UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *Plaintiff*, v. ALEX M. AZAR, II, *et al.*, *Defendants*.	Civil Action No. 18-2394 (RDM)

MEMORANDUM OPINION

Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") brings this action to obtain "immediate injunctive and declaratory relief" barring the Food and Drug Administration ("FDA") from "depriving [Teva] of its statutory right to 180 days of marketing exclusivity for its generic version of the brand-name drug Restasis®." Dkt. 1 at 2 (Compl. ¶ 1). Teva seeks a preliminary injunction. Dkt. 2. The FDA and intervenor defendants—Mylan Pharmaceuticals Inc. ("Mylan"), Deva Holding AS ("Deva"), and Famy Care Private Limited ("Famy Care")—oppose that motion and move to dismiss the case for lack of subject matter jurisdiction. Dkt. 25; Dkt. 27. Because Teva has failed to demonstrate that it has standing, the Court will **DENY** Teva's motion for a preliminary injunction and will **GRANT** the defendants' motions to dismiss for lack of standing.

I. BACKGROUND

A. Statutory and Regulatory Background

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, sets forth the procedures that manufacturers must follow to obtain FDA approval to sell pharmaceutical products. To obtain approval for a brand-name or pioneer drug, a pharmaceutical manufacturer

must file a New Drug Application ("NDA") demonstrating the drug's safety and efficacy using scientific data. *Id.* §§ 355(a)–(b). The NDA must also include "the patent number and the expiration date of any patent . . . to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Id.* § 355(b)(1). If the patent is issued after the NDA is filed, the applicant or holder of the approved NDA must notify the FDA of the patent number and expiration date. *Id*. § 355(c)(2). The FDA then lists this patent information in the "'*Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*' or, as it is commonly known, simply the 'Orange Book.'" *Amneal Pharms. LLC v. FDA*, 285 F. Supp. 3d 328, 332 (D.D.C. 2018).

Prior to 1984, companies that manufactured generic medicines, like Teva, also had to file NDAs supported by full investigative studies. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (recognizing that "the NDA process," which is "costly and time-consuming," impedes the "availab[ility] of low cost generic drugs"). In 1984, however, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), popularly known as the "Hatch-Waxman Amendments." Among other things, the Amendments were designed "to increase competition in the drug industry by facilitating the approval of generic copies of drugs." *Mead Johnson Pharm. Grp. v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988). To that end, the Amendments eliminated the requirement that generic manufacturers submit full NDAs and allowed generic manufacturers to "seek FDA approval by submitting an abbreviated new drug application ('ANDA')." *Serono Labs., Inc.*, 158 F.3d at 1316; *see also* 21 U.S.C. § 355(j). Under the ANDA process, a manufacturer may "piggyback[] on the original manufacturer's evidence of safety and efficacy," *Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008), and need demonstrate only that the

generic drug has the same active ingredient(s), route of administration, dosage form, conditions of use, and strength as the approved drug, and that the generic drug has an appropriate label and is bioequivalent to the approved drug. *See* 21 U.S.C. § 355(j)(2)(A); *id.* § 355(j)(4). Although far less demanding than the full NDA process, "obtaining FDA approval for an ANDA remains a prolonged" and demanding "task," which "can take years to complete." *Amneal Pharms. LLC*, 285 F. Supp. 3d at 333.

An ANDA must also contain one of four certifications "with respect to each" of the Orange Book patents claimed by the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(vii). The four certifications are as follows:

> (I) that such patent information has not been filed [a "Paragraph I certification"],
>
> (II) that such patent has expired [a "Paragraph II certification"],
>
> (III) of the date on which such patent will expire [a "Paragraph III certification"], or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted [a "Paragraph IV certification"].

Id. A generic applicant may not enter the market until every patent in the Orange Book implicated by the generic product has expired, unless it files a Paragraph IV certification. *See Mylan Pharms., Inc. v. FDA*, 789 F. Supp. 2d 1, 3 (D.D.C. 2011) [hereinafter "*Mylan*"].

When a generic applicant submits a Paragraph IV certification in its original ANDA, the applicant must provide notice to the patent owner and holder of the approved NDA "not later than 20 days after the date" on which the FDA "informs the [ANDA] applicant that the [ANDA] has been filed." 21 U.S.C. § 355(j)(2)(B)(ii)(I). The FDA issues an acknowledgement letter informing an applicant that its ANDA has been "received" after it reviews the ANDA and

concludes that the application is sufficiently complete to permit substantive review. 21 C.F.R. § 314.101(b)(2); *see also SB Pharmco P.R., Inc. v. Mutual Pharm. Co.*, 552 F. Supp. 2d 500, 507 (E.D. Pa. 2008). When an applicant submits a Paragraph IV certification through "an amendment or supplement to the" applicant's ANDA, the applicant must notify the patent owner and holder of the NDA "at the time at which the [ANDA] applicant submits the amendment or supplement" to the FDA. 21 U.S.C. § 355(j)(2)(B)(ii)(II).

The filing of an ANDA containing a Paragraph IV certification is treated as an act of patent infringement. 35 U.S.C. § 271(e)(2)(A); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677–78 (1990). If the patent owner fails to sue for infringement within forty-five days of receiving notice, the generic applicant may bring a declaratory judgment action against the patent owner. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa). If, however, the patent owner brings an infringement action, the FDA's approval of the ANDA "shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of" the required notice to the patent owner and holder of the NDA. *Id.* § 355(j)(5)(B)(iii). This period is referred to as the "thirty-month stay." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348–49 (Fed. Cir. 2009). During this time, the agency is limited to issuing "tentative approval"—a "notification . . . that [an] application . . . meets the requirements [for approval]. . . but cannot receive effective approval" because of a patent issue or outstanding period of exclusivity. 21 U.S.C. § 355(j)(2)(B)(iv)(II)(dd). If the ANDA applicant prevails in district court before the thirty-month stay expires, the FDA may immediately approve the ANDA. *Id.* § 355(j)(5)(B)(iii)(I). The thirty-month stay is unavailable, moreover, if the relevant patent was listed after the ANDA was submitted. *Id.* § 355(j)(5)(B)(iii).

Because patent litigation is both expensive and risky, Congress created an incentive to encourage generic manufacturers to submit well-founded Paragraph IV certifications. *See Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) [hereinafter "*Teva v. Sebelius*"]. The statute provides that the "first applicant"—that is, the first generic manufacturer to file a "substantially complete" ANDA containing a Paragraph IV certification and to "lawfully maintain[]" that certification—is entitled to 180 days of generic market exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). A "substantially complete" ANDA is defined as an application that is "sufficiently complete" on "its face" to "permit a substantive review" and that "contains all the [requisite] information." *Id.* § 355(j)(5)(B)(iv)(II)(cc). The FDA represents that it does not designate a first applicant until it is ready to approve the first ANDA. *See* Dkt. 26 at 9. At that time, if the first applicant is approved and ready to go to market, it is entitled to 180 days of generic exclusivity. When more than one generic manufacturer meets the definition of "first applicant," the manufacturers will share the right to exclude other generics (but not each other) from the market.

The FDCA, however, contains six "forfeiture events" under which a first applicant may forfeit eligibility for the 180-day exclusivity period. Under the first, forfeiture occurs if the first applicant "fails to market the drug" by a certain date. *Id.* § 355(j)(5)(D)(i)(I). As is relevant here, that date is 75 days after "a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken," holding that "the patent [listed in the Paragraph IV certification] is invalid or not infringed." *Id.* § 355(j)(5)(D)(i)(I)(bb)(AA). Forfeiture also occurs if the first applicant withdraws its ANDA or the FDA "considers the application to have been withdrawn" because it does not meet the requirements for approval, *id.* § 355(j)(5)(D)(i)(II); the first applicant "amends or withdraws the

certification for all of the patents with respect to which [the] applicant submitted a certification qualifying [it] for the 180-day exclusivity period," *id.* § 355(j)(5)(D)(i)(III); the first applicant "fails to obtain tentative approval of the application within 30 months after the date on which the application is filed" and that delay was not "caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed," *id.* § 355(j)(5)(D)(i)(IV); the first applicant enters into "an agreement with another applicant[,] . . . the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV] certification" and that agreement is found to violate antitrust laws, *id.* § 355(j)(5)(D)(i)(V); or "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired," *id.* § 355(j)(5)(D)(i)(VI). The FDCA further provides that, if all first applicants forfeit their exclusivity, then "no applicant shall be eligible for the 180-day exclusivity period." *Id.* § 355(j)(5)(D)(iii)(II).

B. Factual Background

This case concerns the 180-day exclusivity period for the generic version of Restasis®, a drug used to stimulate tear production. Dkt. 1 at 2 (Compl. ¶ 1). In 2017, the brand-name manufacturer of Restasis®, Allergan, Inc. ("Allergan"), earned more than $1.4 billion in net revenues for the drug. *Id.* at 12 (Compl. ¶ 21). Teva estimates that the 180-day exclusivity period for the generic version, cyclosporine ophthalmic emulsion ("cyclosporine"), is worth "more than $50 million dollars in net revenues." Dkt. 1-1 at 8 (Groff Decl. ¶ 14).

Teva alleges that it qualifies as the "first applicant" to submit a Paragraph IV certification for Restasis® and that, as a result, it is entitled to 180 days of generic exclusivity. Dkt. 1 at 2 (Compl. ¶ 1). Teva fears, however, that its statutory right will be extinguished once the FDA

applies the interpretation of "first applicant" it recently espoused in a letter decision relating to another drug. Dkt. 1 at 25 (Compl. ¶ 41). To avoid that loss, Teva seeks a declaratory judgment that (1) the FDA's interpretation of "first applicant" in that letter decision is invalid under the Administrative Procedure Act ("APA") and that (2) Teva is entitled to the 180-day exclusivity period. *Id.* at 37 (Compl. Prayer). Teva also seeks to enjoin the FDA from "approving any [ANDA] that references Restasis® . . . other than Teva's ANDA" during the pendency of this litigation unless that ANDA meets Teva's definition of "first applicant." Dkt. 2-2 at 2. The relevant events are as follows:

1. *ANDA Submissions and Patent Litigation*

Allergan received FDA approval to market Restasis®, a pioneer drug to treat dry eye, on December 23, 2002. Dkt. 1 at 17 (Compl. ¶ 29). Allergan originally listed two patents associated with Restasis® in the Orange Book: U.S. Patent No. 4,839,342 ("the '342 patent") and No. 5,474,979 ("the '979 patent"). *Id.* The '342 patent expired on August 2, 2009, and the '979 patent expired on May 17, 2014. *Id.* Shortly before the '979 patent expired, Allergan added five new Restasis®-related patents to the Orange Book, beginning with U.S. Patent No. 8,629,111 ("the '111 patent"), which issued on January 14, 2014. Dkt. 26-1 at 4 (Ex. A) (Cyclosporine Comment Request). In February 2016, Allergan added a sixth patent. Dkt. 27-1 at 13 n.4; *see also Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-1455, 2017 WL 4803941, at *12 (E.D. Tex. Oct. 16, 2017) (Bryson, J., sitting by designation). The '111 patent is the subject of the Paragraph IV certification at issue here.

Teva filed its ANDA for cyclosporine on January 23, 2012. Dkt. 1 at 17 (Compl. ¶ 30). At the time, the "only unexpired patent listed in the Orange Book" for Restasis® was the '979 patent. *Id.* That patent was due to expire in May 2014, and Teva filed a Paragraph III

certification, indicating that it intended to enter the market *after* the '979 patent expired. *Id.* (Compl. ¶¶ 29, 30). Once Teva submitted its ANDA, the FDA began "its customary pre-filing review . . . for 'substantial completeness.'" *Id.* at 18 (Comp. ¶ 31) (citing 21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc)). Pursuant to the FDA's regulations, the agency "may not consider an ANDA to be received" if the application is incomplete "on its face." 21 C.F.R. § 314.101(d)(3). According to Teva, the FDA's initial review of its ANDA was "plagued by irregularities." Dkt. 1 at 18 (Compl. ¶ 31). Teva alleges that the FDA failed to act on its ANDA for nearly fifteen months. *Id.* at 17–18 (Compl. ¶¶ 30–31). The agency then allegedly delayed the review process further by requesting "additional information from Teva," "nearly all of which had been provided in Teva's original ANDA." *Id.* Finally, the FDA issued a letter "notif[ying] Teva that it was refusing" to receive "the company's ANDA," *id.* (Compl. ¶ 32)—a decision the agency later rescinded in June 2015, *id.* at 21 (Compl. ¶ 37).

While Teva "was considering its response to the [FDA's letter]," the Patent and Trademark Office issued the '111 patent. *Id.* at 19–20 (Compl. ¶ 34). That same day—January 14, 2014—Teva amended its ANDA to include a Paragraph IV certification with respect to the '111 patent. *Id.* at 20 (Compl. ¶ 35). Although the FDCA requires an ANDA applicant to provide notice of a Paragraph IV certification at the same time it "submits [an] amendment or supplement" to its ANDA, *see* 21 U.S.C. § 355(j)(2)(B)(ii)(II), Teva "informed the FDA" that it would wait until "[the] FDA reversed its . . . decision and received Teva's ANDA for review," citing the "FDA's judicially-affirmed rule" that "legally-required notice will be considered timely-provided only . . . after [the] FDA's acknowledgment letter receiving [the] ANDA" is issued. Dkt. 1 at 21 (Compl. ¶ 36) (citing *Allergan, Inc. v. Actavis, Inc.*, Nos. 14-cv-638 & 14-cv-188, 2014 WL 7336692, at *11–12 (E.D. Tex. Dec. 23, 2014)). On July 9, 2015, thirty

months after Teva submitted its ANDA, the FDA issued a formal acknowledgment letter deeming Teva's ANDA "received . . . as of January 23, 2012." *Id.* (Compl. ¶ 37). Teva, in turn, timely dispatched its Paragraph IV notices to Allergan and the '111 patentees. *Id.* at 22 (Compl. ¶ 37). Teva also filed Paragraph IV certifications with respect to the five other Restasis® patents and timely effected notice. Dkt. 27-1 at 13; *see also Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2017 WL 4803941, at *12, *15.

According to Teva, there are at least eight other known ANDA applicants for cyclosporine.[1] Dkt. 1-1 at 8 (Groff Decl. ¶ 14). The FDA has indicated that "[o]ne or more" ANDAs containing "[P]aragraph IV certifications to the '979 patent" were submitted "before January 14, 2014." Dkt 26-1 at 4 (Ex. A) (Cyclosporine Comment Request). No applicant in this group, however, received an acknowledgment letter from the FDA before "the '979 patent expired." *Id.* In addition, four generic manufacturers confirmed that they have pending ANDAs for cyclosporine in public submissions to the FDA, all of which presumably reference the '111 patent. *See* Dkt. 26-2 (Ex. B) (InnoPharma, Inc.); Dkt. 26-3 (Ex. C) (Apotex Inc.); Dkt. 26-4 (Ex. D) (Axar Pharmaceuticals); Dkt. 26-6 (Ex. F) (Akorn Pharmaceuticals). Finally, the intervenors Mylan, Deva, and Famy Care have all represented that they filed ANDAs for generic cyclosporine. Dkt. 6-1 at 3 (Mylan); Dkt. 10-1 at 5 (Deva); Dkt. 33-1 at 6–7 (Famy Care).

In August 2015, Allergan filed suit against Teva (and other Paragraph IV ANDA applicants) for infringing the six unexpired Restasis® patents listed in the Orange Book. *See Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2017 WL 4803941, at *12. Allergan granted the

[1] Pursuant to agency regulation, the FDA "will not publicly disclose the existence of an application or [ANDA] before an approval letter is sent . . . or tentative approval letter is sent . . . unless [its] existence . . . has been previously publicly disclosed or acknowledged." 21 C.F.R. § 314.430(b).

defendants a covenant not to sue for two of the patents. *Id.* at *15. The district court then invalidated the remaining four patents, including the '111 patent. *See id.* at *65. Allergan appealed the district court's decision, and, on November 13, 2018, the Federal Circuit summarily affirmed the district court's decision. *See Allergan, Inc. v. Teva Pharms. USA, Inc.*, 742 F. App'x 511 (Fed. Cir. 2018). Allergan then petitioned for panel rehearing and rehearing en banc. Dkt. 104, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 18-1130 (Fed. Cir. Dec. 21, 2018). That petition is still pending.

2. *FDA Proceedings Regarding the 180-Day Exclusivity Period*

As originally enacted, the Hatch-Waxman Amendments did not define the phrase, "first applicant." Rather, the 180-day exclusivity provision merely provided that, if an ANDA contains a Paragraph IV certification and "is for a drug for which a previous application has been submitted . . . cont[aining] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the applicant "under the previous application" goes to market or a district court holds the patent "invalid or not infringed," whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv) (2002 version). The Medicare Modernization Act of 2003 ("MMA"), Pub. L. No.108-173, 117 Stat. 2066 (2003), amended the statute to add, *inter alia*, a definition of "first applicant" and "180-day exclusivity period." *See* 21 U.S.C. §§ 355(j)(5)(B)(iv)(II)(aa)–(bb).

Prior to the enactment of the MMA, the FDA construed the Hatch Waxman Amendments to recognize "180-day exclusivity . . . on a patent-by-patent basis, meaning that there could be . . . multiple 180-day periods of exclusivity for a single drug product." Dkt. 1-2 at 5 (Suboxone Ltr. Decision); *see also Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 64 (D.D.C. 2006). In addition, as the D.C. Circuit recognized in *Purepac Pharmaceuticals Co. v. Thompson*, 354

F.3d 877, 888–89 (D.C. Cir. 2004), the FDA employed a "first effective approach" to awarding exclusivity—that is, the agency rewarded the first generic to file a substantially complete ANDA containing a Paragraph IV certification *and* to effect notice. "Although *Purepac* was decided after the MMA was enacted, the MMA did not apply to the amendments and patent certifications at issue in the case[,] and the Court did not opine on whether the outcome would have been the same post-MMA." Dkt. 1-2 at 9 (Suboxone Ltr. Decision). The FDA acknowledges, however, that "some subsequent FDA statements and decisions" made under "the post-MMA statute and regulation with respect to amendments and supplements that contain a [P]aragraph IV certification" continued to apply the "[f]irst [e]ffective approach." *Id.*

In February 2015, the FDA published a proposed rule implementing aspects of the MMA "pertain[ing] to provision of notice . . . of certain patent certifications made by" ANDA applicants and submission of amendments and supplements to ANDAs. *See* Proposed Rule, Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. 6,802 (Feb. 6, 2015) ("Proposed MMA Rule"). Later that year, the FDA opened a docket to solicit comments regarding the 180-day exclusivity period for generic cyclosporine. Dkt 26-1 at 2 (Ex. A) (Cyclosporine Comment Request). The FDA revealed that "one or more" applicants had filed an ANDA containing a Paragraph IV certification referencing the '979 patent *before* the '111 patent was issued on January 14, 2014; however, notice was *not* provided to the patent owners and NDA holder because the '979 patent expired before the FDA accepted any ANDA for review. *Id.* at 4 (Cyclosporine Comment Request). The FDA then sought comment on two questions: First, whether "[t]he one or more applicants that submitted ANDAs or patent amendments with [P]aragraph IV certifications" with respect "to the '979 patent" are "first applicants" for purpose of the 180-day exclusivity. *Id.* at 5 (Cyclosporine Comment Request). Second, whether that

applicant (or those applicants) forfeited generic drug exclusivity "on May 17, 2014, when the '979 patent expired, such that no ANDA applicant for [c]yclosporine [o]phthalmic [e]mulsion, 0.05%, is eligible for 180-day generic drug exclusivity." *Id.* Six companies responded. *See* Dkt. 26-2 (Ex. B) to Dkt. 26-7 (Ex. G). Four answered yes to both questions. Dkt. 26 at 16. Teva and Akorn responded no. *Id.*; *see also* Dkt. 26-6 (Ex. F); Dkt. 26-7 (Ex. G). To date, the FDA has yet to issue a decision addressing either of these questions in the cyclosporine ANDA docket, and it has represented that it will not do so before it determines that an "ANDA applicant for cyclosporine has . . . satisfied the requirements for approval." Dkt. 26 at 17.

In October 2016, the FDA published its final rule implementing portions of the MMA. *See* Final Rule, Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69,580 (Oct. 6, 2016) ("Final MMA Rule"). The parties disagree about whether the final rule codifies the "first effective approach"—that is, they disagree about whether it precludes the FDA from concluding that the "one or more" applicants that submitted ANDAs containing Paragraph IV certifications with respect to the '979 patent were "first applicants," even though the '979 patent expired before they could provide the patent owners and NDA holder with the required notice. According to Teva, the Final MMA Rule clearly provides that "eligibility for 180-day exclusivity requires timely notice of the exclusivity-qualifying Paragraph IV certification;" therefore, only those who have provided notice can qualify as first applicants. Dkt. 2-1 at 32. The FDA disagrees, arguing that the final rule "simply does not address the circumstance . . . where an applicant with a substantially complete ANDA containing a [P]aragraph IV certification is not able to provide valid notice . . . because the relevant patent expires before the FDA sends [the applicant] an Acknowledgement Letter." Dkt. 26 at 28.

All agree, however, that in July 2018, the FDA issued a letter decision in an unrelated matter, which addressed this question. Dkt. 1-2 at 2 ("Suboxone Letter Decision"). In that matter, "[o]n May 14, 2013, one or more first applicants submitted a substantially complete ANDA (or an amendment to a substantially complete ANDA)" for a generic version of Suboxone® "with a [P]aragraph IV certification." *Id*. at 7 (Suboxone Ltr. Decision). That applicant (or those applicants), however, subsequently withdrew their application(s) and "informed [the] FDA that [they] had not given notice to the NDA holder or patent owner." *Id*. "At least one other applicant submitted a substantially complete ANDA (or an amendment to a substantially complete ANDA)" referencing Suboxone® "after May 14, 2013, with a [P]aragraph IV certification and provided notice to the NDA holder and patent holder." *Id.* On those facts, the FDA concluded that the May 14, 2013 applicant qualified as the "first applicant" and, "[a]bsent forfeiture," would have been "eligible for 180-day exclusivity." *Id*. The applicant, however, forfeited its right to exclusivity when it withdrew its application, and, because the "first applicant" did not qualify for 180-day exclusivity, the FDCA imposed "no barriers to approval of subsequent applicants." *Id.* at 13 (Suboxone Ltr. Decision). Significantly, the FDA noted that exclusivity did not roll over to the subsequent applicant. *Id.* at 18 (Suboxone Ltr. Decision).

As the FDA explained in the Suboxone Letter Decision, its conclusion turned on the meaning of the statutory phrase "first applicant." *Id.* at 8 (Suboxone Ltr. Decision). Prior to the enactment of the MMA, and prior to the FDA's Suboxone Letter Decision, the agency applied the "first effective approach." *See Purepac Pharm. Co.*, 354 F.3d at 888–89. But, after studying the issue, the FDA concluded that the "first effective approach" is inconsistent with "the statutory definition of '[f]irst [a]pplicant' as defined by Congress in the MMA," Dkt. 1-2 at 10 (Suboxone Ltr. Decision), and that a "first submitted approach" better coheres with the current

version of the FDCA, *id.* at 11 (Suboxone Ltr. Decision). According to that approach, the definition of "first applicant" sets a specific "static date" on which an applicant must file in order to achieve "first applicant" status, *id.*: that is, "the first day on which a substantially complete application containing a" Paragraph IV certification "is submitted for approval of a drug." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). As a result, the decision further explained, "[a]ny application, whether an original application, amendment, or supplement submitted after this 'first day' cannot satisfy the 'when' prong and cannot be a '[f]irst [a]pplicant,' as there can be only one 'first day on which a substantially complete application containing a [P]aragraph IV certification is submitted.'" Dkt. 1-2 at 11 (Suboxone Ltr. Decision). Nor was the FDA convinced that the second half of the MMA statutory definition, which requires that the applicant "lawfully maintain[] a [Paragraph IV] certification," 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb), changes this result. In the FDA's view, that requirement, which entails providing notice to the patent owner and NDA holder, does not change the "static date." Dkt. 1-2 at 11 (Suboxone Ltr. Decision).

The Suboxone Letter Decision also concluded that the "first submitted approach" "is the most consistent with the structure of the MMA." *Id.* As the decision explains, a reading of "first applicant" that would permit first applicant status to roll over to a subsequent filer would be in "tension" with the MMA's added provisions addressing the forfeiture of eligibility for exclusivity. *Id.* at 12 (Suboxone Ltr. Decision). Finally, the decision observes that the "first submitted approach" "is preferable from a policy perspective" because it "is outcome determinative and not applicant-specific, and because once fixed, the date is immutable and does not move based on later actions or inactions." *Id.* The FDA, accordingly, concluded that "there can only ever be one 'first day on which a substantially complete application'" containing a [P]aragraph IV certification "'is submitted,' regardless of whether the applicant . . . gives or fails

to give timely notice of and/or otherwise lawfully maintains its [P]aragraph IV certification." *Id.* at 10 (Suboxone Ltr. Decision).

3. *Status of ANDA Applicants*

To date, no cyclosporine ANDA has received final (or even tentative) approval. Although Teva alleges (and has alleged since mid-October 2018) that the FDA is poised to grant final approval to Mylan's ANDA, the FDA's deliberations remain confidential. Teva simply speculates that the FDA will imminently approve Mylan's ANDA based on Mylan's representations during a quarterly earnings call. Dkt. 16 at 6–7 (Oct. 26, 2018 Hrg. Tr.). Teva also alleges that it has expended significant resources in anticipation of the FDA's impending approval of Teva's own ANDA. Teva attests, for example, that "the Company began planning for an exclusive launch" in 2017, "placing orders for supplies and components," "expand[ing] its production capacity at the planned manufacturing site," and "hir[ing] additional full-time personnel." Dkt. 1-1 at 7 (Groff Decl. ¶ 11). In 2018, Teva "commenced production activities in anticipation of an upcoming commercial launch." *Id.* (Groff Decl. ¶ 12).

C. Procedural History

Teva filed suit against the FDA on October 17, 2018, and moved for a preliminary injunction that same day. Dkt. 1 (Compl.); Dkt. 2 (Mot. Prelim. Inj.). Three generic manufacturers, in turn, moved to intervene as defendants: Mylan, Deva, and Famy Care. Dkt. 6; Dkt. 10; Dkt. 33. In light of the intervenors' representations that they had pending ANDAs for cyclosporine, the Court granted their motions to intervene. *See* Minute Entry (Oct. 26, 2018) (granting Mylan and Deva leave to intervene); Minute Order (Nov. 20, 2018) (granting Famy Care leave to intervene).

At the initial status conference, the Court set a combined briefing schedule for Teva's preliminary injunction motion and the defendants' combined opposition and motion to dismiss. Minute Entry (Oct. 26, 2018). In order to ensure that Teva "ha[d] the opportunity to be heard" before "it suffer[ed] an irretrievable loss of generic exclusivity," while also protecting confidential information and avoiding any undue intrusion into the FDA's administrative process, the Court entered an order establishing the following procedure: (1) the FDA was required to "provide the Court with 48 hours' notice before issuing a decision that would permit any manufacturer, other than Teva, to market a generic version of [Restasis®];" (2) all counsel were required to be available to appear in Court for a hearing on Teva's "motion for a preliminary injunction on four hours' notice;" (3) both the FDA and the parties were precluded from disclosing or releasing the FDA's decision without authorization from the Court; (4) the FDA was directed to bring copies of its decision to any such hearing; and (5) if summoned to a hearing, the FDA and the parties were precluded from disclosing that a decision from the FDA was "likely forthcoming." Dkt. 15 at 1–2. The FDA objected that the Court lacked jurisdiction to enter the order because Teva does not have standing to bring suit and the case is unripe. Dkt. 19 at 2. The Court subsequently ordered supplemental briefing on the jurisdictional issues and held oral argument. *See* Minute Order (Nov. 1, 2018); Minute Entry (Nov. 5, 2019). The Court then vacated its prior order but still required the FDA to "provide the Court with 48 hours' notice before taking any final action that would directly impact Teva's claim to 180-day generic exclusivity." Minute Order (Nov. 5, 2018). Neither order has required any action to date.

II. LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as of right," *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 24 (2008), but "only when the party seeking the relief,

by a clear showing, carries the burden of persuasion," *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004). To secure a preliminary injunction, a plaintiff "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20. Although the moving party may rely on "evidence that is less complete than in a trial on the merits," *NRDC v. Pena*, 147 F.3d 1012, 1023 (D.C. Cir. 1998) (citation omitted), he nevertheless "bear[s] the burden[] of produc[ing] . . . credible" evidence sufficient to demonstrate his entitlement to injunctive relief, *R.I.L-R v. Johnson*, 80 F. Supp. 3d 164, 173 (D.D.C. 2015) (quotation marks omitted) (first alteration in original).

Before applying the four-part test, however, the Court must address a threshold issue: whether it has jurisdiction over Teva's claim. *See Calif. Ass'n of Private Postsecondary Schs. v. Devos*, 344 F. Supp. 3d 158, 167 (D.D.C. 2018) ("[A] court must—at each successive stage of the proceeding—evaluate whether it has jurisdiction to provide the relief sought, and it must do so through the lens of the standard applicable at that stage of the proceeding." (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992))). As the party seeking to invoke the Court's jurisdiction, Teva bears the burden of establishing that it has standing to sue. *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002). If Plaintiff "fails to show a 'substantial likelihood' of standing," then it "is not entitled to a preliminary injunction." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015) (citation omitted).

Defendants have also moved to dismiss the case for lack of standing pursuant to Federal Rule of Civil Procedure 12(b)(1). To survive a 12(b)(1) motion, Plaintiff's complaint "must state a plausible claim that [it] has suffered an injury in fact fairly traceable to the actions of the defendant that is likely to be redressed by a favorable decision on the merits." *Humane Soc'y of*

the U.S. v. Vilsack, 797 F.3d 4, 8 (D.C. Cir. 2015). In this posture, the Court must accept the factual allegations of the complaint as true but must nonetheless assess the "plausibility" of the plaintiff's standing allegations in light of the relevant context and the Court's "judicial experience and common sense." *Pub. Citizen, Inc. v. Trump*, No. 17-cv-253, 2019 WL 498528, at *6 (D.D.C. Feb. 8, 2019) (internal citations omitted) (quoting *Humane Soc'y of the U.S.*, 797 F.3d at 8). Because predictions of future injury . . . are not normally susceptible to labeling as 'true' or 'false,'" *Arpaio v. Obama*, 797 F.3d 11, 21 (D.C. Cir. 2015), the Court need not accept any such allegations as "true" for purposes of evaluating a motion to dismiss for lack of standing.

III. ANALYSIS

Teva challenges the FDA's interpretation of "first applicant" in the Suboxone Letter Decision and contends that, if allowed to stand, that reading of the MMA will deprive Teva of its statutory right to 180 days of generic exclusivity for cyclosporine. In Teva's view, the FDA erred as a matter of substance and process in defining "first applicant" as the first substantially complete ANDA containing a Paragraph IV certification, regardless of whether the applicant provided the required notice to the patent owner and NDA holder (i.e., the "first submitted approach"). Teva contends that the Suboxone Letter Decision must, therefore, be set aside under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706.

According to Teva, the FDA erred as a matter of substance because the MMA definition of "first applicant" not only requires that the applicant be the first to file a substantially complete ANDA, but also requires that the applicant timely effect notice (i.e., the "first effective approach"). Dkt. 1 at 32–33 (Compl. ¶ 55). Teva argues, moreover, that the statutory purpose of rewarding those who take on the risk and cost of patent infringement litigation is not served by according "first applicant" status to those who submit Paragraph IV certifications to the FDA but

never provide notice to the patent owners and NDA holders. Teva also argues that the Suboxone Letter Decision must be set aside because it was issued in violation of the procedural requirements of the APA. In particular, Teva maintains that the decision countermanded a "legislative rule[] promulgated though the notice-and-comment process without undertaking a new round of notice-and-comment rulemaking," and it failed "to account for the reliance interests" of those manufacturers that had acted based on the FDA's prior account of the law. Dkt. 2-1 at 34.

In support of its motion for preliminary relief, Teva contends that each of the relevant factors tip in favor of issuing a preliminary injunction. For the reasons explained above, Teva contends that it is likely to prevail on the merits. It further argues that, unless the FDA is enjoined, "application of the [Suboxone] Letter Decision to Teva's cyclosporine ANDA will harm Teva irreparably by divesting the company of its statutory right to 180-day exclusivity and imposing at least $50 million in losses that Teva can never recover." *Id*. at 50. Finally, Teva maintains that the balance of hardships and public interest weigh in favor of granting a preliminary injunction. *Id.* at 52–53.

The Court cannot reach the merits of Teva's APA challenge or its motion for a preliminary injunction, however, without first addressing standing, and, as the record now stands, Teva has failed to clear that threshold hurdle. The "irreducible constitutional minimum" of standing requires: "(1) that the plaintiff have suffered an 'injury in fact'—an invasion of a judicially cognizable interest which is (a) concrete and particularized and (b) actual and imminent, not conjectural or hypothetical; (2) that there be a causal connection between the injury and the conduct complained of—the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not

before the court; and (3) that it be likely, as opposed to speculative, that the injury will be redressed by a favorable decision." *Bennett v. Spear*, 520 U.S. 154, 167 (1997) (quoting *Lujan*, 504 U.S. at 560–61).

Teva contends that it has pled two types of injuries sufficient to establish standing: "[F]irst, [it argues] that the [Suboxone Letter Decision] already has divested Teva of its statutory right to exclusivity" and that, in any event, it has adequately alleged that it "will suffer even greater harms when [the] FDA formally applies that decision and approves competing ANDAs in violation of Teva's statutory right to exclusivity." Dkt. 36 at 14, 17. "[S]econd," it argues that, by jettisoning its "first effective approach" to awarding "first applicant" status in the Suboxone Letter Decision, the FDA deprived Teva of procedural rights under the APA, including the right to participate in a notice-and-comment rulemaking. *Id*. at 14. The Court will address each type of alleged injury in turn.

A. Loss of Exclusivity

The parties agree that the loss of generic exclusivity is a concrete injury sufficient to confer standing. They disagree, however, about whether Teva has met its burden of plausibly alleging or otherwise showing that it will suffer an actual and imminent injury that is fairly traceable to the Suboxone Letter Decision. Before addressing that question, a threshold matter requires brief discussion.

The parties dispute whether Teva may bring "a pre-enforcement challenge to an agency interpretation born of an adjudication"—the Suboxone Letter Decision—to which it was not a party.[2] *Teva v. Sebelius*, 595 F.3d at 1312. The D.C. Circuit observed in *Sea-Land Service, Inc.*

[2] For present purposes, the Court need not, and does not, address whether Teva can meet the "final agency action" requirement under the APA because that requirement is non-jurisdictional, *see Trudeau v. FTC*, 456 F.3d 178, 183–84 (D.C. Cir. 2006), and the Court must address

v. Department of Transportation, 137 F.3d 640. 648 (D.C. Cir. 1998), that "the mere precedential effect" of an adjudication "within an agency is not, alone, enough to create Article III standing, no matter how foreseeable the future litigation" involving the plaintiff. Although that principle is undoubtedly correct, it is not very helpful in resolving the present dispute. It is unassailable that the "mere potential precedential effect of an agency action" is not, alone, sufficient to establish standing. *Teva v. Sebelius*, 595 F.3d at 1312–13 (quoting *Shipbuilders Council of Am. v. United States*, 868 F.2d 452, 456 (D.C. Cir. 1989)). But it is equally true that "[a]n agency's imminent application of its established interpretation of a statute" to the plaintiff's concrete detriment is likely sufficient. *Id.* at 1313–14. Although both statements of the law are correct, neither answers the central question presented by the defendants' motions to dismiss: Has Teva shown that it faces a "realistic danger" that the Suboxone Letter Decision's interpretation of the MMA, if let stand, will cause the company to suffer a concrete injury that is "actual or imminent" and that "is likely" to be "redressed by a favorable judicial decision?" *Lujan*, 504 U.S. at 560–61. In other words, has Teva shown that it can satisfy the "irreducible constitutional minimum" that Article III requires? Because the two concepts most relevant here, causation and redressability, "overlap as two sides of the same causation coin," *Dynalantic Corp. v. Dep't of Defense*, 115 F.3d 1012, 1017 (D.C. Cir. 1997); *see also Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 n.1 (D.C. Cir. 2017) (same), the Court will treat them together.

1. *Immediate Loss of Right to Exclude*

Teva first argues that it has already suffered a concrete and redressable injury because the FDA's issuance of the Suboxone Letter Decision stripped the company of its right to 180-day

jurisdiction before reaching the merits, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998).

exclusivity. Dkt. 36 at 14–15, 16. According to Teva, "the key point here is that the challenged FDA decision *already* has destroyed the embedded value in Teva's exclusivity right," regardless of whether Teva or another manufacturer ever receives FDA approval. *Id.* at 26. The Court is unpersuaded.

Teva is, of course, correct that a first applicant can suffer a concrete injury before its ANDA is approved. That is because, once a first applicant files an ANDA containing a Paragraph IV certification (and, according to Teva, provides the required notice to the patent owner and NDA holder), the FDA may not approve any subsequently-filed ANDA until at least "180 days after the date of the first commercial marketing of the drug . . . by any first applicant." 21 U.S.C. § 355(j)(5)(B)(iv)(I). Teva takes this principle a step further, however, and argues that "first applicant status" constitutes a property right "no different from a patent" and that the right exists "[r]egardless of whether the exclusivity holder uses the right itself." Dkt. 36 at 19–20. This "exclusionary right," according to Teva, "[l]ike every other property right, . . . has immediate, real, and tangible value to the first applicant." *Id.* at 20. Most notably, Teva asserts that the right is "alienable" and that the first applicant may "waive or relinquish its exclusivity in exchange for valuable consideration." *Id.* at 21–22. Although Teva acknowledges that it has no intention of waiving its first applicant status, it maintains that the Suboxone Letter Decision "already has eviscerated Teva's current" property right and, "along with it, the embedded value that otherwise-alienable property would have." *Id*. at 23. Finally, Teva argues that the immediate nature of this loss "forecloses the defendants' suggestion" that "Teva must at least show that another applicant's ANDA will be approved" to establish a concrete injury. *Id.* at 26. In other words, even if no cyclosporine ANDA is ever approved, Teva maintains that it has nonetheless suffered a cognizable loss.

Teva's theory of "embedded value" misconceives how the Hatch-Waxman Amendments and the MMA function and what Article III demands. Teva fails to identify any precedent that has ever held that a first applicant acquires a property interest akin to a patent as soon as it files a substantially complete ANDA containing a Paragraph IV certification and provides the requisite notice. That absence of authority is unsurprising for several reasons. First and foremost, a patent differs in fundamental respects from first applicant status. A patent is issued to a qualifying inventor, 35 U.S.C. § 154(a)(1), who may then bring an infringement action against anyone who practices or sells the patent owner's invention without her permission, *id.* § 271. The Patent Act, moreover, provides that "patents shall have the attributes of personal property," *id.* § 261, and the Supreme Court has long recognized that "[a] patent for an invention is as much property as a patent for land," *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 96 (1876). First applicant status, in contrast, dictates only the order and timing with which the FDA may approve ANDAs. A first applicant, to be sure, obtains a benefit, but its rights are only enforceable against the FDA for failing to abide by *its* statutory obligations, and not (at least directly) against another manufacturer who may attempt to market its product prematurely. The benefit conferred, moreover, is far more inchoate than the benefit conferred by a duly issued patent, and neither history nor statutory text suggests that Congress intended to confer first applicants an immediate property interest. Indeed, as discussed further below, an ANDA applicant may not know for years after it files its Paragraph IV certification whether it will attain the ultimate benefit of 180 days of generic exclusivity.

Nor is the Court convinced that a putative first applicant attains an alienable interest in its status immediately upon submitting its ANDA and effecting notice of the Paragraph IV certification. According to Teva, the FDA and courts have recognized that a "first applicant can

in certain circumstances 'waive' its right to another company in exchange for monetary consideration, and that [a] first applicant always is free to 'relinquish' its exclusivity altogether for such consideration." Dkt. 36 at 20. In support of this contention, Teva cites to a letter decision from the FDA, a proposed regulation that was never finalized, and three judicial decisions. None of those sources, however, supports Teva's sweeping view that an ANDA applicant obtains an immediate property interest in its first applicant status.

To start, the FDA letter decision, which contains the most extensive discussion of the issue, actually undercuts Teva's asserted property interest. In that proceeding, the FDA was asked by a brand-name manufacturer to preclude the first applicant from transferring or waiving its right to 180-day exclusivity. *See* Dkt. 42-2 at 2. The FDA declined to do so, concluding that it "is a public health agency" and "generally do[es] not interfere in business arrangements of private parties" in the absence of a "public health impact" or a statutory prohibition. *Id*. at 3. The FDA, nonetheless, drew a distinction between what an ANDA applicant may do *before* and *after* the 180-day "exclusivity period has been triggered."[3] *Id.* at 5–6. Before the date of the first commercial marketing of the generic by a first applicant, a first applicant may relinquish, but may not selectively waive, its claim to exclusivity. *Id.* After the exclusivity period is triggered, however, a first applicant "may relinquish its exclusivity entirely[,] or [it may] selectively waive [that] exclusivity in favor of a single ANDA, or multiple ANDAs, containing a [P]aragraph IV certification." *Id.*

As the FDA explained, it "limited the availability of selective waiver" prior to the trigger-date based on two concerns. *Id.* at 6 n.5. First, "there are many reasons why an ANDA applicant

[3] The relevant trigger date changed with the enactment of the MMA. *Compare* 21 U.S.C. §§ 355(j)(5)(B)(iv)(I)&(II) (2002) *with* 21 U.S.C. § 355(j)(b)(5)(iv)(I) (2018).

might lose its eligibility before the exclusivity period has been triggered;" for instance, "the patent could expire necessitating a change to a Paragraph II certification." *Id.* Second, "permitting selective waiver before exclusivity is triggered could lead to the 'commercialization' of the first 'seat'" and might, accordingly, "encourage applicants to submit only marginally adequate ANDAs solely to obtain the economic benefit of waiving the exclusivity as to an applicant with a more viable ANDA." *Id.* The FDA stressed that, "[a]lthough [it] has stated that it does not consider exclusivity to be a property right that transfers separately and apart from an application," it was concerned that it might be "drawn into complex private disputes regarding the economic and competitive impacts of a selective waiver 'right' that is never 'perfected' because first the applicant loses eligibility for that exclusivity." *Id.*

Contrary to Teva's "embedded value" theory, the FDA has declined to accord any "embedded" right, beyond simple relinquishment, to first applicants *before* the exclusivity period is triggered. The other authorities that Teva cites, moreover, provide no support to the contrary. The proposed regulation addressing this issue mirrors the discussion in the FDA's letter decision. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,881 (Aug. 6, 1999). And none of the three cases hold that a first applicant can selectively waive and thereby monetize the right to exclusivity *before* the 180-day period is triggered. *See Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 350 (D.N.J. 2003); *Boehringer Ingelheim Corp. v Shalala*, 993 F. Supp. 1, 2 (D.D.C. 1997); *Granutec, Inc. v. Shalala*, 1998 WL 153410, at *9 (4th Cir. Apr. 3, 1998). In both *Boehringer* and *Granutec*, the 180-day exclusivity period had already been triggered. *See Boehringer*, 993 F. Supp. 2d at 2; *Granutec*, 1998 WL 153410, at *5. And in *Dr. Reddy's Laboratories*, the court expressly noted that Reddy would not "be able to sell [its] rights to . . . exclusivity" until "the FDA . . . awarde[d]

Reddy exclusivity." 302 F. Supp. 2d at 349. The Court did not specify whether that restriction was due to the law or the market, but, regardless, the decision does not support Teva's contention that the right to exclusivity can be sold before the trigger date.

In sum, Teva has failed to "show that [it] 'has sustained or is immediately in danger of sustaining some direct injury,'" *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) (citation omitted), as the result of the FDA's Suboxone Letter Decision. Whatever "embedded value" that might exist *today* in Teva's alleged first applicant status is simply too inchoate and abstract to support Teva's claim that it has standing.[4]

2. *Future Loss of Right to Exclude*

Teva argues, in the alternative, that it will likely suffer a concrete injury in the near future if the Suboxone Letter Decision is allowed to stand and that this imminent harm is sufficient to sustain its standing to sue. It asserts, in particular, that it will suffer "tens of millions of dollars in lost sales due to the decreased market share it will have when [the] FDA unlawfully approves its competitors during what Teva alleges to be its legally-protected exclusivity period." Dkt. 36 at 15. For support, Teva points to two lines of precedent, which it contends establish that its alleged, putative losses readily satisfy the threshold requirement for pleading standing. The Court is, again, unpersuaded.

[4] Teva's allegation that the Suboxone Letter Decision has "upended the Company's ongoing and previously-initiated 'production activities in anticipation of an upcoming commercial launch,'" Dkt. 36 at 14 (quoting Dkt. 1-1 at 7 (Groff Decl. ¶ 12)), also does not satisfy the injury-in-fact requirement. The Supreme Court has cautioned that plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416 (2013). As explained below, the harm that Teva seeks to avoid here—a determination by the FDA that it is not entitled to 180-day exclusivity for cyclosporine—is *not* "certainly impending." Accordingly, to the extent that Teva has incurred any costs by preventatively "upending" its production activities, that injury is self-inflicted, and it is "not fairly traceable" to the Suboxone Letter Decision.

First, Teva relies on the Supreme Court's decision in *Bennett v. Spear*, 520 U.S. 154. As Teva correctly observes, *Bennett* held that the plaintiffs in that case had met their "relatively modest [burden]" at the pleading stage, *id.* at 170, of alleging that a Biological Opinion issued by the Fish and Wildlife Service ("FWS") was likely to cause them a redressable injury, even though the agency that would ultimately decide how to proceed—the Bureau of Reclamation—was "technically free to disregard the Biological Opinion and [to] proceed with the proposed action . . . at its own peril," *id.* at 170. From this, Teva concludes that it is sufficient at the motion to dismiss stage simply to allege a "future agency action and resulting harm." Dkt. 36 at 16. That contention, however, both misreads *Bennett* and ignores subsequent precedent. It misreads *Bennett* because the Court merely held that the plaintiffs *in that case* had alleged an imminent and redressable injury. As the Court explained, the government itself conceded that, even if technically advisory, the FWS's Biological Opinion has "a powerful coercive effect" and agencies "very rarely choose to engage in conduct that the [FWS] has concluded is likely to jeopardize the continued existence of a listed species" because "any person who knowingly 'takes' an endangered or threatened species is subject to civil and criminal penalties." *Bennett*, 520 U.S. at 169–70.

Teva also ignores developments in the law since *Bennett* was decided. Although it was—and remains—the law that a plaintiff's showing of standing must be evaluated in light of the relevant stage of the proceeding, *see Lujan*, 504 U.S. at 561, the requirement for overcoming a motion to dismiss has evolved since 1997. In describing the "modest" burden, *Bennett* cited to *Lujan*, 504 U.S. 561, which in turn cited language that can be traced to *Conley v. Gibson*, 335 U.S. 41, 45–46 (1957). *See Bennett*, 520 U.S. at 168. The Supreme Court, however, overruled *Conley* in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S.

662 (2009). Under current law, unlike under *Conley*, a complaint must contain "more than an unadorned, the defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. "Threadbare recitals of the elements of [standing], supported by mere conclusory statements, [will] not suffice." *Arpaio*, 797 F.3d at 19 (internal quotations and citations omitted). Moreover, as explained above, the Court "may reject as overly speculative those links which are predictions of future events." *Id.* at 21 (quoting *United Transp. Union v. ICC*, 891 F.2d 908, 913 (D.C. Cir. 1989)). Understood in this light, *Bennett* does not support Teva's claim that it has standing.

Second, and more to the point, Teva relies on *Teva v. Sebelius*, 595 F.3d at 1311, for the proposition that "courts in this circuit routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." Dkt. 36 at 27 (quoting same). That is true, but it is also true that courts in this circuit have routinely declined to reach the merits of disputes of this type because the plaintiff lacks standing or because its claim is unripe. *See, e.g.*, *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999) [hereinafter "*Pfizer v. Shalala*"]; *Mylan*, 789 F. Supp. 2d at 2. The relevant question is: on which side of this divide does Teva's challenge fall?

The two leading D.C. Circuit cases are *Pfizer v. Shalala*, 182 F.3d 975, and *Teva v. Sebelius*, 595 F.3d 1303. In *Pfizer v. Shalala*, Pfizer held an NDA for a drug used to treat angina and hypertension.[5] 182 F.3d at 976. Mylan filed an ANDA seeking approval for a generic

[5] Although Pfizer addressed ripeness, and not standing, the two inquiries overlap. *See Navegar, Inc. v. United States*, 103 F.3d 994, 998 (D.C. Cir. 1997) ("In deciding whether a case is ripe for adjudication, federal courts generally consider the hardship to the parties of withholding court resolution (a factor that overlaps with the "injury in fact" facet of standing doctrine), and the fitness of the issues for judicial resolution (a factor that resembles the prudential concerns applied in the standing context)." (citations omitted)); *see also Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012) ("Part of [ripeness doctrine] is subsumed into the Article III requirement of standing, which requires a petitioner to allege *inter alia* an injury-in-fact that is

version of the drug, although Mylan's product used a "release mechanism different from Pfizer's." *Id.* After unsuccessfully seeking relief from the FDA, Pfizer brought suit challenging the FDA's decision to accept Mylan's ANDA for review on the ground that Mylan's version of the drug used a different delivery mechanism than the referenced drug. *Id*. at 977–78. The D.C. Circuit held that the challenge was not ripe because it remained uncertain whether the FDA would ever approve Mylan's application.[6] *Id.* at 979. For two reasons, moreover, the court rejected Pfizer's contention that the FDA's acceptance of Mylan's ANDA for processing had an immediate effect on "the legal rights of all subsequent applicants." *Id.* First, the contention "assume[d] its own conclusion" that Mylan would be entitled to 180-days of generic exclusivity. *Id.* Second, "the legal rights that [were allegedly] affected [were] not Pfizer's but those of [Mylan's] competitors, about which Pfizer is not in a position to complain." *Id.*

Teva v. Sebelius involved a very different context. In that case, Teva had received tentative approval to market a generic version of a drug used to treat hypertension, and that tentative approval was set to "become final once the 'pediatric exclusivity period' end[ed]." 595 F.3d at 1304. "Thwarting its receipt of that entitlement, however, [was] an FDA interpretation of the [FDCA]," which would have allowed "not only Teva but all generic manufacturers to sell their approved [versions of the drug] right out of the gate." *Id.* Unlike in *Pfizer*, the D.C. Circuit

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'imminent' or 'certainly impending.'" (citations omitted)). *Pfizer* is instructive here for whether Teva has alleged a sufficiently imminent injury-in-fact.

[6] After oral argument, the FDA granted tentative approval for Mylan's drug, but the D.C. Circuit still concluded that the case was not ripe. *Id.* at 980. Although the tentative approval increased the likelihood that the FDA would "eventually approve Mylan's drug," the court held that Pfizer would not suffer any hardship if required to wait to sue because it was entitled to rely on the thirty-month stay, and the case was not fit for review because, if required to wait, Pfizer could renew its claim and also include "any other claim that might arise from the agency's final approval." *Id.*

held that Teva's claim was ripe and that the company had standing to sue, despite the fact that Teva was not yet entitled to go to market and the FDA had not yet made its exclusivity determination. *Id.* at 1305. As the court explained, Teva's claim was ripe and it had standing because there was "virtually no doubt" that the FDA would apply a policy forfeiting Teva's (otherwise certain) right to exclusivity. *Id.* at 1309.

Neither *Pfizer v. Shalala* nor *Teva v. Sebelius* are controlling for present purposes. *Pfizer v. Shalala* differs from this case because Teva is suing to vindicate its *own* right to exclusivity. Teva will, accordingly, have the right—if it is a bona fide first applicant—to challenge a decision by the FDA permitting one its competitors (other than another first applicant) to proceed to market even before Teva's ANDA is approved. As a result, unlike in *Pfizer v. Shalala*, uncertainty about whether and when Teva's ANDA will receive approval, although a relevant consideration, is not dispositive. *Teva v. Sebelius* also differs from the present case in significant respects. Most notably, *Teva v. Sebelius* turned on the facts that (1) Teva had already received tentative approval of its ANDA, and there was "no possible deficiency or uncertainty in Teva's ANDA that could [thwart] final approval," 595 F.3d at 1309; (2) there was "no reason to doubt" that, amongst the ANDA applicants, Teva had filed the first Paragraph IV certification, thereby qualifying Teva as a "first applicant," *id.*; (3) it was "virtually inconceivable" that a 'forfeiture event[]"—other than the one challenged—would "deprive Teva of exclusivity before final approval," *id.* at 1309–10; and (4) the FDA's new policy "will almost certainly" forfeit Teva's exclusivity, *id.* at 1310.

Teva argues that "tentative approval" is a red herring in the present context. To begin, Teva contends that tentative approval is unavailable here because there is currently no impediment to the FDA granting final approval, Dkt. 36 at 27, such as another manufacturer's

entitlement to exclusivity or an existing patent that covers the drug, *see* 21 C.F.R. § 314.105(d). The U.S. District Court for the Eastern District of Texas has declared all relevant Restasis® patents invalid, *see Allergan, Inc. v. Teva Pharms. USA, Inc*., 2017 WL 4803941, at *65, and—if Teva's claim on the merits is correct—no other manufacturer has a superior claim to exclusivity. Teva argues, moreover, that, even if its ANDA is not ready for approval when exclusivity is triggered, as a first applicant, it is entitled to block other generic manufacturers, who are not entitled to exclusivity, from marketing their drugs. Dkt. 36 at 18. Finally, Teva points to the following dicta in *Mylan*, 789 F. Supp. 2d at 8: "Granting first filers pre-tentative-approval standing to challenge the FDA's approval of a competitor's ANDA is at times necessary to prevent imminent harm. Without this standing, first filers . . . would have no means of protecting their hard-earned statutory interest in a period of marketing exclusivity." *See* Dkt. 36 at 24 (quoting same).

With the exception of Teva's conclusion, the Court agrees with much of this. In *Mylan*, this Court held that a generic applicant that was, by its own admission, not a first applicant and that had not yet received tentative approval, lacked standing to compel the FDA to act on a competitor's ANDA. 789 F. Supp. 3d at 9. The court noted, in dicta, however, that a "first filer" might have "pre-tentative approval standing to challenge the FDA's approval of a competitor's ANDA." *Id.* at 8. That is not this case. Teva is neither an undisputed first filer nor is it challenging the FDA's imminent approval of a specific competitor's ANDA. Moreover, as the *Mylan* decision goes on to explain, what was "[c]ritical to" the D.C. Circuit finding that the plaintiff in *Teva v. Sebelius* had standing "was the fact that 'there [was] no material ambiguity about [the] essential facts.'" 789 F. Supp. 2d at 8–9 (citation omitted). Although the presence of tentative approval was not a *sine qua non* of Teva's standing in that case, it was essential to the

court's finding that Teva's alleged injury was certain and impending. Indeed, the D.C. Circuit knew the exact date that the FDA's exclusivity determination (and hence, Teva's alleged injury) would take place: the day that the brand-name drug's pediatric exclusivity period expired. *Id.* at 1304. In short, as the *Mylan* decision itself recognizes, "*Teva v. Sebelius* . . . stands for the narrow[] proposition that where there is no material ambiguity about essential facts—as evidenced by Teva's tentative approval and first filer status—a court may 'reach the merits of [a] generic manufacturer['s] claim[] to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue.'" 789 F. Supp. 2d at 9 (quoting *Teva v. Sebelius*, 595 F.3d at 1311).

For a variety of reasons, the same is not true here. *First*, there is no guarantee that the FDA will approve *any* of the existing ANDAs. *See* 21 C.F.R. § 314.127 (setting forth numerous reasons for which the FDA will refuse to approve an ANDA). Obtaining approval for an ANDA is a demanding task, *Amneal Pharms. LLC*, 285 F. Supp. 3d at 333 (describing process); Dkt. 26 at 19, and approval is by no means a forgone conclusion. Without tentative approval as a signal or any other indication about the status of the FDA's review, the Court has no means of assessing whether any ANDA is likely to receive approval, and if so, when that is likely to occur. *Second*, even if the FDA eventually approves an ANDA for cyclosporine, the Court can only speculate about whether Teva's ANDA will still be under review at that point. Given the rigor of the ANDA process, it is possible that Teva's ANDA will be rejected before the FDA issues its first approval. *Third*, and most significantly, the FDCA includes six "forfeiture events" that result in a first applicant's loss of "[t]he 180-day exclusivity period," 21 U.S.C. § 355(j)(5)(D)(ii), two of which are of particular relevance here.

A dispositive factor in *Teva v. Sebelius* was Teva's ability to demonstrate that none of these forfeiture events would occur. *See* 595 F.3d at 1310. With respect to a number of the statutory forfeiture events, Teva has done so here as well. But, with respect to two, Teva has not cleared this hurdle. First, although Teva contends that much of the delay in the FDA's review of its ANDA is attributable to the FDA, it is too soon to tell whether Teva would, if otherwise qualified, forfeit its entitlement to exclusivity because it has failed to obtain approval within thirty months of the date its ANDA was received. *See* 21 U.S.C. § 355(j)(5)(D)(i)(IV). Teva answers this contention by noting that the FDA will never make the thirty-month determination absent the relief that Teva is seeking in this action because the forfeiture provision applies only to first applicants, and, under the Suboxone Letter Decision, Teva is not a first applicant. Dkt. 36 at 28. But, even if the FDA was prepared to consider whether the thirty-month provision forecloses Teva's claim to exclusivity before considering the issue raised in the Suboxone Letter Decision, it is not possible to determine, on the present record, whether Teva would have any plausible basis for disputing the applicability of the forfeiture event. The Court cannot tell, for example, whether Teva's ANDA is weeks, months, or years away from approval—or, indeed, whether it will ever be approved.

The second possible forfeiture event raises even greater uncertainty. Under that provision, a first applicant loses any entitlement to market exclusivity if it fails to market its drug within 75 days after the entry of a final court decision "from which no appeal (other than a petition to the Supreme Court for a writ of certiorari)" is taken, finding the referenced patents invalid or not infringed. *Id.* § 355(j)(5)(D)(i)(I)(bb). As explained above, that provision may well apply here because the U.S. District Court for the Eastern District of Texas found that each of the relevant Restasis® patents is invalid, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2017 WL

4803941, *65, and the Federal Circuit summarily affirmed that decision on November 13, 2018, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 742 F. App'x at 511. Since then, Allergan filed a timely petition for rehearing and rehearing en banc, Dkt. 103, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 18-1130 (Fed. Cir. Dec. 21, 2018), and the Federal Circuit ordered a response to that petition, Dkt. 108, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 18-1130 (Fed. Cir. Jan. 17, 2019). If the Federal Circuit grants rehearing and reverses the district court's decision invalidating the Restasis® patents, Teva would forfeit its right to exclusivity because it will need to amend its ANDA to assert a Paragraph III certification with respect to the '111 patent. 21 U.S.C. § 355(j)(2)(D)(i)(III). Alternatively, if the Federal Circuit denies rehearing, and Teva fails to market cyclosporine within 75 days the Federal Circuit's final entry of judgment, Teva will forfeit any entitlement to exclusivity. *Id.* § 355(j)(5)(D)(i)(I)(bb). As a result, Teva's interest—or claim of injury—turns on the prospect that the FDA will grant final approval to an ANDA *before* the Federal Circuit renders a final decision, *or*, assuming the Federal Circuit enters a final judgment affirming the district court's decision, that a first applicant will enter the market within seventy-five days of that decision. That is, of course, possible. But it falls far short of the lack of "material ambiguity" that informed the D.C. Circuit's decision in *Teva v. Sebelius*, 595 F.3d at 1310.

The Court, accordingly, concludes that Teva's asserted loss of exclusivity due to the FDA's Suboxone Letter Decision fails to satisfy the causation and redressability requirements for Article III standing.

B. APA Violation

Teva's second claim to standing—that it was injured by the FDA's failure to abide by the procedural requirements set forth in the APA—fares no better. Teva alleges that, because the

FDA's Suboxone Letter Decision "adopted precisely the opposite position from the one taken in its MMA regulations," the FDA was required to (and did not) engage in notice-and-comment rulemaking. Dkt. 1 at 28–29 (Compl. ¶¶ 48–49). The Supreme Court, however, has held that the allegation of "a bare procedural violation, divorced of any concrete harm," does not "satisfy the injury-in-fact requirement of Article III." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016); *see also Ctr. For Law and Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1159 (D.C. Cir. 2005); *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664–65 (D.C. Cir. 1996) (en banc). Rather, a "procedural-rights plaintiff" must also show that "it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest." *Ctr. For Law and Educ.*, 396 F.3d at 1159 (quoting *Fla. Audubon Soc'y*, 94 F.3d at 665)). Although the requirements of "imminence and redressability" are relaxed when a plaintiff alleges a procedural injury, a procedural-rights plaintiff must still "satisfy the general requirements of the constitutional standards of particularized injury and causation." *Id.* In other words, "[a] prospective plaintiff must demonstrate that the defendant caused the particularized injury (or is likely to cause) and *not just* the alleged procedural violation." *Id.* (second alteration in original).

Here, the "essential injury" to Teva's "own interest" *is* the potential loss of exclusivity. And, as explained above, the Court has concluded that the "chain of causation" between the FDA's Suboxone Letter Decision and Teva's alleged loss of exclusivity "is speculative at best." *Id.* The Court, accordingly, holds that Teva's asserted procedural injury also fails to satisfy the constitutional minimum for standing to sue.

CONCLUSION

The Court will, accordingly, **DENY** Plaintiff's motion for a preliminary injunction, Dkt. 2, and **GRANT** the defendants' motions to dismiss for lack of standing, Dkt. 25; Dkt. 27.

A separate order will issue.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: February 26, 2019