co. Inc., v. Teva Pharms. USA, Inc.*, No. 01-1646, 2001 U.S. Dist. LEXIS 12999, at *4 (N.D. Ill. Aug. 24, 2001) (finding that the objectively baseless prong was met, because the patent holder brought suit, notwithstanding the defendant's submission of a letter which indicated why its ANDA did not infringe).

[6] While Zydus's claims are not susceptible to dismissal on Rule 12(b)(6), Takeda may reassert its claim for *Noerr-Pennington* immunity subsequent to the exchange of discovery and the development of a factual record, if appropriate.

iii. Causation

Despite the sufficiency of the pleadings, Takeda maintains that the requirement of but-for causation is not satisfied, because "Zydus has been free of the patents-in-suit since 2014 but never received FDA approval." Pls.' Support Brief, at 29. Therefore, according to Takeda, "Zydus could have never launched even in the absence of the 30-month stay," constituting an independent basis to dismiss Zydus's counterclaims. *Id*. at 30. However, this Court disagrees with Takeda's position.

The Third Circuit has held that "'[a] plaintiff who defeats the defendant's claim to *Noerr* immunity . . . must still prove a substantive antitrust violation.'" *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 149 (3d Cir. 2017) (quoting *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993)). That requirement "includes proving the challenged lawsuit is 'causally linked' to an antitrust injury." *Id*. (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

Here, the Court finds that Zydus's allegations are sufficient for the purpose of pleading an antitrust injury at the dismissal stage. Indeed, as alleged in its Counterclaims, "[o]n January 3, 2018 . . . the FDA indicated to Zydus that it was prepared to approve Zydus' ANDA, as amended[,]" which would have occurred "promptly after the 45-day notice period had concluded, "[b]ut for [Takeda's] anticompetitive conduct," *i.e.*, filing this patent infringement action. *See* Countercls. ¶¶ 6, 46. Thus, the Court finds that these allegations adequately demonstrate a "casual link" between the alleged anticompetitive purpose of Takeda's lawsuit, as pled, and the antitrust injury which allegedly flowed therefrom.

Nonetheless, Takeda maintains that Zydus has failed to obtain regulatory or tentative FDA approval, and therefore, its alleged injuries actually stem from the Hatch-Waxman's

statutory framework as opposed to the instant dispute. However, Takeda's arguments require a factually intensive analysis which this Court cannot perform, because this case is still in its procedural infancy. *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995) ("[T]he existence of an 'antitrust injury' is not typically resolved through motions to dismiss."); *see, e.g.*, *Atlantic Richfield Co.*, 495 U.S. 328, 346 (1990); *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 495 (3d Cir. 1992); *Tunis Bros. Co. v. Ford Motor Co.*, 952 F.2d 715, 727-28 (3d Cir. 1991).

Indeed, various district courts within this Circuit have declined to hold that the absence of FDA approval creates a barrier to establishing the element of causation in a patent antitrust suit. *See, e.g.*, *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, No. 06-71, 2010 U.S. Dist. LEXIS 36303, at *23 (D. Del. April 13, 2010) ("The positioning of tentative FDA approval as the dispositive factor in patent antitrust cases, however, is questionable in view of case law in the Third Circuit and elsewhere."); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) ("Defendants' ability to pose a plausible and legally permissible version of events that explains why generic manufacturers of [the brand drug] have not yet entered the market does not compel this Court to grant their Motion."); *see also Bristol Meyer-Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000) ("There is no dispute that by suing the generic defendants under the Hatch-Waxman Act, [the plaintiff] provoked the automatic moratorium of FDA approval of the generics' ANDAs. For [the plaintiff] to insist that its generic competitors have no standing because they are not in the market, when Bristol itself foreclosed their access to it, is meritless."); *Warner Lambert Co. v. Purepac Pharm. Co.*, No. 98-02749, 2000 U.S. Dist. LEXIS 22559, at *22 (D.N.J. Dec. 22, 2000) ("[T]he generic

manufacturer's injury does not merely result from the 'structure of a regulated industry[]' but from the decision of the pioneer manufacturer to bring suit.") (citation omitted).[7]

III. CONCLUSION

For the foregoing reasons, Takeda's Motion to dismiss Zydus's anticompetitive counterclaims is **DENIED**.[8]

/s/ Freda L. Wolfson
Freda L. Wolfson
United States District Judge

[7] In a supplemental letter brief, Takeda attaches recent correspondences from the FDA to Zydus, which allegedly support the fact that Zydus's delayed market entry is a result of independent market barriers, as opposed to the initiation of this action. Zydus, in response, argues that the FDA's correspondences, dated April 24 and June 26, 2018, subsequent to the date on which Takeda filed this suit, reference immaterial issues which are unrelated to this legal dispute. However, the Court need not resolve the parties' disagreement here, as they involve factual inquiries that are inappropriate for consideration at the dismissal stage. Nonetheless, to the extent that Takeda wishes to pursue this theory as a defense to Zydus's anticompetitive counterclaims, it may do so at a later stage of the litigation.

[8] The Court notes that, on December 18, 2018, at the eleventh hour, Takeda requested leave to file a supplemental memorandum in further support of its motion to dismiss Zydus's Counterclaims. Therein, Takeda raises two arguments: (1) it voluntarily dismissed its patent-infringement claims against Zydus, a circumstance which is already clearly indicated on the docket of this case, as well as (2) Zydus received tentative FDA approval for its formulation on September 13, 2018, and has launched its generic ODT. The Court denies Takeda's request to file a supplemental brief, on the basis that it is clearly untimely; and, it incorporates arguments which could have been raised earlier. Nevertheless, Takeda's additional arguments have either already been discussed in this Opinion, or to the extent that they raise factual issues, are not appropriate for consideration at the dismissal stage of litigation. Furthermore, the arguments regarding actions taken after the filing of Takeda's Complaint do not impact whether a viable antitrust claim was asserted upon Takeda filing its Complaint. Whether any of the additional later actions affect the merits of the antitrust claims are not relevant at this juncture. Accordingly, Takeda's supplemental memorandum does not support the dismissal of Zydus's antitrust counterclaims.