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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs and Counterclaim Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LIMITED, Defendants and Counterclaim Plaintiffs.	Civil Action No. 18-1994 (FLW) **OPINION**

WOLFSON, Chief Judge:

In this patent litigation, Takeda Pharmaceutical Company Limited sued Zydus Pharmaceuticals (USA) Inc. for infringing Prevacid SoluTab, an orally disintegrating tablet used to treat gastroesophageal reflux disease. Zydus counterclaimed, arguing that Takeda filed a "sham suit" to maintain its monopoly power in violation of the Sherman Act and the New Jersey Antitrust Act, and sought damage for the delayed launch of its product. After testing Zydus' generic version in discovery, Takeda voluntarily dismissed its claims, but Zydus did not. Both parties now move for summary judgment on the counterclaims. Takeda argues that its suit is protected by the *Noerr-Pennington* doctrine, which immunizes First Amendment activity such as litigation from antitrust liability. *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). Takeda also argues that Zydus has not established a substantive antitrust violation, but "stymied" its own efforts to enter the market after winning a prior infringement case in 2014. Zydus counters that Takeda's suit falls under the narrow

exception to *Noerr-Pennington* for litigation that is both objectively and subjectively baseless, and as such, Takeda should not be permitted to raise that defense. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 146 (3d Cir. 2017). For the following reasons, Takeda's motion is **GRANTED**, Zydus' motion is **DENIED**, and the counterclaims are **DISMISSED**.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Takeda manufactures Prevacid SoluTab, an orally disintegrating tablet used to treat gastroesophageal reflux disease by suppressing stomach acid. Pl. Statement of Undisputed Material Facts ("SUMF"), ¶¶ 1-3. Prevacid contains the active ingredient lansoprazole, a proton pump inhibitor. *Id.* ¶ 1. Its main innovation is fine granules measuring 400 μm or less in diameter, which dissolve in the mouth and leave behind thousands of coated particles, or microcrystals, that release directly into the bloodstream, obviating the need for patients to swallow. *Id.* ¶¶ 20, 22, 25, 28. First patented in 2001,[1] *id.* ¶¶ 10-12, and approved by the Federal Drug Administration ("FDA") in a New Drug Application ("NDA") in 2002, *id.* ¶¶ 4, 7, Prevacid was the only drug of its type for many years. Def. Supp. SUMF, ¶¶ 222-24 ("[I]f the relevant market is lansoprazole ODT, then [Prevacid] would have had a 100 percent market share from . . . approximately 2011 until . . . 2018.").

A. Hatch-Waxman: The Statutory Framework Governing Generic Drug Entry

1 U.S. Patent Nos. 6,328,994 ("'994 patent"), issued on December 11, 2001, 7,431,942 ("'942 patent"), issued on October 7, 2008, 5,464,632 ("'632 patent"), issued on January 25, 2011, and 7,399,485 ("'485 patent"), issued on July 15, 2008, cover Prevacid. Pl. SUMF, ¶¶ 10-12. Claim 1 of the '994 patent is incorporated as a continuing reference in the other patents, and describes "[a]n orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent." '994 patent, col. 37 II. 43-53. All but the '485 patent expired on May 17, 2019. Pl. SUMF, ¶ 14. Pediatric exclusivity on the '485 patent ran through November 17, 2018, but Takeda waived it in September of that year. *Id.*

To better explain the issues in this case, it is necessary to begin with the statutory framework applicable when a generic seeks to enter the market for a branded drug. Under the Drug Price Competition and Patent Term Restoration Act of 1984, *see* 98 Stat. 1585, Pub. L. No. 98-417, commonly known as Hatch-Waxman, a generic manufacturer may file an Abbreviated New Drug Application ("ANDA") to "piggy-back on the brand's NDA." *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012). "Rather than providing independent evidence of safety and efficacy," as a brand-name manufacturer must do when it files an NDA, *see* 21 U.S.C. § 355(b)(1)(A)(i), which often entails "a long, comprehensive, and costly testing process," *see Wellbutrin*, 868 F.3d at 143, "the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug," and thus receives expedited review. *Caraco*, 566 U.S. at 405.

Submitting an ANDA is "by statutory definition an infringing act," *see Wellbutrin*, 868 F. 3d at 149; 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit [ ] an [ANDA] for a drug claimed in a patent."), so generic entry generates many intellectual property disputes.[2] Hatch-Waxman sets out "special procedures" for resolving them. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 143 (2013). For instance, a brand-name manufacturer must "list in its [NDA] the number and the expiration date of any relevant patent," *id.*, which the FDA compiles into an Orange Book. 21 U.S.C. § 355(j)(5)(B)(iii). The generic must then "assure the FDA [in its ANDA] that [it] will not infringe the brand-name's patents." *Actavis*, 570 U.S. at 143 (quotations and citations omitted).

2 "Infringement" in this sense is a legal construct that permits a brand-name to initiate suit without having to wait for the generic to actually make, use, or sell its drug. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (explaining that "the defined act of infringement [is] artificial" and exists to "enable the judicial adjudication upon which the ANDA . . . scheme[ ] depend[s]"). An ANDA does not speak to whether a disclosed generic in fact infringes a branded drug. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("The occurrence of the defined 'act of infringement' does not determine the ultimate question whether what will be sold will infringe any relevant patent.").

One way to do so is to affirm that "any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the drug described in the [ANDA]," otherwise known as a Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(A)(vii); *In re Omeprazole Pat. Litig.*, 490 F. Supp. 2d 381, 395-96 (S.D.N.Y. 2007) ("Only one type of certification is pertinent here: a 'Paragraph IV' certification. In a Paragraph IV certification, the generic manufacturer seeks to obtain FDA approval before a listed patent expires and asserts that the patent listed in the Orange Book is either not infringed or invalid."), *aff'd*, 281 Fed. App'x. 974 (Fed. Cir. 2008). Because the generic must send its Paragraph IV Certification to the brand-name, *see* 21 C.F.R. §§ 314.96(d)(1)(i)-(iii), this usually "means provoking litigation." *Caraco*, 566 U.S. at 407.

There is a strong economic incentive to litigate Hatch-Waxman cases in a timely manner. If, within 45 days of receiving a Paragraph IV Certification, a brand-name sues for infringement, the FDA cannot approve the generic's product for up to 30 months.[3] 21 U.S.C. § 355(j)(5)(B)(iii). This provides "some breathing space before competition can begin." *Wellbutrin*, 868 F.3d at 144. The 30-month stay lifts when the generic wins, the parties settle, or the patents expire. Similarly, there is a special incentive to file the first ANDA: the generic who does so obtains the exclusive right to sell its drug for 180 days. 21 U.S.C. § 355(j)(5)(B)(iv). This period can be "possibly" be "worth several hundred million dollars." *Actavis*, 570 U.S. at 144 (quoting Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

B. The Parties' Prior Litigation: Zydus I, Zydus II, and Zydus III

Generics have long sought entry into the Prevacid market. *See, e.g.*, *Takeda Pharm. Co. v. Teva Pharm. USA, Inc.*, 668 F. Supp. 2d 614 (D. Del. 2009); Pl. SUMF, ¶¶ 15-16 (listing nine

3 A brand-name manufacturer may sue outside of the 45-day notice period, but its suit would not trigger a stay.

ANDAs in twelve years). Teva Pharmaceuticals USA, Inc., was the first to receive FDA approval in October 2010, but withdrew its product in April 2011 because it risked clogging a patient's nasogastric (*i.e.*, feeding) tubes when injected by syringe.[4] Pl. SUMF, ¶ 17. No other generic succeeded until September 2017, when the FDA authorized Teva's second formulation. *Id.* ¶ 18. Teva launched on March 8, 2018.[5] *Id.* ¶ 19.

Zydus sought to enter the Prevacid market around the same time as Teva. *Id.* ¶ 25; Def. SUMF, Ex. 7. In February 2010, it served Takeda with a Paragraph IV Certification for its original ANDA. Def. SUMF, ¶ 31. Takeda promptly sued for infringement. Pl. SUMF, ¶ 26. The present dispute hinges in large part on that litigation. The parties disagreed on how to construe the claim language "fine granules having an average particle diameter of 400 μm or less" in the '994 patent. *Takeda Pharm. Co. v. Zydus Pharms. USA Inc.*, No. 10-1723, 2011 WL 4736306, at *3 (D.N.J. Oct. 5, 2011). Judge Pisano[6] adopted Takeda's construction, finding Claim 1 to mean "granules up to and including the enteric coating layer having an average particle diameter of 400 μm (+/- 10%) or less." *Id.* at *4.

In 2012, in response to an FDA inquiry, Zydus incorporated into its ANDA an "in-process quality control specification" resulting from a product reformulation, which would require a median particle diameter "not less than 450 μm" and discard any non-conforming particles. Def.

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4 No other generic could obtain the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(D); *Actavis*, 570 U.S. at 144.

5 Leading up to this date, Takeda "ran analyses to test the impact of [Teva's] entrance" on Prevacid. Pl. SUMF, ¶ 130. It concluded that Teva's generic would "erode sales . . . by about 90% and that later entrants [*i.e.*, multiple generics] would not likely have any effect on [Prevacid's] sales volume." *Id.* The numbers bore this out, to an extent. Takeda sold $15,187,296 in Prevacid in January 2018, $13,879,434 in February 2018, $11,754,303 in March 2018, and $8,493,891 in April 2018. *Id.* ¶ 131. This equaled approximately a 30 percent decrease in market share within a two-month period. *Id.* ¶ 132. At the same time, Takeda earned about $16 million in additional revenue (compared to its forecasts) because Teva did not erode sales to the degree expected. Def. Supp. SUMF, ¶¶ 170-75, 218-19.

6 The case was assigned to the late Hon. Joel Pisano, U.S.D.J.

SUMF, Ex. 17. Judge Pisano permitted Takeda to re-test Zydus' new product to ensure the accuracy of its assertions, despite Zydus' objections. Pl. SUMF, ¶ 31; *see also* Case No. 10-1723, ECF No. 265, at 2. As a result, he extended the 30-month stay for six months and reopened discovery. *Id.* After this round of discovery concluded, Zydus moved *in limine* to "preclude evidence of particle size diameter" from trial on the grounds that "the Court need not look beyond the ANDA to resolve infringement." Case No. 10-1723, ECF No. 317, at 4. According to Zydus, because it changed its ANDA to require its granules to be at least 450 µm, 10 µm bigger than the 440 µm upper limit in the '994 patent, its generic could not literally infringe Prevacid. Pl. SUMF, ¶ 33. Judge Pisano denied Zydus' motion, holding that "the focus of the infringement inquiry in this case, like a typical ANDA case, is on what the ANDA applicant will likely market if the application is approved," not merely on what the ANDA recites. Case No. 10-1723, ECF No. 317, at 4. Judge Pisano also noted that "a focus of the infringement portion of the trial" would be whether the '994 patent requires Prevacid's granules to be "deagglomerated," or broken apart without breaking the microcrystals themselves, prior to testing size. *Id.* at 11; Def. Supp. SUMF, ¶ 26.

The parties went to trial on the '994 patent.[7] Def. Supp. SUMF, ¶ 23. Takeda's expert testified that, based on testing requiring deagglomeration, Zydus' reformulated particles averaged between 412.28 µm and 420.46 µm in diameter, "below the upper limit of Claim 1 of the '994 patent" as well as the in-process specification Zydus added to its ANDA, and infringed Prevacid to that extent. Pl. SUMF, ¶¶ 37-38. Zydus again argued that its ANDA was "dispositive," because it "represented to the FDA" that its quality control specification would eliminate particles "less

7 Takeda voluntary dismissed its claims as to '942 and '292 with prejudice. Pl. SUMF, ¶¶ 35, 39-40. Takeda earlier entered into a covenant not to sue Zydus for infringing the '485 patent after conducting pre-trial testing on Zydus' original formulation and finding that it "d[id] not include hydroxypropyl cellulose in any amount," the core of the '485 patent. *Id.* ¶¶ 36-38; Def. SUMF, ¶¶ 21-22.

than 450 μm." *Id.* ¶ 39. Judge Pisano rejected Zydus' position, reasoning that Takeda "ha[d] done actual testing and ha[d] evidence that the ANDA product that Zydus intend[ed] to commercialize d[id] infringe the Takeda patent." *Id.* ¶ 41. Zydus then argued that, based on testing requiring no deagglomeration, its samples yielded average particle diameters between 443.4 μm and 457.1 μm. Def. Supp. SUMF, ¶ 29. But Judge Pisano construed the '994 patent to require deagglomeration, and ultimately found Zydus' ANDA to literally infringe Prevacid. *Id.* ¶ 31.

Zydus appealed. *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014) [*Zydus II*]. The Federal Circuit "reverse[d] the district court's claim construction ruling and resulting finding of literal infringement," and "remand[ed] for further proceedings consistent with this opinion." *Id.* at 1370. In particular, the Federal Circuit interpreted the claim language in Prevacid to mean "an average particle diameter of precisely 400 μm or less," as Zydus had proposed, not plus or minus ten percent of 400 μm.[8] *Id.* at 1363. It also held that, without deagglomeration, which "for the record" the trial judge "clearly erred" in requiring, Zydus' particles averaged between 457.1 μm and 443.4 μm in diameter, numbers which exceeded the upper limit in the Prevacid patent.[9] *Id.* at 1367 n.3, 1369. In light of the Federal Circuit's decision,

8 The Federal Circuit found that "the specification contrasts the 'fine granules' of the claimed invention with larger 'conventional' granules, which it defines as '400 μm or more of average particle diameter.' '994 patent col. 2 ll. 17-18. The specification explains that conventional granules of that size 'produce a feeling of roughness in the mouth'—one of the very problems the claimed invention purports to solve. *Id*. col. 2 ll. 16-17. That clear dividing line between the 'fine' granules of 400 μm or less (which avoid a feeling of roughness in the mouth) and 'conventional' granules of 400 μm or more (which do not) disappears if the 'fine granules' are construed as incorporating a 10% deviation. Thus, there can be little doubt that the narrower construction most naturally aligns with the patent's description of the invention." *Id.* at 1364. (internal citations omitted).

9 The Federal Circuit wrote that "there is no indication in the specification that the inventors themselves undertook deagglomeration of their own samples prior to measurement, or even evaluated whether deagglomeration was necessary. We cannot conclude that the patent affirmatively *requires* a step that was entirely absent from (and even precluded by) the procedure described in the specification." *Id.* at 1369 (emphasis in original).

Judge Pisano entered judgment against Takeda.[10] *Takeda Pharm. Co, Ltd. v. Zydus Pharm. USA Inc.*, No. 10-1723, 2014 WL 12629965, at *2 (D.N.J. Oct. 16, 2014) [*Zydus III*].

*C. Efforts to Obtain FDA Approval Post-*Zydus III

i. Safety Issues Raised by the FDA

Although the 30-month stay lifted as soon as Takeda lost in October 2014, *see* 35 U.S.C. § 355(j)(5)(B)(iii)(I), Zydus did not obtain FDA approval for its generic until 2018. The reasons why—though many—are critical to deciding the parties' summary judgment motions, so I recount them fully. On June 26, 2013, with *Zydus II* pending, the FDA issued a Complete Response Letter ("CRL") denying Zydus' ANDA because of a "serious safety concern" with its formulation: a clogging risk not unlike that which thwarted Teva's initial entry in 2011. Pl. SUMF, ¶¶ 49-51 (describing a "considerable difference in the particle size distribution between the test and the reference products after disintegration/dispersion"). The FDA sends a CRL when it "will not approve" an ANDA "in its present form" due to a deficiency that is not easily correctible. 21 C.F.R. § 314.110(a). The FDA suggested that Zydus "reformulate [its] test product to be bioequivalent to the reference product." Pl. SUMF, ¶ 52. Zydus complied, and on October 30, 2014, amended its ANDA with a new formulation. *Id.* ¶¶ 53-54. Specifically, Zydus proposed "incorporat[ing] new excipients [or inactive ingredients] at the extra-granular stage with no other changes made at the pellet [granule] stage." Def. SUMF, ¶¶ 61, 63, 65, 69, 71. Zydus designated the amendment as "MAJOR." Pl. SUMF, ¶ 55. The FDA rejected the new ANDA as "not acceptable." Pl. SUMF, ¶¶

10 Takeda attempted to raise a doctrine of equivalents ("DOE") claim on remand. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) ("A product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention."). Judge Pisano determined that Takeda waived that argument by failing to pursue it during trial. Def. SUMF, ¶ 49.

56-57. Zydus then amended on March 30, 2016, *id.* ¶ 58, and once more on March 29, 2017, to address ongoing issues related to bioequivalence, product quality, and dissolution. *Id.* ¶¶ 60-62.

ii. Inaction on Paragraph IV Certification

As discussed *supra*, when a generic submits an ANDA, it must certify that its drug does not infringe the branded version and issue a Paragraph IV Certification attesting to that fact. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *id.* § 355(j)(2)(B)(i). The same is true for an amendment to an unapproved ANDA. 21 C.F.R. § 314.96(d)(1)(iii). The Paragraph IV Certification must contain a "detailed statement of the factual and legal basis of the applicant's opinion that the patent . . . will not be infringed," and a "full . . . explanation of why," so that the brand-name manufacturer can make an informed but prompt decision about whether to sue. 21 C.F.R. § 314.95(c)(7).

Zydus did not send Takeda a Paragraph IV Certification in October 2014, when it filed its reformulation with the FDA. Pl. SUMF, ¶ 66. Nor did it do so the next year, when the FDA instructed it to "renotify all patent holders and patent assignees, etc." *Id.* ¶ 68; Def. Supp. SUMF, ¶ 74. Zydus argued instead that it need not take that step because Judge Pisano declared its generic not to literally infringe Prevacid in *Zydus III*. Pl. SUMF, ¶ 70. Zydus also argued that its alteration "ha[d] no impact on the coated pellet average particle diameter." Def. Supp. SUMF, ¶ 77. The FDA rejected Zydus' position in a CRL on November 4, 2015, and reiterated that Zydus must send a new Paragraph IV Certification to Takeda. Pl. SUMF, ¶ 72. In the letter, the FDA described its role as "ministerial," meaning that it could not "make a determination as to whether the reformulation provided in your October 31, 2014[,] amendment would infringe on any listed patents," regardless of Judge Pisano's findings as to the original formulation or the nature of the alleged changes, *id.* ¶ 73, and the FDA's "practice generally is to require a resubmission of patent certifications . . . at the time that an ANDA applicant amends its application to reformulate the

drug product." Def. Supp. SUMF, ¶ 79. The FDA also reasoned that "[o]ne purpose of the notice requirement is to allow . . . 'any legal disputes regarding the scope of the patent and the possibility of infringement [to] be resolved as quickly as possible." Pl. SUMF, ¶ 74 (quoting FDA letter (quoting *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003))).

Over two years later, on December 27, 2017, the FDA issued another CRL to Zydus stating that the agency could not approve its ANDA absent a new Paragraph IV Certification, which Zydus still had not submitted—or sent to Takeda. Pl. SUMF, ¶ 76. Otherwise, Zydus' ANDA was complete and apparently approvable. Def. SUMF, ¶ 84. The FDA encouraged Zydus to "monitor for the availability of new and revised product-specific guidances . . . . [check] available labeling resources . . . for recent updates, and make any necessary revisions to your labels and labeling" in the meantime. *Id.* ¶ 77.

Zydus sent a Paragraph IV Certification to Takeda on January 4, 2018, more than four years after first revising its ANDA. *Id.* ¶ 79; Def. SUMF, ¶ 87. The Certification stated in relevant part:

> This document contains the detailed factual and legal bases for [Zydus'] certification that, in its opinion and to the best of its knowledge, claims of [the '994 patent] . . . will not be infringed by the commercial manufacture, use or sale of the drug product described in Zydus's amended ANDA . . . . Zydus's amended ANDA [ ] still requires that its fine granules of common pellets, used in its lansoprazole orally disintegrating tablets to have a d_{50} of not less than 440 µm . . . well above the hard cutoff dictated by the District Court and the Federal Circuit Opinions.
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> . . . .
>
> In short, due to . . . the finding of the Courts in respect of the hard cut-off of the average particle diameter of fine granules in the '994 patent (which has a common specification with the '942 and '292 patent via continuation applications), in conjunction with no change being made with respect to the fine granule average particle size being above 400 µm as delineated in Zydus' In- process Specification set forth in ANDA No. 200816, Zydus's amended ANDA Product cannot infringe any of the claims of the '994, '485, '942 and '292 patents.

Pl. SUMF, ¶¶ 80, 83; Def. SUMF, ¶¶ 95-96. Along with the Certification, Zydus included an Offer of Confidential Access ("OCA") to the ANDA, *see* 21 U.S.C. § 355(j)(5)(C)(i)(III), which Takeda did not accept. Pl. SUMF, ¶ 84. Zydus offered to "negotiate the OCA" and emailed/called Takeda eight times between January 11, 2018, and February 12, 2018, to that end. Def. SUMF, ¶¶ 99-114. The ANDA stated that Zydus' reformulation altered only the "excipients" or "inactive ingredients," information which the Paragraph IV Certification did not expressly contain. Zydus did not offer reformulated samples, despite the parties' prior litigation during which Judge Pisano extended discovery for that purpose. Pl. SUMF, ¶ 85. Zydus now maintains that it would have "promptly shipped them" had Takeda requested them. Def. Supp. SUMF, ¶ 104.

iii. Ongoing and Required Labeling Changes to Prevacid

When it submitted its January 2018 ANDA, Zydus sought priority review under the Generic Drug User Fee Act of 2012 ("GDUFA"), Pl. SUMF, ¶ 137, which expediates the timeline for drug approval decisions to get generics to the market more efficiently. 126 Stat. 993, Pub. L. No. 112-144. The FDA granted Zydus' request and gave its ANDA a three-month goal date of April 24, 2018. Pl. SUMF, ¶¶ 137-38, 144.

At the same time, Takeda was working with the FDA to update Prevacid's labeling. 21 U.S.C. § 355(*o*)(4)(I). On April 13, 2018, the FDA approved a label change necessary to comply with a new agency rule on pregnancy and lactation.[11] Pl. SUMF, ¶¶ 146-47. The FDA sent Zydus a third CRL on April 24, 2018, rejecting its ANDA because it did not conform to this new label. *Id.* ¶ 150. Zydus updated its labeling and resubmitted its ANDA the same day. *Id.* ¶ 151. Little more than a month passed before the FDA approved another label change to Prevacid, this time to

11 Takeda submitted this label change on December 21, 2016. Pl. SUMF, ¶ 146. The reasons for the two-year delay are unclear.

comply with new safety information.[12] *Id.* ¶ 153. Zydus then amended its ANDA yet again on June 14, 2018. *Id.* ¶ 156. The FDA gave Zydus' amendment a new three-month goal date under the GDUFA of September 13, 2018. *Id.* ¶ 157. No further developments disrupted the FDA's review or changed the expected approval date.

iv. FDA Approval and the '485 Patent's Pediatric Exclusivity

The FDA "tentatively approved" Zydus' ANDA on the same day as the three-month goal deadline. *Id.* ¶ 158; Def. Supp. SUMF, ¶¶ 191-92. The agency could not, however, grant final approval because pediatric exclusivity applied to the '485 patent. 21 U.S.C. § 355a(1)(B)(i); Def. Supp. SUMF, ¶¶ 187-88. Congress authorized a pediatric exclusivity period in the Food and Drug Administration Modernization Act of 1997. 111 Stat. 2296, Pub. L. No. 105-115. Pursuant to that provision, if an NDA demonstrates that a drug "may produce health benefits" to children, the FDA will extend a drug's patent protection by six months, contingent on the manufacturer conducting relevant studies. 21. U.S.C. §§ 355a(b)-(c).

On September 18, 2018, Zydus asked Takeda to waive exclusivity. Pl. SUMF, ¶ 164. Takeda agreed to do so on September 24, 2018, and notified Zydus of its decision two days later. *Id.* ¶¶ 165-66. The FDA granted final approval to Zydus' generic version of Prevacid on November 27, 2018. *Id.* ¶ 167; *see also* FDA, Guidance for Industry: ANDA Submissions – Amendments to Abbreviated New Drug Applications under GDUFA 14 (July 2018) (explaining that the agency generally needs 90 days to convert a tentative approval to a final one). According to Zydus' regulatory expert, the "FDA likely would have granted final approval to Zydus' ANDA without first granting tentative approval" had Takeda not sued. Def. Supp. SUMF, ¶¶ 194, 196.

D. The Parties' Present Litigation

12 The FDA informed Takeda that it needed to make this label change on January 24, 2018, and February 16, 2018. Pl. SUMF, ¶ 154. Takeda submitted the required amendments on March 16, 2018, and April 23, 2018. *Id.* ¶ 155.

Takeda filed the instant infringement suit[13] on February 12, 2018, within 45 days of receiving Zydus' Paragraph IV Certification. *See* ECF No. 1. In doing so, Takeda triggered a new 30-month stay. Takeda's actions before and during this litigation are, like much of the factual history, essential to resolving Zydus' counterclaims.

i. Takeda's Decision to Sue Based on the Paragraph IV Certification and Prior Litigation History

After receiving Zydus' Paragraph IV Certification, Takeda's in-house counsel, George Kokkines, asked outside counsel Eric Lobenfeld if he could "review and let us know if you recommend any follow-up or other actions." Pl. SUMF, ¶ 88. The next week, Lobenfeld answered, and presumably on the basis of his answer, Takeda sued for infringement.[14] The parties sharply contest Lobenfeld's reasoning, so I excerpt it nearly in full:

> We have had a chance to review the ANDA notice letter from Steve Moore on behalf of Zydus. We have also looked at certain pleadings and filings from the prior Zydus case which are relevant to our analysis. As explained below, Takeda has a good faith basis to bring suit against Zydus, and obtain a 30-month stay (which will terminate earlier when the patent and pediatric exclusivity expires in 11/19). We recommend suing on all four of the Orange Book patents: the '994, '942, '292, and '485 Patents.
>
> [W]e gave Zydus a covenant not to sue on the '485 Patent in the prior case, but the covenant was limited to Zydus' ANDA 'as produced to Takeda,' and does not cover the amended formulation.
>
> Further, the notice letter asserts that Takeda dismissed the '942 and '292 claims 'with prejudice' in the prior case. But that dismissal was of 'claims that were brought in this action' or which 'could have been brought in this action'. We don't think it would apply to a new case on an amended formulation.

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13 Although not pertinent at this point because Takeda dismissed its claims, *see infra*, a defendant is liable for infringement under 35 U.S.C. § 271(a) if it "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." Intent is usually irrelevant. *Soitec, S.A. v. Silicon Genesis Corp.*, 81 Fed. App'x. 734, 737 (Fed. Cir. 2001). A plaintiff bears the burden to prove infringement by a preponderance of the evidence. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984).

14 Takeda waived attorney-client privilege, an issue I discuss *infra*.

> With respect to the '994 Patent, Zydus relies on the 400 µm cut-off for particle size. You will recall that after the appeal in the prior case in which the Federal Circuit rejected Judge Pisano's 400 µm (+/-10%) claim construction, the matter was remanded to him for proceedings on the doctrine of equivalents. Judge Pisano held that we had waived such a claim by not presenting evidence at trial. Although we filed a notice of appeal to the Federal Circuit, we did not pursue it and the prior case came to an end. It is our view that the DOE decision in the prior case does not present a bar to a DOE claim in what will be a new case. It was not a decision on the merits, but simply a procedural matter.
>
> Another issue from the prior litigation which Zydus will push should we file suit, is their reliance on *Bayer v. Elan*, 212 F.3d 1241 (Fed. Cir. 2000). You will recall that there is language in that case to the effect that an ANDA filer can rely on the content of the ANDA to argue that the ANDA product will not infringe a particular patent. During the course of the prior litigation, Zydus added to its ANDA an 'In-Process Specification' to the effect that its particles would be no smaller than 450 microns. Zydus argued that, since any smaller particle would be discarded and not included in its commercial product, it could not infringe the '994 Patent and Judgment should be entered for it. Without detailing the arguments back and forth, Judge Pisano rejected Zydus' position. His reasoning that is most relevant for this case is the fact that we had actually tested Zydus' product and had expert testimony that it fell within the particle size limitation as construed by the Court. In short, evidence of infringement based on testing supersedes representations in the ANDA.
>
> In the current situation, should we sue, we would have new tests conducted on the new product and would make a decision whether to pursue the case based on actual testing.
>
> Zydus' letter includes an 'Offer of Confidential Access'. Without detailing its deficiencies, the principal one is that there is no offer to provide us with products to test. Our practice in the prior cases has been to sue and conduct the tests, without seeking to negotiate the OCA. We would recommend the same practice in this case.

Id. ¶¶ 89-95; *see also id.* ¶¶ 98-101 (describing, at deposition, the usual practice of obtaining testing samples in cases like this, the fact that the doctrine of equivalents "expands potentially the breadth of the patents" but was not litigated before Judge Pisano, the "prior history in this case, that such assertions [in the ANDA] are not always true, [and] the previous history regarding testing of samples where certain assertions are made about the in-process and the eventual result of that testing," and counsel's "prior experience in litigating against other generic manufacturers of

Prevacid SoluTab [where] infringement cannot be determined until samples . . . are obtained and tested").

In short, although Takeda did not accept Zydus' OCA or review its full ANDA before bringing suit, did not possess explicit evidence of infringement, did not respond to Zydus' entreaties to negotiate, and admitted that Zydus' product likely did not infringe, Takeda's patent lawyers nonetheless evaluated in detail Zydus' Paragraph IV Certification and the parties' litigation history, and recommended suing. Takeda also did not request samples before bringing suit, but Takeda's counsel testified at his deposition that "generally speaking . . . it's not feasible to get samples of [] products within the 45 day notice period." *Id.* ¶ 123; *id.* ¶ 121 ("It can take some months [to test product samples] to my understanding."). Similarly, Zydus' counsel testified in a hearing on discovery issues: "Do you know how hard it is to get in a sample into the United States at this moment . . . I've had so many drugs held up by the Post Office because now they're watching these things like a hawk." *Id.* ¶ 120.

ii. Takeda's Conduct During Discovery and Its Voluntary Dismissal

The parties also dispute whether Takeda dragged out its lawsuit unnecessarily in order to delay Zydus' entry into the Prevacid market. Takeda first wrote to Zydus to request samples on March 27, 2018, about six weeks after initiating litigation and one week after Zydus indicated that it would file antitrust counterclaims. *Id.* ¶ 105. Takeda noted at the time that the OCA "contain[ed] no promise . . . to provide tablets and particles for testing," which "rendered [it] unacceptable." *Id.* ¶ 106. Takeda believed—and asserted—that it was "entitled under the law to test the product that embodies the new formulation; if such testing leads us to conclude there is no infringement, we will drop the case, as we have done in the past with Mylan, Lupin, and Teva's second formulation." *Id.* ¶ 108.

Zydus filed its Answer on March 29, 2018, at which time it asserted the pending antitrust counterclaims, but did not respond to Takeda's sample inquiry. *See* ECF No. 22. That day, Takeda reiterated to Zydus that "tablets and particles are critical items, and you have neither produced those or offered to do [so]." Pl. SUMF, ¶ 111. No response followed. On April 24, 2018, after the parties' Rule 26(f) conference and several "prior requests," Takeda inquired again about sample tablets. *Id.* ¶ 112. This time, it asked for "500 unexpired samples of each of Zydus' 15 mg and 30 mg tablets . . . . [and] 150 grams of each of Zydus' unexpired enteric-coated granules and mannitol-coated granules." *Id.* ¶ 113. According to Takeda, these amounts derived from a ruling in a different case on the same patents, wherein the Hon. Mary Judge L. Cooper, U.S.D.J. (retired), raised issues about Takeda's testing methods and validation protocols. *Dexcel Pharma Techs. Ltd. v. Takeda Pharma. Co. Ltd.*, No. 16-04957 (D.N.J. Apr. 27, 2017). Zydus finally replied that, while it was "willing to make samples available," Takeda wanted "excessive and unwarranted" amounts. Pl. SUMF, ¶ 114. Zydus then offered "between 40 [and] 100 tablets of each strength—and granule samples in the range of 1 gram if such are available." *Id.* Zydus also stated that Takeda "never made any 'prior requests' for samples," *id.* ¶ 115, presumably because Takeda did not specify an exact amount until April 24. *Id.*

Zydus ultimately sent Takeda "1 Box containing 100 tablets (10 x 10 unit dose) of 15mg" and "1 Box containing 100 tablets (10 x 10 unit dose) of 30mg" on May 17, 2018. *Id.* ¶ 118; Def. Supp. SUMF, ¶ 177. After Takeda insisted that it needed more samples for testing, consistent with Judge Cooper's observations in *Dexcel*, Zydus sent one more box of each dosage on June 11, 2018. Pl. SUMF, ¶ 119. One month later, after analyzing preliminary test results, Takeda's counsel "recommend[ed] dismissing the current suit against Zydus." *Id.* ¶ 124. Takeda agreed, and informed its employees on July 16, 2018. *Id.* ¶ 125 ("[W]e have concluded that we no longer have

a reasonable basis to move forward with this litigation."). Takeda sent Zydus a draft Stipulation of Dismissal on July 18, 2018. *Id.* ¶ 126. I granted the Order on July 26, 2018, at which point the 30-month stay lifted. *Id.* ¶ 127; ECF No. 55. In all, the litigation lasted five months. Zydus declined to dismiss its antitrust counterclaims, Def. Supp. SUMF, ¶ 181, and I denied Takeda's request to dismiss the counterclaims at that time. *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 395 (D.N.J. 2018).

E. The Parties' Summary Judgment Motions

Both parties now move for summary judgment on Zydus' antitrust counterclaims. Takeda contends that its infringement suit is protected First Amendment activity under *Noerr-Pennington*, which immunizes citizens who "petition the government for redress" from antitrust liability, *Noerr*, 365 U.S. at 127; *Pennington*, 381 U.S. at 657, and it asks me to reject Zydus' counterclaims in full on that basis. Zydus responds that Takeda weaponized the 30-month stay to maintain monopoly power over Prevacid, even though the FDA was "prepared to grant final approval to [Zydus'] ANDA as early as February 2018, immediately after the expiration of the 45-day notice period." Def. Supp. SUMF, ¶¶ 109, 111-12, 199-200 (stating that the 30-month stay "lessened the [FDA's] urgency to act on the ANDA" because the agency "often applies its limited resources to other matters instead of . . . ANDAs that are subject to [a stay]"). Accordingly, Zydus argues, Takeda's suit falls under the narrow "sham litigation" exception to *Noerr* immunity. Takeda, in turn, insists that it had both an objective and subjective basis to sue, which by definition means that its suit could not be a sham. *Wellbutrin*, 868 F.3d at 146. Takeda also contends that, even if *Noerr* is not a bar to liability, Zydus has failed to demonstrate a substantive antitrust injury because it cannot show that Takeda's lawsuit—the alleged anticompetitive act—delayed its market entry. Rather, according to Takeda, FDA regulations and Zydus' own actions/inactions "stymied" it.

II. LEGAL STANDARD

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits if any, . . . demonstrate the absence of a genuine issue of material fact" and that the moving party is entitled to a judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (quotations omitted); Fed. R. Civ. P. 56(a). An issue is "genuine" when "a reasonable jury could return a verdict for the non-moving party." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). A fact is "material" when it "might affect the outcome of the suit under the governing law." *Id.* I construe all facts in the light most favorable to the nonmoving party, *see Boyle v. Cty. of Allegheny Pa.*, 139 F.3d 386, 393 (3d Cir. 1998), whose evidence "is to be believed," and I make "all justifiable inferences . . . in [its] favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004); *see also Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007).

The moving party "always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex*, 477 U.S. at 323. That party may discharge its burden by "showing — that is, pointing out to the district court — that there is an absence of evidence to support the nonmoving party's case when the nonmoving party bears the ultimate burden of proof." *Singletary v. Pa. Dep't of Corr.*, 266 F.3d 186, 192 n.2 (3d Cir. 2001) (quotations and citations omitted). The nonmoving party must then identify, by affidavits or otherwise, specific facts showing that there is a triable issue. *Celotex*, 477 U.S. at 324. To do so, the nonmoving party "may not rest upon the mere allegations or denials of the . . . pleading[s]." *Saldana v. Kmart Corp.*, 260 F.3d 228, 232 (3d Cir. 2001) (quotations omitted). Instead, "[it] must make a showing sufficient to establish the existence of [every] element essential to [its] case, and on which [it] will bear the burden of proof at trial." *Cooper v. Sniezek*, 418 Fed. App'x. 56, 58 (3d Cir. 2011)

(quotations and citations omitted). "While the evidence that the non-moving party presents may be either direct or circumstantial, and need not be as great as a preponderance, [it] must be more than a scintilla," *Hugh v. Butler Cnty. Family YMCA*, 418 F.3d 265, 267 (3d Cir. 2005), and conclusory declarations, even if made in sworn statements, will not suffice. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990).

III. DISCUSSION

In what the Third Circuit has called "sweeping language," *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007), the Sherman Act makes it unlawful for a firm to monopolize or attempt to monopolize trade. 15 U.S.C. § 2. Despite § 2's far-reaching prohibition on monopolistic practices, "[t]hose who petition government for redress are generally immune from antitrust liability." *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) [hereinafter *PRE*]. The archetype example is litigation. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510, 515 (1972) (holding that "the right to petition extends to all departments of the Government"); *PRE*, 508 U.S. at 60 (extending *Noerr* to patent suits); *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 361 (D.N.J. 2009) (applying *Noerr* to same). Courts will nonetheless withhold immunity, and subject a firm to antitrust liability, if it files a lawsuit as "a mere sham." *Noerr*, 365 U.S. at 144.

The Supreme Court has outlined a "two-part definition of 'sham' litigation." *PRE*, 508 U.S. at 60. "First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* Second, the lawsuit must "conceal 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 60-61 (internal quotations and citations omitted). "This two-tiered process requires

the [party alleging an antitrust violation] to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability." *PRE*, 508 U.S. at 61 (emphasis in original); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 311 (E.D. Pa. 2011) ("[T]he burden falls on the party invoking the sham exception . . . to show that the conduct at issue constitutes a sham.").

The sham litigation exception is narrow. "[A]n objectively reasonable effort to litigate cannot be a sham regardless of subjective intent." *PRE*, 508 U.S. at 58. "If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr,* and an antitrust claim premised on the sham exception must fail." *Id.* at 60. A winning lawsuit by definition is not a sham, but a losing one rarely denotes the opposite. *Christiansburg Garment Co. v. EEOC*, 434 U.S. 412, 421-22 (1978). Courts must resist the temptation to engage in *post-hoc* reasoning whereby they deem a suit a sham merely because it ultimately fails. *Hughes v. Rowe*, 449 U.S. 5, 14-15 (1980) (per curiam). Further, "[e]ven when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit." *Christiansburg*, 434 U.S. at 422.

This is especially true in the context of Hatch-Waxman, where "applying the sham-litigation standard is a delicate task" because of competing "congressional policy" and the fact that a "First Amendment right . . . is at stake." *Fed. Trade Comm'n v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020). On the one hand, I must not "penalize a brand-name manufacturer whose 'litigiousness [is] a product of Hatch-Waxman,'" *Wellbutrin*, 868 F.3d. at 158 (quoting *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009)), which "incentivizes [brands] to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so." *Id.* at 157-58. To reflexively rely on the sham litigation exception

would "punish behavior that Congress sought to encourage." *Id.* at 158. A party alleging sham litigation hence faces an "uphill battle." *Id.* at 147. That hill is "steeper" still "in the context of an ANDA case." *AbbVie*, 976 F.3d at 361. On the other hand, courts "must not immunize a brand-name manufacturer who uses the . . . 30-month stay to thwart competition," which would "excuse behavior that Congress proscribed in the antitrust laws." *AbbVie*, 976 F.3d at 361.

What is more, "even a plaintiff who defeats [a] defendant's claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham must still prove a substantive antitrust violation. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim." *PRE*, 508 U.S. at 61. Liability under § 2 requires antitrust standing, *see Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997) ("Antitrust injury is a necessary . . . condition of antitrust standing."), plus "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

Finally, whether litigation is a sham "is generally a question of fact for the jury." *Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co.*, 760 F.2d 607, 612 n.9 (5th Cir. 1985); *Catch Curve, Inc. v. Venali, Inc.*, 519 F. Supp. 2d 1028, 1037 (C.D. Cal. 2007) ("[W]hether something is a genuine effort to influence governmental action, or a mere sham, is a question of fact.") (quoting *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1253 (9th Cir. 1982)); *Kravco Co. v. Valley Forge Ctr. Assocs.,* No. 91-4932, 1992 WL 97926, at *3 (E.D. Pa. Apr. 30, 1992) ("Whether or not the acts of the defendants fit the sham exception is a factual issue."). But "if there is no dispute over the predicate facts of the underlying legal

proceeding," rather only a dispute over whether those facts are "sufficient to establish probable cause for the objective baselessness inquiry," as here, then the Court faces "a legal question, not a factual one," which it may appropriately decide at summary judgment. *Wellbutrin*, 868 F.3d at 151 (citing *PRE*, 508 U.S. at 60-61); *Stewart v. Sonneborn*, 98 U.S. 187, 194 (1878) ("[P]robable cause is a question of law in a very important sense . . . . Whether the circumstances alleged to show it probable are true, and existed, is a matter of fact; but whether, supposing them to be true, they amount to a probable cause, is a question of law."); *cf. In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 361 (D. Mass. 2004) (finding that "'the facts tending to establish the existence or want of existence of probable cause' were disputed, rendering the question inappropriate for decision as matter of law") (citation omitted).

A. Noerr Immunity

i. Objective Baselessness

A lawsuit is not objectively baseless if it is supported by the equivalent of probable cause, which "irrefutably demonstrates" immunity and constitutes "an absolute defense" to antitrust liability. *PRE*, 508 U.S. at 63; *AbbVie*, 976 F.3d at 360. Probable cause in this context refers to a "reasonable belief that there is a chance that a claim may be held valid upon adjudication." *PRE*, 508 U.S. at 62-63 (internal quotations, citations, and alterations omitted); *see also id.* at 65 (finding defendant immune because "[a]ny reasonable [litigant] . . . could have believed that it had some chance of winning"). Showing that the law or the facts are "questionable or unfavorable at the outset" is not enough, *PRE*, 508 U.S. at 61 n.5, nor is showing that the infringement claim "would have been subject to a serious defense" or is doubtful. *United Food & Com. Workers Unions & Employers Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 15 (1st Cir. 2018).

1. The Paragraph IV Certification[15]

Zydus attempts to carry its burden by arguing that its 2018 Paragraph IV Certification foreclosed all reasonable grounds for suit—on its own terms, and especially in light of *Zydus I*, *II*, and *III*. Zydus begins by pointing to the declaration in its Certification that its generic does not infringe Prevacid, which it asserts Takeda should have taken at face value. I do not agree. A boilerplate noninfringement assertion in an ANDA is insufficient to demonstrate objective baselessness, just like "[t]he occurrence of the defined 'act of infringement' [by filing the ANDA] does not determine the ultimate question whether what will be sold will infringe any relevant patent." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Not only did Judge Pisano reject an identical argument in 2013, when he reopened discovery after Zydus first amended its ANDA, but suing is a common way for a brand-name to obtain further information about a generic's product, notwithstanding an ANDA's representations. *See, e.g.*, *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995) ("Once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit.");

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15 Zydus' Paragraph IV Certification constituted a legal act of infringement under 35 U.S.C. § 271(e)(2)(A). Some courts have suggested a suit is not objectively baseless for that reason alone. *See AstraZeneca AB v. Mylan Lab'ys, Inc.*, No. 00-6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) ("[A]t the outset of Astra's case, Mylan gave Astra an objectively reasonable basis to sue: Mylan provided Astra notice of its Paragraph IV certification. This is an act of infringement."), *aff'd sub nom. In re Omeprazole Pat. Litig.*, 412 Fed. App'x. 297 (Fed. Cir. 2011); *Celgene Corp. v. KV Pharm. Co.*, No. 07-4819, 2008 WL 2856469, at *2-5 (D.N.J. July 22, 2008) ("Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch-Waxman ANDA case the attorney need only conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed. In the instant case, the Notice Letter provided sufficient basis for an attorney to reasonably believe that a relevant ANDA had been filed, and thus that an actionable act of infringement had occurred."). Other courts have rejected the notion that a Paragraph IV Certification *ipso facto* triggers *Noerr* immunity or renders an infringement suit *per se* reasonable. *See, e.g.*, *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 656 n.10 (D.N.J. 2015). I agreed with the court in *Otsuka* when I denied Takeda's motion to dismiss. *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 395 (D.N.J. 2018). Takeda does not renew this argument on summary judgment. Pl. Br., at 12.

Warner-Lambert Co. v. Apotex Corp., No. 98-4293, 2003 WL 22887861, at *4-5 (N.D. Ill. Dec. 4, 2003) (holding that plaintiff "had the right to conduct a fair and reasonable investigation of its claims [in discovery]"). The entire purpose of the 45-day notice period is to give the brand-name manufacturer time to evaluate the noninfringement claims and decide whether to sue despite them. *Wellbutrin*, 868 F.3d at 151 n.22 ("[M]any details about the potentially infringing drug . . . cannot be known at the time a suit is filed and where there are congressionally designed pressures to file suit quickly . . . . The time limits imposed by the Hatch-Waxman Act embody a 'file-now, discover-details-later' policy, and while the merit of that policy may make for an interesting debate . . . it is not our place—nor was it GSK's—to take that debate on.") (internal citations omitted); *AstraZeneca AB v. Mylan Lab'ys, Inc.*, No. 00-6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) ("[A] reasonable plaintiff in a Hatch-Waxman case would be expected to know few details about the accused product at the outset of litigation and plaintiff's counsel may reasonably rely on discovery to learn the material details."). In short, an ANDA filer cannot rest on its own *ipse dixit* to defeat *Noerr* immunity,[16] and Takeda need not take Zydus' word that "nothing" in its new formulation "ha[d] changed." Def. SUMF, ¶ 108.

Zydus next points to specific language in its 2018 Paragraph IV Certification to demonstrate that Takeda lacked a basis to sue. The gist of Zydus' theory is that this "not an ordinary case" because "the patents at issue have already been litigated." Def. Rep. Br., at 6. In light of that history, Zydus posits, "there is no longer any ambiguity . . . that would warrant looking

16 The Federal Rules of Civil Procedure also contemplate a liberal discovery process, *see Katz v. Batavia Marine & Sporting Supplies, Inc.*, 984 F.2d 422, 424 (Fed. Cir. 1993), and the purpose of 35 U.S.C. § 271(e)(2)(A)'s cause of action is to allow courts to promptly resolve infringement disputes using it. *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) ("[W]hile the Paragraph IV Certification provides the legal trigger for an infringement action, the inquiry truly begins [at the time of suit].").

beyond the specifications in the amended ANDA for Zydus' reformulated product." *Id.* at 15. Zydus' Paragraph IV Certification states in relevant part:

> Zydus's amended ANDA [ ] still requires that its fine granules of common pellets, used in its lansoprazole orally disintegrating tablets to have a d_{50} of not less than 440 µm . . . well above the hard cutoff dictated by the District Court and the Federal Circuit Opinions . . . . In short, due to . . . no change being made with respect to the fine granule average particle size being above 400 µm as delineated in Zydus' In-process Specification set forth in ANDA No. 200816, Zydus's amended ANDA Product cannot infringe any of the claims of the '994, '485, '942 and '292 patents.

Pl. SUMF, ¶¶ 80, 83. Zydus reads this to mean that the only drug it could lawfully make is one that did not infringe Prevacid, since the Certification specifies a particle diameter greater than 400 µm. For support, Zydus relies on *Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), where the Federal Circuit held that an ANDA that recites a particle size "falling outside the range claimed in the relevant patents" resolves the infringement inquiry in favor of the ANDA filer. *Id.* at 1248-50. Zydus correctly describes the holding in *Elan*, but the Federal Circuit has otherwise rejected a position like the one Zydus now takes, reasoning that it "ignores other decisions of this court, and language in *Elan* itself, that could give a patentee in [Takeda's] position a reasonable expectation of a favorable outcome even though the generic manufacturer's ANDA application describes a generic drug with characteristics that take it outside the patent's claims." *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014). The question is not solely what an ANDA or Paragraph IV Certification recites, but whether the product the generic will sell will infringe, which "can occur in spite of the ANDA specification if, for example, the ANDA is based on faulty testing or screening procedures." *Id.* That is, 35 U.S.C. § 271(e)(2)(A) contemplates "an infringement inquiry focused on what is likely to be sold following FDA approval," which "must be based on all of the relevant evidence including the ANDA" but certainly not limited to it. *Glaxo*, 110 F.3d at 1568. *Elan* itself recognizes as much in

language Zydus does not discuss. 212 F.3d at 1248-49 ("[I]t is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder."); *see also Inline Packaging, LLC v. Graphic Packaging International, Inc.*, No. 15-3183, 2016 WL 7042117 at *19 (D. Minn. July 25, 2016) (stating that relevant evidence may include "the patent holder's history of litigation regarding the specific patent at issue" and "evidence concerning the extent of the patent holder's investigation of possible infringement of the patent at issue").

Here, Takeda had enough information on hand at the time it filed suit to proceed with a second infringement action, which would not *necessarily* meet the same fate as the one in 2014, Zydus' new ANDA aside. First, when Takeda tested Zydus' product after Judge Pisano reopened discovery, it found that Zydus' particles did not conform to the size specified in its ANDA, despite its in-process quality control mechanism, raising the likelihood of an ongoing or recurring discrepancy between purported and actual particle size, or "faulty" screening procedures insufficient to discard smaller particles. *Accord Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1346-47 (Fed. Cir. 2002) (holding that "nearly identical" ANDA in second infringement action did not directly resolve case, and ordering district court to consider evidence outside the ANDA). Zydus, of course, responds with the Federal Circuit's decision in *Zydus II*, which held that the '994 patent did not require deagglomeration before testing. With that measurement technique, Zydus' particles literally infringed Prevacid, but without it, they did not. *Compare* Pl. SUMF, ¶¶ 37-38, *with* Def. SUMF, ¶ 29. In light of *Zydus II*, Zydus contends, a reasonable litigant evaluating its 2018 Paragraph IV Certification could not have expected literal infringement.

If Takeda sued immediately after *Zydus II*, on the very same formulation as was at issue in that case, Zydus may well be right. But that did not happen. Most significantly, the FDA rejected

Zydus' ANDA around the same time as *Zydus II* because the particles risked clogging patients' feeding tubes, a "serious safety concern" similar to the one Teva faced in 2011. Pl. SUMF, ¶¶ 49-55. The FDA then suggested a reformulation. Zydus admits that the ANDA underlying this litigation "intended to address [these] issues," primarily by introducing an anti-swelling agent. Def. SUMF, ¶¶ 56-57. Zydus' recertification process with the FDA post-*Zydus II* lasted over three years and involved multiple revisions. *See, e.g.*, Pl. SUMF, ¶¶ 53-54, 56-58, 60-62; Def. SUMF, ¶¶ 61, 63, 65, 69, 71. Zydus designated the changes to its ANDA as "MAJOR" during this process. Pl. SUMF, ¶ 55. Likewise, the FDA does not require a generic to recertify an amendment unless the generic makes certain *critical* changes. 21 C.F.R. § 314.96(d)(1) (requiring an ANDA filer to recertify if it seeks to "to add a new indication . . . strength . . . make other than minor changes in a product formulation[,] or to change the . . . structure of the active ingredient"). The FDA did just that here. Pl. SUMF, ¶¶ 66, 72-74, 76; Def. Supp. SUMF, ¶ 79. These facts permit a non-baseless inference that Zydus may have changed its generic in a way that was material to the literal infringement analysis. *Accord Glaxo*, 110 F.3d at 1569 (holding that, "where the subject matter is a compound capable of existing in multiple crystalline forms, or mixtures thereof, the ultimate question of infringement is not so simple").

Takeda also knew that generics had long struggled to obtain FDA approval because their products had larger particles. That is why Teva withdrew its initial formulation in 2011, *see* Pl. SUMF, ¶ 17, and why the FDA rejected Zydus' ANDA around 2014. *Id.* ¶¶ 49-50. This further suggests that Zydus may have decreased its particle size to win approval. Indeed, Takeda proceeded in a similar manner—sue, conduct discovery, and dismiss if necessary—with three other generics without issue. Pl. SUMF, Ex. 53 ("Our practice in the prior cases has been to sue and conduct the tests, without seeking to negotiate [access to the ANDA]."); *id.*, Ex. 54 ("[I]f such

testing leads us to conclude there is no infringement, we will drop the case, as we have done in the past with Mylan, Lupin, and Teva's second formulation."). In each of these instances, Takeda and the generic had litigated Prevacid's patent previously, but that did not bar a second infringement action. *Id.* ¶ 15 (listing cases). This warrants the conclusion that Takeda had sufficient reason to question Zydus' representations on particle size, regardless of its 2018 Paragraph IV Certification in combination with *Zydus II*, and probable cause to sue to that extent.[17] *Accord Wellbutrin*, 868 F.3d at 150 (holding that brand-name had enough information from mere "excerpt" of ANDA to "suggest[]" that noninfringement claim "was, or at least could be, infirm"). Zydus' contrary position underestimates the extent of the temporal, factual, and competitive differences in 2018, and the intervening series of events. *See, e.g.*, *Ben Venue Lab'ys, Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 583-84 (D.N.J. 2001) (Because as a matter of law the analysis in that infringement action must examine not just the product covered by [the ANDA's] original certification but the product that Ben Venue now seeks to market, the Court must necessarily consider the 'new formulation.'").

Even if Takeda had "no information" that Zydus' generic literally infringed Prevacid when it sued for a second time, *see* Def. Br., at 18, or that Zydus made changes to its particles since *Zydus II*, Takeda had a non-frivolous Doctrine of Equivalents ("DOE") claim, under which "[t]he scope of a patent . . . embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002). Takeda did not assert a DOE claim in

17 Zydus also argues that Takeda knew its particles did not infringe Prevacid because, in 2016, Takeda said so in internal documents. Def. SUMF, ¶¶ 162-67 ("Mylan, Lupin, Zydus lawsuits dismissed; all can launch if they obtain FDA approval . . . . all of their products' particles substantially greater than 400 mc."). Takeda's statements refer to Zydus' prior formulation, as adjudicated in *Zydus I*, *II*, and *III*, not the reformulation in its 2018 ANDA. They do not establish objective baselessness because Takeda had probable cause to believe that the formulation may have changed in the interim in a manner relevant to its Prevacid patent.

Zydus I or *II*, but attempted to do so on remand in *Zydus III*. Without reaching the merits, Judge Pisano deemed it waived. *Zydus III*, 2014 WL 12629965, at *2 ("Having not pursued an infringement claim under the doctrine of equivalents at trial, Plaintiff cannot do so now. The Court finds Plaintiff has waived that claim."). As a procedural ruling addressing a prior formulation, Judge Pisano's decision on waiver would not have foreclosed Takeda's DOE claim in this litigation. Zydus does not contend otherwise. Zydus does, however, point to the Federal Circuit's decision in *Zydus II* for the proposition that no reasonable litigant could have believed it would win on equivalence. While I tend to agree with Zydus that Takeda's DOE claim faced steep odds, I disagree that *Zydus II* foreclosed *any* chance of winning. In *Zydus II*, the Federal Circuit found Zydus' particles to fall outside of the literal terms of Claim 1 when tested without deagglomeration. But a DOE claim focuses on whether a generic made "insubstantial changes and substitutions . . . which, though adding nothing, could be enough to take the copied matter outside the claim, and hence outside the reach of the law." *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)). The test is whether "an element of an accused product 'performs substantially the same function in substantially the same way to obtain the same result.'" *Id.* (quoting *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1376 (Fed. Cir. 2008)). A DOE claim is available even if a patent recites a specific numerical value or range, as with Prevacid. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1291-93 (Fed. Cir. 2010) (collecting cases); *U.S. Philips Corp. v. Iwasaki Co.*, 505 F.3d 1371, 1378 (Fed. Cir. 2007).[18] Zydus seems to recognize as much. *See, e.g.*, Def. Rep. Br., at 1 ("The Federal Circuit

18 Judge Cooper analyzed—though ultimately rejected—a DOE claim on Prevacid's patent in *Dexcel*. a different case. No. 16-04957, slip op., at 58, 63. However, the reasons for her decision are specific to the generic at issue in that case, *see* Def. Rep. Br., at 11 n.2, and would not necessarily foreclose any chance of winning a DOE claim here.

cited Takeda's inaccurate measurement . . . *solely* to demonstrate that . . . 'there can be no dispute that Zydus' ANDA product does not *literally infringe*.'") (quoting *Zydus II*, 965 F.3d at 1365) (some alterations added). In this sense, *Zydus II* does not directly address equivalence, and does not suggest what level of variance from Takeda's particle size would be "substantially" versus "insubstantially" different under the DOE.

Zydus responds that "merely identifying a *possible*, albeit nebulous, DOE argument" is not enough to establish *Noerr* immunity. Def. Br., at 22. But that is more or less the standard for objective reasonableness. *Wellbutrin*, 868 F.3d at 148 ("A litigant has probable cause to initiate a suit if the litigant has 'a reasonable belief that there is *a chance* that a claim may be held valid.'") (emphasis added). Zydus also relies on *AbbVie*, where the Federal Circuit found an infringement suit against Perrigo (but not one against Teva) to be objectively baseless because the brand-name expressly narrowed its patent during prosecution to disclaim the relevant ingredient in Perrigo's product, such that Perrigo could not infringe under what is known as prosecution history estoppel. 967 F.3d at 366. Supreme Court precedent said so directly and explicitly. *Id.* at 366-67 ("[A]ny reasonable person who reads the prosecution history . . . can reach no other conclusion than that the defendants have purposefully and not tangentially excluded [the relevant ingredient].") (citing *Warner-Jenkinson Co. v. Hilton Davis Chem Co.*, 520 U.S. 17 (1997)). As such, the Federal Circuit held, AbbVie's DOE claim against Perrigo "must have been motivated by something other than success on the merits." *Id.* at 370.

Zydus attempts to set this case on equal footing with *AbbVie* by claiming that "Takeda [ ] disclaimed 'conventional granules' with average particle diameters above 400 μm" in *Zydus II*. Def. Br., at 3, 11-12. Zydus points to the Federal Circuit's claim construction in that case for support. The flaw in Zydus' position is that it does not provide any authority equating an adverse

claim construction to prosecution history estoppel, or applying that exception where the estoppel-creating event is a federal court decision rather than a manufacturer's own actions before the Patent & Trademark Office, which "surrender" certain subject matter. *See, e.g.*, *Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015) (holding that exception applies when "an application *during prosecution* . . . narrows a claim to avoid the prior art or otherwise address a specific concern . . . that arguably would have rendered the claimed subject matter unpatentable") (emphasis added); *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013) (holding patentee cannot use DOE to "recapture subject matter surrendered from the literal scope of a claim during prosecution"). At the very least, the law is unclear on whether prosecution history estoppel would extend to these circumstances, where a second infringement suit arises in a different factual scenario after a court narrowed a patent's claim in the first suit. And a "suit is not a sham if the state of the law is 'uncertain.'" *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1358 (S.D. Fla. 2004); *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 462 (D.N.J. 2003) (concluding same).

In short, if Takeda had no "evidence" that Zydus' product might fall within or close to Prevacid's range and outside of the ANDA's, and Takeda did not "allege that the generic manufacturer's commercial product would infringe in spite of the ANDA," as in *Elan*, then there likely would not be "a legitimate question" under 35 U.S.C. § 271(e)(2)(A) about whether Zydus might "make a . . . product that [] infringes." *Elan*, 212 F.3d at 1249 & n.6; *Bayer*, 279 F.3d at 2346-47. Zydus likely could, in turn, show objective baselessness by resting on the representations in its ANDA coupled with *Zydus II*. Zydus is certain that is the case here. Nothing that has happened since 2013, it argues, calls for a different conclusion than the Federal Circuit reached on its original formulation. Ultimately, Zydus turned out to be right, and Takeda voluntarily dismissed

its suit. Takeda even knew its odds were long before this litigation began. Pl. SUMF, Ex. 53 ("As a practical matter, we think it unlikely that Zydus infringes."). But that does not mean that, at the time Takeda sued, it had *no* reason to perceive *some* chance of winning, a small bar indeed for invoking *Noerr* immunity. *Wellbutrin*, 868 F.3d at 150 ("[T]he fact that one might conclude, after a thorough investigation, that [the] ANDA did not definitively indicate that the product infringed the patent does not mean that it was unreasonable for [the patent holders] to file their suit."); *Bayer*, 279 F.3d at 1346 (rejecting collateral estoppel in second suit on the same patent, a "nearly identical ANDA," and a "very similar issue"); *Tyco*, 762 F.3d at 1345-46 ("[I]t will be a rare case in which a patentee's assertion . . . will be so unreasonable as to support a claim that the patentee has engaged in sham litigation.").

There is enough evidence in the record here to establish probable cause to sue, even if failure was more likely than not: some samples in *Zydus I* tested under 450 μm both with and without deagglomeration, indicating a potentially imperfect in-process specification or an ongoing inconsistency between claimed and actual particle size; Zydus amended its ANDA several times both during and after *Zydus II*, over the course of three years, partly in response to FDA concerns about particle swelling; Zydus designated the changes to its ANDA as major during this time; the FDA required recertification in 2018, which it will only do for certain types of amendments; Takeda did not pursue a DOE claim in *Zydus I*, under which literal infringement is irrelevant; an excipient change can entail a particle change, even if unintended, *see infra*; in the past generics failed to develop an approvable Prevacid product due to problems with particle size; and in the past Takeda sued to test products in discovery without issue. *Accord Tyco*, 762 F.3d at 1345 ("[I]t is not unreasonable for a patent owner to allege infringement under section 271(e)(2)(A) if the patent owner has [factual] evidence that the as-marketed commercial ANDA product will infringe,

even though the hypothetical product specified in the ANDA could not infringe."); *Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002) (stating, post-*Elan*, that "other evidence may directly contradict the clear representations of the ANDA and create a dispute . . . regarding the identity of the compound that is likely to be sold following FDA approval"); *Bayer*, 279 F.3d at 1346 (finding a declaration from a professor sufficient evidence).

2. Zydus' Other Counterarguments

Zydus' remaining arguments do not compel a different conclusion. Zydus first faults Takeda for failing to review its full ANDA during the 45-day notice period. A reasonable litigant would not have passed up that opportunity, Zydus claims. Had Takeda taken up the offer, it could have learned that Zydus' formulation altered the "excipients" or "inactive ingredients" only, and its particles averaged 450 μm after testing. That may well be true, but Congress has never required a brand-name to request or review more than a Paragraph IV Certification during the 45-day notice period. 21 U.S.C. § 355(b)(3)(D); 21 C.F.R. § 314.95(c)(7); *Wellbutrin*, 868 F.3d at 150 (confirming suit was reasonable even though patent holder had access to "an excerpt of the [] ANDA" only). Zydus' position to the contrary would impose a burdensome and extra-statutory requirement on brand-names in Hatch-Waxman cases. *Celgene Corp. v. KV Pharm. Co.*, No. 07-4819, 2008 WL 2856469, at *4 (D.N.J. July 22, 2008) ("KV seeks to impose on pharmaceutical patent owners who have received a paragraph IV notification an obligation to perform a *Q-Pharma* infringement analysis in the limited time period that the Act allows for filing suit. The Act sets a time limit on instituting suit that . . . makes it quite difficult for a patent owner to perform the kind of analysis that KV contends is necessary . . . . If this Court were to grant KV's motion, it would put pharmaceutical patent owners in an untenable position. After receipt of notification of an ANDA application for a generic pharmaceutical, the patent owner would need to conduct

what is likely to be a highly technical infringement analysis, make the decision to file suit, and then do so, all within 45 days."); *Eisai Co. v. Mut. Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *13 (D.N.J. Dec. 20, 2007) ("[A] Paragraph IV certification triggers a 30-month stay of FDA approval of the ANDA if the patent holder, *upon receiving ANDA Notice* [which accompanies the Paragraph IV Certification], files [an] infringement action within [45 days].") (citations omitted) (emphasis added). In any event, by plain statutory language, Zydus *had* to present the OCA, but Takeda did not *have* to accept it. 21 U.S.C. § 355(j)(5)(C)(i)(III); *Nycomed US Inc. v. Tolmar, Inc.*, No. 10-2635, 2011 WL 1675027, at *5 (D.N.J. Apr. 28, 2011) ("[T]he process clearly set forth in the confidential access provision of the [Hatch-Waxman] Act . . . contemplates an offer of confidential access.").

Even if (based on the Paragraph IV Certification or full ANDA) Takeda knew that Zydus changed only its excipients, the fact remains that a new excipient *can* affect particle size, and it would not have been unreasonable for Takeda to take that position given the circumstances here. Three pieces of evidence support this. First, the excipients in Zydus' 2014 formulation in part caused patients' feeding tubes to clog by causing particles in the formulation to swell. Pl. SUMF, Ex. 22. Second, Zydus added citric acid to its reformulation to reduce swelling, which was present in Prevacid all along. *Id.* Copying that ingredient meant Zydus' "pellets size [did] not change significantly" when administered through a syringe or a feeding tube. *Id.* With decreased or minimized swelling could come smaller average particles, even if unintentional. Pl. Supp. SUMF, ¶ 4 (quoting deposition testimony stating that "[w]e had a long experience with testing these products where formulation changes implicate particle size"). Third, a new excipient may entail a different manner or degree of clumping, even if it does not change each clumped particle's individual diameter. Since the Federal Circuit construed the '994 patent to measure particle size in

clumps, or "hard agglomerates" where granule cores fuse together, a new excipient could have altered the measurements.

Zydus also argues that Takeda did not conduct a sufficient pre-suit investigation because it did not request samples to test during the 45-day notice period, but waited until discovery to do so. Def. Br., at 19-21. "The resolution of the question whether plaintiffs' suit is objectively baseless . . . involves the determination of whether plaintiffs undertook a reasonable investigation before filing suit [and] whether plaintiffs knew or should have known that Genpharm had not infringed the … patents." *Hoffman-LaRoche, Inc. v. Genpharm, Inc.*, 50 F. Supp. 2d 367, 380 (D.N.J. 1999); *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 657 (D.N.J. 2015) ("[R]esolution of these inherently factual issues requires consideration of whether Otsuka undertook a reasonable investigation in advance of pursuing its infringement claims."). The key question is what kind of investigation constitutes a reasonable one. In these circumstances, it is sufficient that Takeda reviewed Zydus' Paragraph IV Certification and the parties' prior litigation. Hatch-Waxman does not demand more. Additionally, both parties recognize that an independent investigation into particle size during the 45-day notice period would have been a tall task. *See, e.g.*, Pl. SUMF, ¶ 123 (quoting deposition testimony from Takeda's witness stating that "generally speaking . . . it's not feasible to [even] get samples of [ ] products within the 45 day notice period"); *id.* ¶ 121 (same, but that "[i]t can take some months [to test product samples] to my understanding"); *id.* ¶ 120 (same, but from Zydus' witness stating: "[d]o you know how hard it is to get in a sample into the United States at this moment . . . I've had so many drugs held up by the Post Office because now they're watching these things like a hawk"). The present litigation largely confirms that conclusion. It took the parties several weeks to negotiate sample size, then a few more weeks to mail samples, then about a month to test them. *See infra*.

In sum, Takeda had an objective basis to sue Zydus for patent infringement despite Zydus' 2018 ANDA and *Zydus I*, *II*, and *III*. To conclude otherwise, Zydus must string together contested inferences from three years of patent litigation and three more years of ANDA revisions, which shows why Takeda's suit is not *objectively* baseless.

ii. Subjective Baselessness Prong

Assuming that Zydus could establish objective baselessness, it must still show subjective baselessness. *Campbell v. Penn. Sch. Bds. Assoc.*, 972 F.3d 213, 219 (3d Cir. 2020) ("[T]he fact that a suit may lack any objective merit is not itself determinative."). A lawsuit is subjectively baseless if a party files it "in an attempt to thwart competition (*i.e.*, in bad faith)." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014). Stated differently, a suit is subjectively baseless if a party's "actual motivation is to dragoon the 'governmental process itself' into use as a competitive tool." *Campbell*, 972 F.3d at 219. Certain "economic motivations" indicate a bare desire to harm competition or brandish the legal process—rather than the outcome of that process—as an anticompetitive weapon. Examples include: the party suing is "indifferent to the outcome on the merits . . . any damages for infringement would be too low to justify . . . investment in the suit, or [it] decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." *PRE*, 508 U.S. at 65-66.

A party's goal in initiating a lawsuit is irrelevant as long as it intends to achieve the goal by actually succeeding. *Campbell*, 972 F.3d at 227. If a party intends to succeed, then even "harboring personal animus" is insufficient to defeat *Noerr* immunity. *Id.* ("If animus alone were the test, it would readily devour the rule, since litigation is rarely sparked by feelings of warmth and amity. The protection of *Noerr-Pennington* immunity cannot be swept away by simple dislike."). Likewise, mere knowledge that filing a suit may collaterally damage a competitor is not

evidence of bad faith. *PRE*, 508 U.S. at 69 (Stevens, J., concurring) ("We may presume that every litigant intends harm to his adversary . . . [but] [a]ccess to the courts is far too precious a right for us to infer wrongdoing from nothing more than using the judicial process to seek a competitive advantage in a doubtful case."); *see also Terazosin*, 335 F. Supp. 2d at 1365. This "places a heavy thumb on the scale" for *Noerr* immunity. *Hanover 3201 Realty, LLC v. Vill. Supermarkets*, 806 F.3d 162, 180 (3d Cir. 2015).

The crux of Zydus' contention is that Takeda never intended to bring suit on the merits, but instead wanted to slow down the FDA's review process and/or keep Zydus' ANDA pending for as long as possible to pad Takeda's bottom-line. "[T]he number of lawsuits a brand-name drug manufacturer files will sometimes reveal little about its subjective motivation for suing." *AbbVie*, 976 F.3d at 361. Here, however, Takeda's reasons for suing are not unknown. It submitted a lengthy letter from outside-counsel detailing them. Pl. SUMF, ¶¶ 89-95. The letter recites several legitimate grounds for the present infringement action, including Takeda's usual practice of obtaining samples regardless of the assertions in an ANDA, its potential DOE claim, the parties' prior litigation and testing history, and counsel's experience with other generics. *Id.* While Zydus now disputes whether the letter makes a difference, it moved to compel production of privileged materials in the first instance, arguing that the letter would "reveal the true bases for [Takeda's] decision-making." Def. Supp. SUMF, ¶ 13.

Zydus challenges the letter by claiming that it is "beside the point," and by contending that what matters is Takeda's "subjective motivation," not merely its "subjective belief about the merits," as the letter sets forth. Def. Rep. Br., at 18 (quoting *AbbVie*, 976 F.3d at 369). According to Zydus, "the undisputed evidence . . . show[s] that Takeda's purpose in filing suit . . . was to delay its rival's entry." *Id.* at 19. Zydus first points to Takeda's *actions*: namely, the numerous

unanswered emails about Zydus' OCA. Def. Supp. SUMF, ¶¶ 129-144. Zydus asserts that Takeda did not respond or negotiate the OCA so as to forestall FDA approval. Def. Rep. Br., at 20 (quoting *Hanover*, 806 F.3d at 181-82). But Takeda, a brand-name manufacturer, need not review an ANDA in full (rather than the Paragraph IV Certification) during the 45-day notice period. It is difficult to infer bad faith from Takeda's failure to undertake an action which Hatch-Waxman does not require it to take.

Zydus next points to Takeda's *comments*, which Zydus believes reveal Takeda's true motivations for suing. For instance, a "forecasting manager" wrote in a presentation in 2018 that Zydus' Paragraph IV Certification "allowed [Takeda] to sue again for a 30-month stay," Def. SUMF, ¶¶ 168-69, and Takeda's in-house patent counsel and Rule 30(b)(6) witness Mark Buonaiuto wrote that the Certification provided the "opportunity" to bring "new" litigation. *Id.* ¶ 140. Contrary to the inference that Zydus draws from these, they do not evince a desire to harm Zydus, but merely express a fact about Hatch-Waxman. Zydus also cites a statement on Takeda's "Intellectual Property Litigation Tracker" by Eiji Nara, "counterpart" to Buonaiuto, noting that "[w]e are now studying [Zydus'] ANDA carefully to decide our next step." Def. SUMF, ¶123. From this, Zydus infers that Takeda knew it should review the ANDA in full and intentionally misrepresented doing so. Def. Br., at 35. I am not convinced that this constitutes a sound basis for such a negative inference. Takeda's position is seemingly more plausible given the circumstances: Nara and Buonaiuto used the term "ANDA" as "shorthand" for either the ANDA Notice, which accompanied Zydus' Paragraph IV Certification, or the Certification itself. Pl. Opp. Br., at 28.

Apart from Takeda's actions and comments, Zydus claims that Takeda knew it would reap "extensive financial benefits" from "pushing off a competitor" for even a few months, in view of its greater-than-expected market share after Teva launched a generic version of Prevacid in March

2018 and the price of its prior patent suits. Def. Br., at 36. Zydus relies on two pieces of evidence for support. First, Takeda realized an additional $16 million in revenue in 2018, compared to its projections, due to "improved [year-to-date] Rx trends as generic erosion [was] slower than expected." Def. SUMF, ¶¶ 174-75; *supra*, note 5. Second, Takeda undertook a cost-benefit analysis in 2017 to help it determine the "break even" point for litigation with Aurobindo, another generic. Def. SUMF, ¶¶ 170-73 ("We have a potential decision to continue to litigate, or discontinue litigation w/ one of our competitors (Aurobindo). Legal believes that if we proceed, it would be ~$1M in legal costs in FY17. We want to understand if it is worth 'protecting' the current demand curve from this additional entrant (ie. it would protect revenue losses > cost of litigation)."). This analysis showed that Takeda needed to "retain about 1.4% Rx (< 1 week)" to justify the spend on litigation. *Id.* ¶ 171. In light of these forecasts, Zydus contends, Takeda understood that securing even a fraction of the 30-month stay would not only cover the litigation costs associated with doing so, but increase revenue.

Zydus' conclusions here do not follow from the totality of evidence. To start, Takeda not only analyzed expected revenue streams with Teva as a competitor and the break-even point for litigation with Aurobindo, but the "loss curve" for one generic versus multiple, and determined that Prevacid would suffer the same sales erosion "regardless" of how many generics entered the market. Def. SUMF, ¶ 173 (quoting Takeda email explaining this); Pl. SUMF, ¶ 130 ("[L]ater entrants would not likely have any effect on [Prevacid's] sales volume."). Likewise, when Takeda sued Zydus in 2018, the FDA had already approved Teva, whose entrance was "imminent" and for which Takeda "was preparing" all year. Pl. SUMF, ¶¶ 128-29. Taking these together, "Takeda did not [ ] have a strong business incentive to delay Zydus' entry" at the time it filed this infringement suit, nor a material economic incentive to keep Zydus' generic from the market, and

likely could not have expected a "windfall" from doing so. The fact that Takeda realized more revenue than anticipated after Teva launched its product (*i.e.*, it was wrong about the degree of erosion) does not suggest Takeda would also realize more revenue when competing against one generic rather than two (*i.e.*, it was also wrong about the nature of the loss curve).[19] At least, Zydus has not demonstrated any correlation between the two, such that I might draw a different inference.

In much the same way, Zydus argues that Takeda slowed down the proceedings in bad faith after initiating litigation. The record does not bear this out either. Within the course of five months, Takeda asked for, received, tested, and voluntarily dismissed its action. Pl. SUMF, ¶¶ 105-06, 108, 111-19, 124-27. Zydus argues that Takeda did not request samples fast enough.[20] But Takeda did so six weeks after filing suit, a few days before Zydus filed its Answer, and a month before the parties' initial scheduling conference where, under local patent rules, they would normally negotiate product samples. Pl. SUMF, ¶¶ 27, 105, 108, 111; L. Patent R. 2.1(a)(6). While that may constitute some delay, it is an insignificant one in the overall scheme of Hatch-Waxman. Zydus also argues that Takeda asked for too much product to test, which prolonged the litigation by perhaps a month. *Id.* ¶ 115. Yet, Takeda based its request on the *Dexcel* case, Pl. SUMF, ¶¶ 112-13, where Judge Cooper raised issues about control procedures, validation, and methodology, and questioned Takeda's protocols. Pl. Supp. SUMF, ¶¶ 29, 31, 35. That does not strike me as unreasonable. Zydus then declined to send what Takeda requested. *Id.* ¶ 30. Takeda, in turn, agreed

19 Zydus further argues that, in 2013, Buonaiuto testified that "revenues generated by Prevacid [ ] became much more important for funding research and development opportunities at Takeda Japan." Def. SUMF, ¶ 141. Zydus takes this to mean that Takeda had an economic interest in protecting Prevacid from "going generic." However, a brand-name *always* has that interest, and Hatch-Waxman contemplates that such a manufacturer will use the courts to pursue it. The testimony on which Zydus relies also goes to Prevacid's value to Takeda years before Zydus' ANDA filing.

20 Zydus claims that Takeda "stall[ed] for months" on testing. Def. Rep. Br., at 19. But to get to that amount of time, Zydus improperly adds the 45-day notice period to the post-suit discovery period, during which Takeda was not under any legal obligation to request or test product samples.

to accept the smaller sample size if Zydus agreed to waive any challenge to the validity of the results. *Id.* ¶ 32. Zydus did not do so, and only some weeks later, sent more samples. Pl. SUMF, ¶ 119.

Takeda further waived attorney-client privilege after filing suit and proposed that Zydus could re-depose Buonaiuto.[21] *Id.* ¶¶ 86-87. Zydus proclaims that it took Takeda too long to do so, Takeda "selectively" did so,[22] and in general Takeda hid behind the privilege.[23] Def. Br., at 27. Even if Takeda *never* agreed to *any* waiver in this context—and hence did not produce its outside counsel's letter, which formed the basis of its pre-suit deliberations—that alone would not cause me to draw an adverse inference against it. *See, e.g.*, *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed. Cir. 2004) ("[N]o adverse inference shall arise from invocation of the attorney-client and/or work product privilege."); *Nabisco, Inc. v. PF Brands, Inc.*, 191 F.3d 208, 225-26 (2d Cir. 1999) ("We are particularly troubled by the court's reliance on Nabisco's assertion of the attorney-client privilege."). I would simply focus on circumstantial evidence of Takeda's motive, which, like the letter, does not permit an inference of bad faith. *AbbVie*, 976 F.3d at 366-71. Takeda also promptly waived pediatric exclusivity when asked to do so in September 2018, despite protection lasting through November 2018. Pl. SUMF,

21 The parties contest whether Takeda actually offered a new deposition, or merely "considered" it. They also contest whether Buonaiuto in fact invoked the privilege in the first place. I do not need to wade into this dispute because Takeda ultimately waived the privilege, which the Magistrate Judge deemed sufficient, *see infra*, and produced the letter that would have been the basis of Buonaiuto's disputed/privileged testimony.

22 The Magistrate Judge found the scope of Takeda's waiver to be sufficient, writing that "Takeda has produced all communications, including otherwise privileged communications, regarding both its decision to file its patent infringement Complaint against Zydus as well as its decision to dismiss said lawsuit." Pl. SUMF, ¶ 87.

23 Although Zydus now claims that Buonauito hid behind privilege, Zydus insisted the opposite was true after his deposition: Buonaiuto waived the privilege by testifying to the very topics Zydus accuses Takeda of blocking. Pl. Supp. SUMF, ¶ 49.

¶¶ 165-66. A firm seeking to thwart a competitor's market entry by unnecessarily dragging out litigation or dragooning the legal process into an anticompetitive weapon would likely not take these actions. *Cf. Hanover*, 806 F.3d at 167-70, 182 (noting that defendants filed serial administrative complaints with agencies that had no jurisdiction, then repeatedly amended their filings without a good reason, and distinguishing cases "[w]here there is only one alleged sham petition," as here). Accordingly, I find that Takeda had a subjective basis to sue Zydus.

3. Substantive Antitrust Injury

Finally, because Takeda is entitled to *Noerr* immunity, which is a *legal* obstacle to the viability of Zydus' antitrust counterclaims, I need not determine whether Zydus has demonstrated a sufficient substantive injury to establish *economic* viability under the Sherman Act.[24] *PRE*, 508 U.S. at 61. The same is true for Zydus' claim under the New Jersey Antitrust Act, *see* N.J.S.A. § 56:9-1, which I construe as coextensive with the Sherman Act. *St. Clair v. Citizens Fin. Group*, No. 08-1257, 2008 WL 4911870, at *5 n.10 (D.N.J. Nov. 12, 2008) ("The language of the New Jersey Antitrust Act is virtually identical to the antitrust provisions in the Sherman Act . . .

24 Without deciding the merits of Zydus' antitrust counterclaims, I nonetheless note that they face a high bar. For one thing, patents inherently grant a right to exclude. Actions that are permissible under the patent laws cannot give rise to antitrust liability. *See, e.g.*, *Hoffman-La Roche*, 50 F. Supp. 2d at 378; *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at *2-3 (E.D. Pa. July 18, 2000). Additionally, a threshold requirement for antitrust liability is proof of "antitrust injury," which requires an alleged injury to be "causally linked to an illegal presence in the market." *Brunswick v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); *see also Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997) ("Antitrust injury is a necessary . . . condition of antitrust standing."). To establish such an injury, a party must show both the same type of harm as the antitrust laws are designed to prevent and an injury flowing from that which makes the alleged actions unlawful. *Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 429 (3d Cir. 1993). Then, once it meets that bar, the party must demonstrate possession of monopoly power and willful maintenance thereof, including the ability to *keep* prices high "for a significant period of time without erosion by new entry or expansion," also known as durable monopoly. *ADSAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 227 (2d Cir. 1999). Because there are numerous reasons why the FDA did not approve Zydus' generic until September 2018, and Teva entered the market in March 2018 after the FDA approved it in September 2017, there are potentially significant independent obstacles to Zydus' substantive antitrust counterclaims at the summary judgment stage.

[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.") (citations omitted); *Main Street at Woolwich, LLC v. Ammons Supermarket, Inc*., 451 N.J. Super. 135, 144 (App. Div. 2017) (collecting cases showing New Jersey courts recognize *Noerr* immunity); *Tris Pharma, Inc. v. UCB Mfg., Inc.*, No. 5808-13T3, 2016 WL 4506129, at *4 (N.J. Super. Ct. App. Div. Aug. 29, 2016) (adopting the federal standard for determining whether *Noerr* immunity applies, and citing *PRE*, 508 U.S. at 60-61).

IV. CONCLUSION

Takeda is entitled to *Noerr* immunity because Zydus has not demonstrated that Takeda's patent infringement suit was both objectively and subjectively baseless. I **GRANT** Takeda's summary judgment motion, **DENY** Zydus' motion, and **DISMISS** Zydus' antitrust counterclaims.

DATED: July 26, 2021

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge