**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| PERRIGO RESEARCH & DEVELOPMENT COMPANY,<br><br>Plaintiff,<br><br>v.<br><br>UNITED STATES FOOD AND DRUG ADMINISTRATION<br><br>Defendant,<br><br>and<br><br>AUROBINDO PHARMA LTD., *et al*.<br><br>Intervenor Defendants. | Civil Action No. 17-2517 (ABJ) |

**MEMORANDUM OPINION**

Plaintiff Perrigo Research & Development Company ("Perrigo") brings this action against defendant United States Food and Drug Administration ("FDA") under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 501–706, the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02. It seeks redress for FDA's refusal to answer Perrigo's request to confirm that a Consent Judgment and Decree entered on September 20, 2017 is legally insufficient to trigger the running of a 75-day period during which Perrigo must begin marketing its product or risk forfeiting its eligibility for a 180-day period of generic drug marketing exclusivity. *See* Compl. [Dkt. # 1] ¶¶ 2–3. Perrigo claims in Count I that the FDA has violated the APA by "fail[ing] to act," and that therefore, this Court should step in and rule on the question Perrigo posed to the agency. *Id.* ¶¶ 32–34. In Count II, it

asks the Court to enter a declaratory judgment stating that the Consent Judgment and Decree did not trigger the 75-day period under the statute. *Id.* ¶ 37.

Because Perrigo has failed to allege a violation of the APA, defendant's motion to dismiss Count I will be granted. And without a viable claim under the APA and in the absence of a case or controversy, the Court lacks subject matter jurisdiction to issue a declaratory judgment under Count II, so that count will also be dismissed.

## BACKGROUND

### I. Statutory Background

The FDCA requires all new drugs to be approved by the FDA before they are introduced into interstate commerce. 21 U.S.C. § 355(a). It provides two primary pathways for obtaining approval: (1) the new drug application ("NDA"), described in section 355(b); and (2) the abbreviated new drug application ("ANDA") for generic products, set forth in section 355(j). The NDA procedure requires the applicant to conduct a spectrum of safety and effectiveness tests and to inform FDA of the results. *See* 21 U.S.C. § 355(b)(1). It also requires the applicant to file information about any patents filed in connection with the drug. *See id.* Once the drug is approved, it is referred to as a "listed drug." *See* 21 C.F.R. § 314.3(b).

Congress added the truncated ANDA approval process to the FDCA as part of the 1984 Hatch-Waxman amendments, which sought "to make available more low cost generic drugs" by providing a pathway that was less costly and time consuming than the NDA process. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998), quoting H.R. Rep. No. 98-857, pt. 1, at 14 (1984). A drug manufacturer that follows the ANDA pathway may rely on research conducted by a third party – the maker of the listed drug – in order to meet the approval requirements. *See* 21 U.S.C. §§ 355(b)(2), j(2)(A). ANDA applicants must file information showing that the

conditions of use, active ingredient, route of administration, dosage form, strength, and labeling of the generic drug are "the same as" those of the listed drug that was previously approved. 21 U.S.C. §§ 355(j)(2)(A)(i)–(iii), (v). They are thereby relieved of the obligation to perform the extensive testing to demonstrate safety and effectiveness that is the hallmark of the NDA process. *See* § 355(b)(1)(A).

To protect the patent rights of the makers of the listed drugs, ANDA applicants must provide one of four "certifications" for "each patent which claims the listed drug . . . or which claims a use for such listed drug for which the application is seeking approval." § 355(j)(2)(A)(vii); *see also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001). Thus, for each relevant patent, ANDA applicants must certify either:

> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) of the date on which such patent will expire, 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.

§ 355(j)(2)(A)(vii)(I)–(IV). FDA may approve an ANDA containing either of the first two certifications effective immediately, § 355(j)(5)(B)(i), and it may approve an ANDA containing the third type of certification to be effective as of the relevant patent's expiration date. § 355(j)(5)(B)(ii). But the filing of the fourth type of certification – referred to as a "paragraph IV certification" – is an act of patent infringement on the part of the ANDA applicant, *see* 35 U.S.C. § 271(e)(2)(A), and it can trigger patent infringement litigation. The FDCA requires an ANDA applicant to notify the patent holder of the filing of a paragraph IV certification, 21 U.S.C. § 355(j)(2)(B), and the patent holder has 45 days from the receipt of notice to bring suit against the applicant. § 355(j)(5)(B)(iii). If the patent holder does not file a lawsuit within that time period, the ANDA will become effective immediately. *Id.*

The FDCA provides an incentive and reward to generic drug applicants willing to expose themselves to the litigation risk. It grants the "first applicant" – the applicant that is first to file a substantially complete ANDA that contains and lawfully maintains a paragraph IV certification to a listed patent – an opportunity to be the only generic product in the market competing with the listed drug for a period of time. *See* §§ 355(j)(5)(B)(iv)(II)(aa), (bb). During this 180-day period of marketing exclusivity, FDA may not approve any competing generic version of the drug if the ANDA for the subsequent applicant also contains a paragraph IV certification. *See* § 355(j)(5)(B)(iv)(I). The 180-day period begins to run when the first applicant begins marketing the product. *See id.*

But an applicant can forfeit its 180-day exclusivity period, thereby opening the market to other generic drug manufacturers. *See* § 355(j)(5)(D). A first applicant forfeits its eligibility for 180-day generic exclusivity if it fails to market the drug within certain time periods prescribed in the statute. § 355(j)(5)(D)(i)(I). Under the FDCA, a forfeiture event occurs if a first applicant fails to market the drug by the later of two dates. The parties agree that the only date relevant to this dispute is the second "bookend" date, which is defined as follows:

> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval),[1] the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period . . . at least 1 of the following has occurred:
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> (AA) In an infringement action brought against the applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, 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 that the patent is invalid or not infringed.

1 The statute defines "tentative approval" as "notification to an applicant . . . that an application . . . meets the requirements . . . but cannot receive effective approval because . . . there is a period of exclusivity for the listed drug." § 355(j)(5)(B)(iv)(II)(dd)(AA).

> (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

§ 355(j)(5)(D)(i)(I)(bb).[2]

The specific provision at issue in this dispute is (bb)(BB), under which a first generic applicant can forfeit its 180-day exclusivity period if it fails to market the drug within 75 days of a consent decree in the second applicant's lawsuit against the patent holder.

## II. Factual Background

On March 30, 2012, Perrigo submitted an ANDA for approval to market a generic version of AstraZeneca's Prilosec OTC Delayed-Release Tablets. Compl. ¶ 4. Perrigo's ANDA included paragraph IV certifications for both U.S. patents listed in the Orange Book[3] for AstraZeneca's drug. *Id.* ¶ 5. FDA approved Perrigo's ANDA on July 30, 2015, and it informed Perrigo that it was eligible for 180-day marketing exclusivity because it was the first company to file a substantially complete ANDA for the product with a paragraph IV certification. *Id.* ¶ 6. While more than two years have gone by, Perrigo has not yet marketed its generic omeprazole magnesium drug product. *Id.* ¶ 7.

On June 16, 2016, FDA granted tentative approval to a second ANDA filed by Aurobindo Pharma Limited and Aurobindo Pharma Inc. (collectively, "Aurobindo") for Omeprazole Magnesium Tablets (OTC). Compl. ¶ 8. Aurobindo's application cannot receive final approval

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2 The first "bookend" date is the earlier of "75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii)," or "30 months after the date of submission of the application of the first applicant." § 355(j)(5)(D)(i)(I)(aa).

3 Once an NDA is approved, FDA publishes the patent information it receives in the agency's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is referred to as the "Orange Book." Mem. in Supp. of Def.'s Mot. to Dismiss & Opp. to Pl.'s Req. for Injunctive & Declaratory Relief [Dkt. # 5-1] at 3.

"until the expiration of Perrigo's 180-day generic exclusivity, unless Perrigo forfeits that exclusivity." *Id.*

On August 18, 2016, Aurobindo filed an action against AstraZeneca in the United States District Court for the District of New Jersey under 21 U.S.C. § 355(j)(5)(C), the FDCA provision authorizing civil actions for patent certainty. *See Aurobindo Pharma Ltd. v. AstraZeneca AB*, No. 3:16-cv-05079 (D.N.J. Aug. 18, 2016). It sought a declaratory judgment that Aurobindo's omeprazole magnesium product does not infringe the two unexpired patents listed in the Orange Book for Prilosec OTC, or that those patents are invalid. *See id.*; Certification of Marc D. Youngelson [Dkt. # 8] ("Youngelson Certification") ¶ 3; Ex. A to Youngelson Certification [Dkt. # 8] ("Aurobindo Compl."). In its complaint, Aurobindo specifically referenced its need to obtain a judgment that would trigger the 75-day period in which Perrigo would have to begin marketing its omeprazole magnesium ANDA product to avoid forfeiture of its eligibility for 180-day exclusivity. *See* Aurobindo Compl. ¶¶ 34, 48, 50, 53.

The court entered a Consent Judgment and Decree in the Aurobindo lawsuit on September 20, 2017, which ordered, adjudged and decreed:

> In light of the license granted under Article 5 of the Settlement Agreement, the Court enters final judgment in Civil Action No. 3:16-cv-07330-MLC-TJB that the making, having made, using, selling, offering to sell, importing or distributing of the Aurobindo Product by Aurobindo or any of its Affiliates, successors and assigns does not infringe the AstraZeneca Patents.

Ex. 2 to Compl. [Dkt. # 1-3] ¶ 3 ("Consent Judgment and Decree"); *see also* Compl. ¶ 12. Perrigo did not become aware of this order until October 10, 2017 because it had originally been filed under seal. *See* Compl. ¶ 9.

On October 18, 2017, Perrigo sent FDA a letter, requesting a "formal – and prompt – decision from FDA with respect to forfeiture of eligibility of 180-day exclusivity under the so-called 'failure-to-market provisions.'" Ex. 3 to Compl. [Dkt. # 1-4] ("Perrigo Letter") at 1.

It asked the agency to confirm that the Consent Judgment and Decree obtained by Aurobindo "is wholly insufficient to trigger the 75-day period under" the FDCA, and that Perrigo would not forfeit its exclusivity eligibility 75 days after the date of the Consent Judgment and Decree (on or about December 4, 2017) if it failed to begin commercial marketing of the drug product approved under its ANDA. Perrigo Letter at 1–2; Compl. ¶ 13. Given the urgency of the situation, Perrigo asked FDA to respond to its letter within two weeks. *See* Perrigo Letter at 2.

FDA responded on November 17, 2017. Ex. 1 to Compl. [Dkt. # 1-2] ("FDA Letter") at 1. Citing its "longstanding policy and practice," FDA told Perrigo that it "does not intend to decide [Perrigo's] forfeiture question at this time, and will do so, if necessary, if and when [FDA is] ready to approve a subsequent [ANDA] for omeprazole magnesium." *Id.* FDA explained:

> One reason for this practice is to avoid expending limited agency resources on exclusivity and forfeiture decisions when subsequent events may render those decisions moot. For example, a forfeiture decision would become moot if no other ANDA applicant is ready for approval until the 180-day exclusivity period has expired. As another example, a decision that a consent judgment falls within section 355(j)(5)(D)(i)(I)(bb)(BB) would become moot if the first-filed applicant were to begin marketing the product within 75 days of the consent judgment.

FDA Letter at 2 (internal citations omitted).

## III. Procedural History

On November 21, 2017, Perrigo filed this lawsuit against FDA. *See* Compl. Plaintiff also filed a motion for a temporary restraining order that would (1) enjoin FDA from finding that based on the September 20, 2017 Consent Judgment and Decree, Perrigo could forfeit its eligibility for a 180-day period of generic drug marketing exclusivity on December 4, 2017, and (2) enjoin FDA from granting final approval to Aurobindo's ANDA for Omeprazole Magnesium Delayed-release Tablets, or any other ANDA from a generic drug applicant with a pending application for omeprazole magnesium tablets. Appl. for TRO [Dkt. # 2]. The Court held a telephonic conference

on November 22, 2017 with Perrigo, FDA, and Aurobindo, a potential intervenor in the case, to discuss a briefing schedule. After the telephonic conference, the Court consolidated the application for injunctive relief with the merits under Federal Rule of Civil Procedure 65(a)(2) and it denied the motion for temporary restraining order as moot. *See* Min. Order (Nov. 22, 2017).

Plaintiff's complaint contains two counts. Count I alleges that "FDA has unlawfully failed to render a determination whether the September 20 Consent Judgment meets the statutory requirements to trigger the 75-day failure-to-market period." Compl. ¶ 33. Count II seeks a declaratory judgment from the Court that the Consent Judgment and Decree "did not trigger the 75-day period under the statute for Perrigo to commence marketing by December 3 or forfeit eligibility for 180-day generic exclusivity." *Id.* ¶ 37.

On November 28, 2017, FDA filed a motion to dismiss both counts in the complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), and to dismiss Count II for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). Def.'s Mot. to Dismiss [Dkt. # 5] ("Def.'s Mot."); Mem. in Supp. of Def.'s Mot. & Opp. to Pl.'s Req. for Injunctive & Declaratory Relief [Dkt. # 5-1] ("Def.'s Mem."). On the same day, Aurobindo filed a motion to intervene in the case, which the Court granted, as well as an opposition to Perrigo's application for temporary restraining order. *See* Notice of Mot. to Intervene [Dkt. # 6]; Min. Order (Nov. 28, 2017); Aurobindo's Mem. of Law in Opp. to Pl.'s Appl. for TRO [Dkt. # 9] ("Aurobindo's Mem.").[4] Perrigo filed its opposition to defendant's motion to dismiss on

4 Even though the Court had already denied Perrigo's application for a temporary restraining order as moot, and made it clear to the parties that the case was consolidated with the merits and that defendant and "any potential intervenor" must file a "responsive pleading," Aurobindo opted to file an opposition to the application for a temporary restraining order. *See* Min. Order (Nov. 22, 2017). But the Court must address whether it has subject matter jurisdiction over plaintiff's claims whether or not each defendant has moved to dismiss on that basis.

November 29, 2017. Perrigo's Omnibus Opp. to Def.'s Mot. & Aurobindo's Mem. [Dkt. # 13] ("Pl.'s Opp.").[5]

## STANDARD OF REVIEW

In evaluating a motion to dismiss under either Rule 12(b)(1) or 12(b)(6), the Court must "treat the complaint's factual allegations as true and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C. Cir. 2000) (internal citations omitted), quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979); *see also Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011). Nevertheless, the Court need not accept inferences drawn by the plaintiff if those inferences are unsupported by facts alleged in the complaint, nor must the Court accept plaintiff's legal conclusions. *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002).

### I. Subject Matter Jurisdiction

Under Rule 12(b)(1), the plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992); *Shekoyan v. Sibley Int'l Corp.*, 217 F. Supp. 2d 59, 63 (D.D.C. 2002). Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *see also Gen. Motors Corp. v. EPA*, 363 F.3d 442, 448 (D.C. Cir. 2004) ("As a court of limited jurisdiction, we begin, and end, with an examination of our jurisdiction."). "[B]ecause subject-matter jurisdiction is 'an Art[icle] III as well as a statutory requirement . . . no action of the parties can confer subject-matter jurisdiction

5 Since plaintiff failed to address the motion to dismiss Count II in its pleading, the Court ordered plaintiff to show cause why, if the Court concluded that plaintiff had failed to allege a violation of the APA in Count I, it would have subject matter jurisdiction over Count II. Min. Order (Nov. 29, 2017). Plaintiff responded the next day. *See* Perrigo's Resp. to Order to Show Cause [Dkt. # 14].

upon a federal court.'" *Akinseye v. Dist. of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003), quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982).

When considering a motion to dismiss for lack of jurisdiction, unlike when deciding a motion to dismiss under Rule 12(b)(6), the court "is not limited to the allegations of the complaint." *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Rather, "a court may consider such materials outside the pleadings as it deems appropriate to resolve the question [of] whether it has jurisdiction to hear the case." *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000), citing *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992); *see also Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

## II. Failure to State a Claim

"To survive a [Rule 12(b)(6)] motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In *Iqbal*, the Supreme Court reiterated the two principles underlying its decision in *Twombly*: "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions," and "[s]econd, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 678–79.

A claim is facially plausible when the pleaded factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678, citing *Twombly*, 550 U.S. at 556. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*, quoting *Twombly*, 550 U.S. at 556. A pleading must offer more than "labels and conclusions" or a

"formulaic recitation of the elements of a cause of action," *id.*, quoting *Twombly*, 550 U.S. at 555, and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*, citing *Twombly*, 550 U.S. at 555.

When considering a motion to dismiss under Rule 12(b)(6), the Court is bound to construe a complaint liberally in the plaintiff's favor, and it should grant the plaintiff "the benefit of all inferences that can be derived from the facts alleged." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994). Nevertheless, the Court need not accept inferences drawn by the plaintiff if those inferences are unsupported by facts alleged in the complaint, nor must the Court accept plaintiff's legal conclusions. *See id.*; *see also Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). In ruling upon a motion to dismiss for failure to state a claim, a court may ordinarily consider only "the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint, and matters about which the Court may take judicial notice." *Gustave-Schmidt v. Chao*, 226 F. Supp. 2d 191, 196 (D.D.C. 2002), citing *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624–25 (D.C. Cir. 1997).

**ANALYSIS**

The APA authorizes judicial review where "[a] person suffer[s] legal wrong because of agency action, or [is] adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. "Agency action" is defined to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or *failure to act*." 5 U.S.C. § 551(13) (emphasis added). Where no other statute provides a private right of action, as is the case here, the agency action complained of must be "final agency action." *See* 5 U.S.C. § 704; *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 61–62 (2004).

The APA provides two methods by which a plaintiff may seek relief. A court may (1) "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), or (2) "hold unlawful and set aside agency action" that is, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2). Although Perrigo points out in Count I that section 702 authorizes a party wronged by agency action to seek review, *see* Compl. ¶ 32, it does not identify the specific APA provision under which it purports to bring its claim. *See id.* ¶¶ 31–34. The complaint is replete with references to "unreasonable delay," *see, e.g.*, *id.* ¶ 30; *id.* at 7–8 (headings), but plaintiff's memorandum in opposition to the motion to dismiss advances an argument that the FDA letter constitutes final agency action that was arbitrary and capricious. Pl.'s Opp. at 6–8. Perrigo states in its opposition that Count I is grounded on both sections 706(1) and 706(2), but it fails to state a claim under either section.

## I. The Court will dismiss Count I because plaintiff has failed to state a claim under the APA.

To state a claim under section 706(1), a plaintiff must ask the Court to "compel agency action," and the agency must be statutorily required to take that action. Plaintiff has not alleged sufficient facts to meet either requirement here.

As an initial matter, the complaint does not contain any request that the Court "compel agency action," but instead it asks the Court to step into FDA's shoes and decide the exclusivity issue itself. *See* Compl. ¶ 34 ("Because FDA has failed to render a timely decision, this Court should address the issue that FDA will not – and has refused to – address."). So plaintiff's claim under section 706(1) fails on this ground alone.

Moreover, a claim under section 706(1) "can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *Norton*, 542 U.S. at 64 (emphasis in original). Perrigo does not allege that FDA was required by statute or regulation to

answer its inquiry regarding its exclusivity eligibility at all, much less that it was bound to do so by any particular date. *See Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 9 (D.D.C. 2008) (holding that the company failed to demonstrate any success on the merits because under section 706(1), "resolving Hi-Tech's entitlement to exclusivity is not a discrete agency action that the FDA is required to take, pursuant to statute or regulation, by a time certain"). Nor does Perrigo provide any authority for this proposition in its opposition.[6]

Plaintiff has also failed to state a claim under section 706(2) that FDA's agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law," because plaintiff has not alleged that FDA took a "final agency action." *See* 5 U.S.C. § 704; *Nat'l Ass'n of Home Builders v. EPA*, 786 F.3d 34, 40 n.6 (D.C. Cir. 2015) ("Under the law of this Circuit, final agency action is not a jurisdictional requirement, but bears on the existence of an APA claim."), citing *Trudeau v. FTC*, 456 F.3d 178, 183–85 (D.C. Cir. 2006).

The Supreme Court established a two-part test for determining whether an agency action qualifies as final so as to be subject to judicial review:

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6 Perrigo contends that "FDA is required to timely approve ANDA's" under 5 U.S.C. § 555(b), and that it must provide "prompt notice of the denial" of a written application under 5 U.S.C. § 555(e). Pl.'s Opp. at 3–4, 7–8. But those obligations relate to the approval of Aurobindo's ANDA, and the complaint contains no allegations that the failure to decide Aurobindo's application and give Perrigo notice of a denial prior to December 4, 2017 violates the APA. Further, any reliance on § 555(b) as a "statutory directive" that required FDA to make a decision by December 4, 2017 is unpersuasive. *See* Appl. for TRO at 11–12; Pl.'s Opp. at 7–8. Section 555(b) provides: "[w]ith due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it." 5 U.S.C. § 555(b). Together, sections 555(b) and 706(1) "give courts authority to review ongoing agency proceedings to ensure that they resolve the questions in issue within a reasonable time." *Pub. Citizen Health Research Grp. v. Comm'r, FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984), citing *Public Citizen Health Research Grp. v. Auchter*, 702 F.2d 1150, 1158 (D.C. Cir. 1983). But section 555(b)'s general directive "is a far cry from the 'discrete agency action' that courts require when issuing an order compelling agency action 'unlawfully withheld or unreasonably delayed.'" *Hi-Tech Pharmacal Co.*, 587 F. Supp. 2d at 9. And, as noted above, Perrigo has not actually asked the Court to compel any agency action in this case.

> First, the action must mark the consummation of the agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

*Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal quotation marks and citations omitted). Plaintiff's complaint does not contain sufficient facts to allege that FDA's failure to "render a timely decision" was a final agency action. *See* Compl. ¶¶ 33–34.

FDA's letter to Perrigo itself illustrates that FDA's refusal to decide the exclusivity issue did not qualify as final agency action under the Supreme Court's two-part test. When the agency gives an indication that its decision is subject to further consideration or possible modification, its action is not final. *See FTC v. Standard Oil Co.*, 449 U.S. 232, 241 (1980); *Sw. Airlines Co. v. DOT*, 832 F.3d 270, 275 (D.C. Cir. 2016) (finding DOT's letter, which initiated a proceeding to deal with issues described in the letter, did not qualify as final agency action). Here, FDA stated that it would not decide the forfeiture question in response to Perrigo's inquiry, but it would "do so, if necessary, if and when [it is] ready to approve a subsequent abbreviated new drug application ("ANDA") for omeprazole magnesium." FDA Letter at 1. FDA also told Perrigo that it was "in the process of asking any other applicants with an ANDA for omeprazole magnesium for their views," and that it would "consider their views in making [a] decision." *Id.* at 2. Putting off a decision is certainly not a consummation of the agency's decisionmaking process. *See Bennett*, 520 U.S. at 177–78.

More important, FDA's failure to answer Perrigo's question on the forfeiture issue did not determine either party's legal rights or obligations. *See Bennett*, 520 U.S. at 177–78; *Envtl. Def. Fund, Inc. v. Hardin*, 428 F.2d 1093, 1099 (D.C. Cir. 1970) (observing that judicial review of an agency's failure to act is authorized "when administrative inaction has precisely the same impact on the rights of the parties as denial of relief"). FDA's inaction has not had the same impact on

Perrigo as an express denial of relief (i.e., a finding that the forfeiture provision has been triggered), which would determine the scope of the parties rights. *See Hi-Tech Pharmacal Co.*, 587 F. Supp. 2d at 10. Perrigo insists that the "absence of an FDA decision . . . has the same practical impact on Perrigo as a hypothetical FDA decision that Perrigo has forfeited exclusivity" since both force "Perrigo to launch prior to the potential date of forfeiture or risk complete forfeiture." Pl.'s Opp. at 6–7. However, Perrigo glosses over the main difference between the two scenarios: forfeiture and *risk* of forfeiture. A decision from FDA that the 75-day period was triggered would result in forfeiture of the exclusivity period if Perrigo chose not to market its product, while the absence of an FDA decision leaves Perrigo in the position that it *risks* forfeiture if it does not market its product. Although FDA's inaction has denied Perrigo the certainty it requested as to the parties' rights, it does not rise to the level of a final agency action because the status of the parties' rights remains unchanged. As before, Perrigo holds the keys to enjoying its exclusivity period.

Absent final agency action to review, any claim under section 706(2) is premature. Therefore, the Court will grant defendant's motion and dismiss Count I.

**II. The Court will dismiss Count II seeking a declaratory judgment.**

Perrigo also seeks a declaration that the "Consent Judgment and Decree does not meet the requirements of the [FDCA] and did not trigger the 75-day period under the statute for Perrigo to commence marketing by December 3 or forfeit eligibility for 180-day generic exclusivity." Compl. ¶ 37. However, plaintiffs have not alleged a cognizable cause of action and therefore have no basis upon which to seek declaratory relief. *See Ali v. Rumsfeld*, 649 F.3d 762, 778 (D.C. Cir. 2011).

The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction," a court "may declare the rights and other legal relations of any interested party

seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). But the Declaratory Judgment Act "is not an independent source of federal jurisdiction." *C&E Servs., Inc. v. D.C. Water & Sewer Auth.*, 310 F.3d 197, 201 (D.C. Cir. 2002), quoting *Schilling v. Rogers*, 363 U.S. 666, 677 (1960). "Rather, 'the availability of declaratory relief presupposes the existence of a judicially remediable right.'" *Rumsfeld*, 649 F.3d at 778, quoting *C&E Servs., Inc.*, 310 F.3d at 201 (internal edits omitted).

Plaintiff insists nonetheless that it has alleged the existence of an actual controversy which the Court may resolve under the Declaratory Judgment Act. But the complaint does not articulate an actual controversy between the parties, *see McManus v. Dist. of Columbia*, 530 F. Supp. 2d 46, 80 (D.D.C. 2007); plaintiff only states conclusorily that "[t]here is a case of actual controversy within the jurisdiction of this Court." Compl. ¶ 36. And the complaint does not specify any cause of action through which the Court may exercise subject matter jurisdiction since Perrigo has failed to state a claim under the APA. *See Rumsfeld*, 649 F.3d at 778. Perrigo is essentially asking the Court to issue an advisory opinion, but the Court is prohibited from doing so. *Golden v. Zwickler*, 394 U.S. 103, 108 (1969) ("The federal courts established pursuant to Article III of the Constitution do not render advisory opinions.") (internal edits omitted); *see Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937) ("It must be a real and substantial controversy admitting of specific relief

through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.").[7]

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7 Perrigo suggests that the case presents an actual controversy between the two ANDA applicants concerning whether Perrigo will have forfeited its exclusivity as of Monday, December 4. That issue is not ripe since the FDA has not yet granted Aurobindo's application, and it is possible that the FDA will determine that the consent decree did not start the clock and that Perrigo has not forfeited its exclusivity. But as Perrigo points out, if the FDA grants Aurobindo's ANDA, the moment Perrigo's claim becomes ripe, it will also become moot: the 75 days will have elapsed. Perrigo urges the Court to act given those unique circumstances. The Court is not persuaded that this gives rise to subject matter jurisdiction, but in any event, the Court observes that there several significant problems with Perrigo's approach.

First of all, the conundrum is largely self-inflicted since there is no allegation that either the FDA or Aurobindo has interfered in any way with Perrigo's launch of its product under the terms of the ANDA it obtained twenty-eight months ago. And second, Perrigo's claimed lack of certainty about the legal landscape seems entirely inconsistent with the law and the facts.

On September 20, 2017, the United States District Court for the District of New Jersey signed a consent decree in a declaratory judgment action, *Aurobindo Pharma Ltd. v. AstraZeneca AB*, No. 3:16-cv-5079 (D.N.J. Aug. 18, 2016). It said:

> In light of the license granted under Article 5 of the Settlement Agreement, the Court enters final judgment in Civil Action No. 3:16-cv-07330-MLC-TJB that the making, having made, using, selling, offering to sell, importing or distributing of the Aurobindo Product by Aurobindo or any of its Affiliates, successors and assigns does not infringe the AstraZeneca Patents.

Consent Judgment and Decree. This certainly appears to be a "consent decree that enters a final judgment that includes a finding that the patent is . . . not infringed," *see* 5 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB), and therefore this Court would not have been inclined to enter judgment in plaintiff's favor on Count II. The Consent Judgment and Decree dated September 20, 2017 is a consent decree, it entered final judgment, and it found that the patent is not infringed, whether it utilized the word "find" or not. The fact that the judgment was predicated on a license is immaterial – the definition of the forfeiture event in the statute does not make any distinction between patent cases resolved through licensing arrangements or other negotiated dispositions and those that require judicial analyses of the underlying patents.

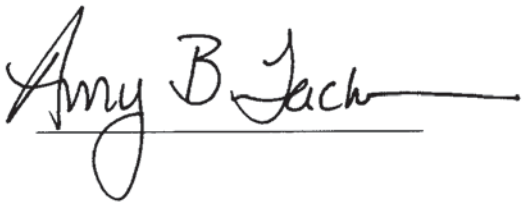
Plaintiff alleges in its complaint:

> The September 20 Consent Judgment contains no finding that the relevant patents (the '616 and '810 patents) are invalid or not infringed by Aurobindo's application. Indeed, it does not identify any patents. Instead, the September 20 Consent Judgment contains a very different type of conclusion, namely that pursuant to a license granted in a non-public settlement agreement, Aurobindo can (once its application is approved by FDA) market its product with the consent of AstraZeneca.

Therefore, the Court will dismiss Count II for lack of subject matter jurisdiction.

## CONCLUSION

For the foregoing reasons, the Court will grant defendant FDA's motion to dismiss. A separate order will issue.



AMY BERMAN JACKSON
United States District Judge

DATE: December 1, 2017

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Compl. ¶ 11. But this sort of judicial determination seems to be plainly covered by the section of the statute related to forfeiture of the 180-day exclusivity period. Subsection (D)(i)(I)(bb)(BB) specifically provides that a "settlement order or consent decree" in a declaratory judgment action, such as the one filed by Aurobindo in this case, may serve as the critical forfeiture event that starts the clock ticking; there is no legal requirement in that provision that the judgment include a ruling on the infringement question on the merits. This seems even more clear when one reads the previous provision, subsection (D)(i)(I)(bb)(AA), which states that the failure-to-market date could also fall 75 days after a court enters "a final decision . . . that the patent is invalid or not infringed" in an infringement action brought against the other applicant or a declaratory judgment brought by that applicant. In other words, it is subsection (AA) that deals with final determinations on the merits and subsection (BB) that reflects Congress's recognition that patent actions are often resolved by agreement of the parties. Indeed, plaintiff cites no authority for its strained interpretation of the word "finding," other than Federal Rule of Civil Procedure 52, which deals with "an action tried on the facts without a jury," and has no bearing on a consent decree.

Plaintiff also suggests that the operative paragraph in the consent decree is too vague to constitute the necessary finding that a patent is not infringed since it does not specifically identify the patents involved but simply refers to them as "the AstraZeneca patents." But the consent decree was not handed down in a vacuum – it is the final document on the docket in a lawsuit concerning the only patents that could have any bearing on this case – the two patents listed in the Orange Book for the listed drug. *See* Aurobindo Compl. ¶ 1.

Thus, while Perrigo has urged the Court to give unambiguous language its plain meaning, it appears that it is Perrigo that is resisting the commonsense interpretation of the texts involved.