UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AVADEL CNS PHARMACEUTICALS, LLC,	
Plaintiff,	
v.	
XAVIER BECERRA, *et al.*,	**Case No. 22-cv-02159 (APM)**
Defendants.	
JAZZ PHARMACEUTICALS, INC.,	
Intervenor-Defendant.	

MEMORANDUM OPINION

I.

Plaintiff Avadel CNS Pharmaceuticals, LLC ("Avadel") is a pharmaceutical company specializing in the development of LUMRYZ,[1] a drug for the treatment of narcolepsy. In December 2020, Avadel submitted a new drug application ("NDA") to the FDA, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval for LUMRYZ. The active ingredient in LUMRYZ is sodium oxybate, which is the same active ingredient used in two narcolepsy drugs—XYREM and XYWAV—presently approved for marketing by Defendant-Intervenor Jazz Pharmaceuticals, Inc. ("Jazz").

In support of an NDA, a Section 505(b)(2) applicant must file either (1) a "Patent Certification," which triggers a statutorily required notice to an existing patentholder of the

[1] LUMRYZ is the proposed brand name for the drug at issue, the investigational name for which is "FT218." An investigational new drug product like FT218 cannot be marketed in the United States, 21 U.S.C. §§ 331(a), 355(d), but the court will refer to the drug by its proposed brand name throughout the opinion for ease of identification.

potential impact on the holder's intellectual property rights, or (2) a "Patent Statement," which represents that no existing patents listed in the FDA's patent database are implicated by the new drug. Avadel initially filed a Patent Statement with its NDA indicating that its application did not implicate any listed patents. The FDA then sought additional information from Avadel to justify its grounds for submitting a Patent Statement.

On May 24, 2022, the FDA rejected Avadel's Patent Statement. It advised instead that Avadel must submit a Patent Certification because Avadel's application sought approval of a method of use of the sodium oxybate drug that was already claimed by an existing method-of-use patent held by Jazz (the "Patent Decision"). On June 6, 2022, Avadel submitted the requested Patent Certification but under protest. That filing triggered a statutory notice requirement that compelled Avadel to inform Jazz about a potential patent infringement. Jazz then filed a patent infringement action in the District of Delaware. Avadel filed a statutorily created counterclaim in response that seeks to have Jazz's patent removed from the FDA patent database.

Before this court, Avadel asserts two claims: first, that Federal Defendants'[2] decision requiring Avadel to submit a Patent Certification violated the Administrative Procedure Act ("APA"), and second, that Federal Defendants have unreasonably delayed approval of LUMRYZ. Avadel seeks a preliminary injunction or an expedited entry of judgment releasing it from the obligation to file a Patent Certification and an order requiring the FDA to rule on its NDA. *See* Pl.'s Mot. for Prelim. Inj. or Summ. J., ECF No. 2 [hereinafter Pl.'s Mot.]. Federal Defendants have cross-moved for summary judgment, as has Intervenor-Defendant Jazz. *See* Fed. Defs.' Cross-Mot. for Summ. J., ECF No. 25 [hereinafter Fed. Defs.' Cross-Mot.]; Def.-Int.'s Cross-Mot.

[2] Defendants in this matter are Secretary of Health and Human Services Xavier Becerra, in his official capacity; the U.S. Department of Health and Human Services; the U.S. Food and Drug Administration ("FDA"), and FDA Commissioner Robert M. Califf, in his official capacity (collectively, "Federal Defendants").

for Summ. J. and Opp. to Pl.'s Mot. for Prelim. Inj., ECF No. 27 [hereinafter Def.-Int.'s Cross-Mot.].

As discussed below, the court holds that Avadel is not entitled to relief under the APA because of the availability of adequate alternative relief—namely, the ongoing, statutorily prescribed patent infringement and counterclaim proceedings in the District of Delaware. Accordingly, Federal Defendants' and Intervenor-Defendant's Cross-Motions for Summary Judgment are granted, and Plaintiff's Motion for Preliminary Injunction or Summary Judgment is denied.

II.

Section 505(b)(2) of the FDCA provides a streamlined pathway for approval of drugs that are based on the same active ingredient as a previously approved drug. To facilitate notice to existing patentholders that their intellectual property rights may be impacted by an NDA, a Section 505(b)(2) applicant must file either a "Patent Certification" or a "Patent Statement" in support of their NDA. Whether an applicant must file a Statement versus a Certification depends on, as relevant here, whether an existing patent claims the proposed use for the drug at issue. 21 U.S.C. § 355(b)(2)(A), (B).[3]

Patent Certification. A Patent Certification must be filed when an NDA *does* implicate an existing patent listed in the "Orange Book"—an FDA database that contains summary information about active drug patents submitted by patentholders. *See* 21 U.S.C. § 355(b)(2)(B). If a method-of-use patent claims a use of the drug for which the applicant seeks approval, then the applicant must file a Patent Certification that explains why the proposed use would not infringe on the existing patent or why the existing patent is invalid. *Id.* § 355(b)(2)(A)(i)–(iv).

[3] A Patent Certification also is required "with respect to each patent which claims the drug" on which the applicant's NDA is based. 21 U.S.C. § 355(b)(2)(A). That provision is not at issue in this case.

In addition, when filing a Patent Certification, the NDA applicant must provide notice to the original patentholder of the application and "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." *Id.* § 355(b)(3)(D)(ii). Such notice triggers a 45-day period within which the original patentholder can bring a patent infringement claim. *See id.* § 355(c)(3)(C). If the original patentholder timely files suit, the FDA is barred from approving the NDA for up to 30 months, unless the court shortens the time or the patent litigation resolves sooner. *See id.* The FDCA also creates a unique right of action for the NDA applicant. The applicant may "assert a counterclaim seeking an order requiring the [patentholder] to correct or delete" an Orange Book listing. *Id.* § 355(c)(3)(D)(ii)(I). That claim of relief is not available in any other civil action or proceeding. *Id.* § 355(c)(3)(D)(ii)(II).

Patent Statement. A Patent Statement is appropriately filed when an NDA does *not* implicate a method-of-use patent listed in the Orange Book. *See* 21 U.S.C. § 355(b)(2)(A). The FDCA provides that a Patent Statement may be filed only when an existing "method of use patent . . . does not claim a use for which the applicant is seeking approval." *See* 21 U.S.C. § 355(b)(2)(B). There is no statutory notice required to a putative method-of-use patentholder upon the filing of a Patent Statement.

III.

A.

Jazz is the holder of a method-of-use patent pertaining to how it distributes its oxybate drugs. *See Sensitive Drug Distribution System and Method,* U.S. Patent No. 8,731,963 ("the '963 Patent"). Jazz's oxybate drugs are distributed pursuant to an FDA-mandated Risk Evaluation and Mitigation Strategy ("REMS") that seeks to prevent misuse and diversion of the drug. *See*

21 U.S.C. § 355-1(a); 21 C.F.R. § 314.520 (2022). The Jazz REMS sets up a system of drug distribution through a single, central pharmacy and central computer database.

Upon approval of an NDA, the applicant must provide a description of any method-of-use patents it holds. That description is known as a "use code." "[T]he FDA does not attempt to verify the accuracy of the use codes that brand manufacturers supply. It simply publishes the codes, along with the corresponding patent numbers and expiration dates," in the Orange Book. *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405–06 (2012). Jazz listed the '963 Patent as Use Code U-1110, which describes the patent as covering its "method of treating a patient with a prescription drug using a computer database in a computer system for distribution." Pl.'s Mot., Ex. 6, ECF No. 2-12, at 2.

On December 15, 2020, Avadel submitted an NDA for LUMRYZ. With its NDA, Avadel filed a Patent Statement certifying that Jazz's '963 Patent did not claim "a use for which [Avadel] is seeking approval." FDA Joint Appendix, ECF No. 36 [hereinafter "FDA"], at 000221–22. Like Jazz's products, Avadel proposed a REMS for LUMRYZ. But Avadel asserted that its REMS was "materially different" than the REMS for XYREM and XYWAV. *Id.* In September 2021, the FDA asked Avadel for a "detailed justification" for why it submitted merely a Patent Statement. FDA 000469–71. Avadel responded that, because LUMRYZ's REMS would use "multiple" databases instead of one, the '963 Patent did not claim a use for which Avadel was seeking approval, and thus Avadel did not have to submit a Patent Certification. FDA 000473–79.

The FDA concluded otherwise. On May 24, 2022, the agency issued the Patent Decision, finding that Avadel's Patent Statement was inappropriate and that Avadel was required to submit a Patent Certification because its application seeks "approval of a condition of use that is claimed

by the '963 patent, as described by the U-1110 use code." FDA 000994. On June 6, 2022, Avadel submitted the required Patent Certification "under protest." FDA 001045.

B.

1.

On July 21, 2022, Avadel filed this action. Compl. for Decl. and Inj. Relief, ECF No. 1. Within a week, Jazz intervened. Order Granting Unopp. Mot. to Int., ECF No. 18. Avadel seeks a declaration that the Patent Decision is arbitrary and capricious in violation of the APA (Claim I) and that the agency has unlawfully delayed approval of LUMRYZ (Claim II). Pl.'s Mot., Pl.'s Mem. of P. & A., ECF No. 2-1 [hereinafter Pl.'s Mem], at 20–45; 5 U.S.C. §§ 706(1), (2). Avadel also seeks injunctive relief vacating the Patent Decision, enjoining the FDA from requiring it to submit a Patent Certification, and directing the FDA to take final action on the NDA. Pl.'s Mem. at 20–45.

Avadel asserts that Federal Defendants violated the APA on four grounds: (1) the FDA lacks the statutory authority to second-guess and reject an applicant's submission of a Patent Statement; (2) the FDA's decision to compel a Patent Certification was erroneous because the LUMRYZ NDA does not seek approval of a "use for" sodium oxybate, nor a "condition of use" claimed by U-1110; (3) the FDA violated its own regulations by referring to LUMRYZ's REMS information beyond the proposed drug's labeling; and (4) U-1110 does not describe a use of sodium oxybate for which Avadel seeks approval. Pl.'s Mem. at 20–36. Avadel also argues that "Defendants should be ordered to comply with their statutory duty to fully adjudicate the LUMRYZ NDA" without further delay. *Id.* at 41–45.

Jazz counters that the court does not have jurisdiction in the first instance to consider Avadel's APA suit, and that Avadel has no cause of action under the APA because the Patent

Decision is not final agency action and Avadel has other adequate remedies. Def.-Int.'s Cross-Mot. at 13–18. All Defendants challenge Avadel's merits arguments, asserting that the FDA acted within its statutory authority and did not unlawfully withhold a decision on the NDA. Fed. Defs.' Cross-Mot., Fed. Defs.' Mem. of P. & A., ECF No. 28, at 11–26; Def.-Int.'s Cross-Mot. at 18–43. As discussed below, because the court determines that Avadel has another adequate remedy at law and therefore cannot state an APA claim, the court does not reach Federal Defendants' and Jazz's other arguments, including whether the Patent Decision is a final agency action.

2.

Separately, Jazz and Avadel are engaged in two patent infringement actions concerning the '963 patent in the U.S. District Court for the District of Delaware. Jazz first initiated suit against Avadel in May 2021, alleging infringement of the '963 patent. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC* (*Jazz Pharms. I*), No. 1:21-cv-00691-MN (D. Del. May 12, 2021). Avadel counterclaimed, seeking to require Jazz to delist the '963 Patent from the Orange Book. *See* Answer to Compl. and Counterclaim, *Jazz Pharms. I*, ECF No. 11, at 41–43.

In July 2022, after receiving statutory notice of Avadel's Patent Certification, Jazz filed a second patent infringement lawsuit before the same court. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC* (*Jazz Pharms. II*), No. 1:22-cv-00941-MN (D. Del. July 15, 2022). Because Jazz filed its lawsuit within 45 days of receiving Avadel's Patent Certification notice, this second lawsuit triggered the attendant 30-month stay of FDA approval under 21 U.S.C. § 355(c)(3)(C). In the second patent infringement lawsuit, Avadel also has counterclaimed seeking the delisting of the '963 Patent. *See* 21 U.S.C. § 355(c)(3)(D)(ii)(I); Answer to Compl. and Counterclaim, *Jazz Pharms. II*, ECF No. 14, at 39–41.

IV.

The court first addresses its subject matter jurisdiction. Defendant-Intervenor Jazz asserts that jurisdiction to review the Patent Decision lies only in the D.C. Circuit. According to Jazz, Section 505(h) of the FDCA strips district courts of authority to review final orders rejecting NDAs and, even though the Patent Decision is not itself a final rejection of Avadel's NDA, were this court to review the Patent Decision such action would affect the Circuit's future jurisdiction. Def.-Int.'s Cross-Mot. at 13–15 (relying on *Telecomms. Rsch. & Action Ctr. v. FCC* (*TRAC*), 750 F.2d 70 (D.C. Cir. 1984)); Reply in Supp. of Def.-Int.'s Cross-Mot., ECF No. 38 [hereinafter Def-Int.'s Reply], at 3–5.[4] Avadel counters that Section 505(h) does not authorize original review of the Patent Decision in a court of appeals and that action by this court would not implicate the D.C. Circuit's future jurisdiction. Reply to Pl.'s Mot. and Opp. to All Defs.' Mot. for Summ. J., ECF No. 32 [hereinafter Pl.'s Reply], at 8–11. The court agrees with Avadel that Section 505(h) does not strip this court of jurisdiction over the present case.

Absent "a provision authorizing review in the court of appeals, challenges to agency action to which the APA's judicial review provisions apply fall within the district court's federal question jurisdiction under 28 U.S.C. § 1331." *Micei Int'l v. Dep't of Com.*, 613 F.3d 1147, 1152 (D.C. Cir. 2010). Section 505(h) of the FDCA is such a provision. It vests jurisdiction in the courts of appeals over "order[s] of the Secretary *refusing or withdrawing* approval of a[] [drug] application."

[4] At oral argument, Jazz also suggested that the court could avoid jurisdiction because the claims at issue are premised on the court's statutory jurisdiction, as opposed to its Article III jurisdiction, and "the court can look through . . . statutory jurisdiction." Transcript of Oral Argument Proceedings, ECF No. 40, at 45. Jazz cited *American Hospital Association v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020), in support of this position. *Id.* The court thinks *American Hospital Association* inapposite, as the case dealt with circumstances in which "the relevant statutory bar . . . [was] effectively coextensive with the merits," such that the relevant "bar on judicial review does not apply if the[] merits argument is correct." 964 F.3d at 1239. While the Supreme Court has made clear that courts may resolve certain "threshold issues," like abstention or prudential standing, before addressing jurisdiction, this court need not come to a conclusion regarding whether the APA "adequate remedy" issue constitutes the kind of threshold issue that "may be resolved before addressing jurisdiction" because the court is satisfied it has jurisdiction to decide this case. *See Tenet v. Doe*, 544 U.S. 1, 6 n.4 (2005).

21 U.S.C § 355(h) (emphasis added); *Nostrum Pharms., LLC v. FDA*, 35 F.4th 820, 825 (D.C. Cir. 2022) (stating that "our review [under Section 505(h)] is limited to final rejections of drug applications, not interim decisions or nonbinding statements subject to further [agency] review or change"). But while "an order denying an NDA or withdrawing one is reviewable by the Court of Appeals" under Section 505(h), "an order that does not deny or withdraw an NDA is reviewable [by a district court] under the Administrative Procedure Act." *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 651 (1973); 21 U.S.C. § 355(h). Although Jazz concedes that the Patent Decision is not itself an order "refusing or withdrawing" approval of an NDA, the company asserts that this court is stripped of jurisdiction over the Patent Decision based on the Circuit's decision in *TRAC*. *See* 750 F.2d at 78–79. According to Jazz, *TRAC* stands for the proposition that the courts of appeals have jurisdiction over any "interlocutory orders" involved in the NDA approval process because review of such an order could affect the Circuit's ultimate jurisdiction. *See* Def-Int.'s Cross-Mot. at 13–14. The court disagrees.

In *TRAC*, the D.C. Circuit held that where "a statute commits review of agency action to the Court of Appeals, any suit seeking relief that might affect the Circuit Court's future jurisdiction is subject to the exclusive review of the Court of Appeals." 750 F.2d at 75. There, the judicial review provision provided for near plenary review over all final orders of the Federal Communications Commission ("FCC"). *Id.* (addressing 28 U.S.C. § 2342(1); 47 U.S.C. § 402(a)). The question before the court was whether it had original jurisdiction over an unreasonable delay claim even though such a suit did not involve a "final" action. The court held that it did. "Because the statutory obligation of a Court of Appeals to review on the merits may be defeated by an agency that fails to resolve disputes, a Circuit Court may resolve claims of unreasonable delay in order to protect its future jurisdiction." *Id.* at 76.

TRAC's jurisdictional holding, however, has no application here. The D.C. Circuit made clear in *Cutler v. Hayes* that "[e]ssential to our holding [in *TRAC*] were statutory provisions enabling us to review *any* final FCC order." 818 F.2d 879, 887 n.61 (D.C. Cir. 1987) (emphasis added). The court in *Cutler* contrasted the breadth of the FCC jurisdictional review provision with that of the FDCA. The FDCA, the court observed, "contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions," including Section 505(h). *Id.* Such provisions should be construed "narrowly." *Id.* Because the claim there did not involve a challenge to a disapproval of an NDA, the court held, Section 505(h) did not apply. *See id.* So, too, here. The Patent Decision is not a final order disapproving of an NDA. It is merely a ruling about an interim step along the NDA pathway. A review of that decision will not affect the D.C. Circuit's exclusive jurisdiction to hear disapprovals of NDAs. Even if this court were to rule in favor of Avadel, the FDA still will have to decide whether to approve the NDA or not. If, after this court's review, the FDA rejects the NDA for whatever reason, the Circuit's exclusive jurisdiction under Section 505(h) remains intact.

If what Jazz means to say is that an *unfavorable* ruling for Avadel might lead to the denial of its NDA, which is reviewable only in the D.C. Circuit, the court declines to theorize about that outcome. The Circuit has made clear that it will not "assert jurisdiction on the basis of hypothetical scenarios" where "the basis of prospective jurisdiction is a speculative chain of events." *In re NRDC*, 645 F.3d 400, 405 (D.C. Cir. 2011). Thus, if an FDA order does not clearly fall within a direct review provision under the FDCA, as is the case here, jurisdiction fairly lies in the district court. *Id.*[5]

[5] A decision on Avadel's unlawful withholding argument—if indeed it can be considered a fully constituted claim, *see* n.6 below—would also not deprive the D.C. Circuit of jurisdiction. Avadel asserts that the FDA "unreasonably withheld" a final decision on its NDA. Pl.'s Mot. at 41. To remedy the alleged unlawful withholding, Avadel merely seeks a *decision* on its application—not an actual grant of the application. *See id.* An order to compel a final

V.

The court now addresses whether the availability of another adequate remedy forecloses Avadel's APA challenge. *See* Def.-Int.'s Cross-Mot. at 17–18; Def-Int.'s Reply at 8. According to Jazz, Avadel is not entitled to relief under the APA because it may seek—and indeed, is presently seeking—an adequate alternative remedy in a patent infringement counterclaim. *See* Def.-Int.'s Cross-Mot. at 17–18; Def-Int.'s Reply at 8. The court agrees.

The APA "authorizes review only when" a plaintiff lacks another "adequate remedy in a court." *Bennett v. Spear*, 520 U.S. 154, 161–62 (1997); 5 U.S.C. § 704. "Section 704 reflects Congress' judgment that 'the general grant of review in the APA' ought not 'duplicate existing procedures for review of agency action' or 'provide additional judicial remedies in situations where Congress has provided special and adequate review procedures.'" *Citizens for Resp. & Ethics in Washington v. United States Dep't of Just.* (*CREW*), 846 F.3d 1235, 1245 (D.C. Cir. 2017) (quoting *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988)). "Courts must, however, avoid lightly 'constru[ing] [Section 704] to defeat the [APA's] central purpose of providing a broad spectrum of judicial review of agency action.'" *Id.* (quoting *Bowen*, 487 U.S. at 903).

When determining whether an adequate alternative remedy exists, and thus whether APA review is precluded, the court must look for "clear and convincing evidence" of "legislative intent" to create a special, alternative remedy and thereby bar APA review. *Garcia v. Vilsack*, 563 F.3d 519, 523 (D.C. Cir. 2009) (quoting *El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. HHS*, 396 F.3d 1265, 1270 (D.C. Cir. 2005)). One way in which such intent is manifest is if Congress has provided "an independent cause of action or an alternative review procedure." *El Rio*, 396 F.3d at

adjudication is not itself a decision "denying or withdrawing" an NDA. And if this court were to compel such action, the D.C. Circuit still would have original jurisdiction over a denial of the application in accordance with Section 505(h). *See* 21 U.S.C. § 355(h).

1270. Provision by Congress of such a cause of action or an alternative review procedure provides a "clear marker[] of legislative intent" to preclude an action under the APA. *CREW*, 846 F.3d at 1245.

Here, Congress has prescribed both an independent cause of action and an alternative review procedure that would afford Avadel the ultimate relief it seeks—a pathway to approval cleared of Jazz's claimed method-of-use patent. In 2003, Congress amended the FDCA to create a specific cause of action for an NDA applicant, like Avadel, to challenge an existing method-of-use patent that is blocking the FDA's approval of its application. Recall, Section 505(b)(2) requires an NDA applicant that files a Patent Certification to provide notice of such Certification to the holder of the method-of-use patent. Such patentholder then has the choice to file a patent infringement action within 45 days. If no such action is filed, the approval of the application "shall be made effective immediately." 21 U.S.C. § 355(c)(3)(C). If, however, the patentholder brings an infringement action within the 45 days, Congress granted the NDA applicant a cause of action of its own: a counterclaim to challenge the patentholder's Orange Book listing. *See* 21 U.S.C. § 355(c)(3)(D)(ii). The statute was amended to expressly provide that if a patent owner "brings a patent infringement action against [a new drug] applicant," the applicant may countersue to compel the patent owner to "correct or delete the patent information" submitted to the FDA "on the ground that the patent does not claim . . . an approved method of using the drug." *Id.*

Congress made explicit that the counterclaim it created was available only in response to a patent infringement suit brought by the patentholder within the 45-day period. Under the heading, "No independent cause of action," the FDCA states that the statute "does not authorize the assertion of [the statutorily created counterclaim] in any civil action or proceeding" other than in

the prescribed patent infringement action. 21 U.S.C. § 355(c)(3)(D)(ii)(II). And, indeed, Avadel has pursued this alternative avenue to seek the precise end envisioned by Congress: Avadel's currently pending counterclaim seeks a "declaratory judgment requiring delisting of the '963 Patent." *See* Answer to Compl. and Counterclaim, *Jazz Pharms. II*, at 40–41. The availability of this unique counterclaim is a "clear marker[] of legislative intent" that Congress meant to channel Orange Book-listing challenges through the FDCA's remedial scheme. *CREW*, 846 F.3d at 1245.

Even if an aggrieved NDA applicant were not to file a counterclaim, Congress plainly contemplated that the affirmative patent infringement action filed pursuant to Section 355(c)(3)(C) would itself resolve any dispute between the patentholder and the NDA applicant and lead to the establishment of the effective date of approval for the NDA. *See* 21 U.S.C. § 355(c)(3)(C). Once again, Congress gave a patentholder who receives notice of a Patent Certification 45 days to file suit against the NDA applicant for patent infringement. If the patentholder does not file suit, the approval of the NDA "shall be made effective immediately." *Id.* If the patentholder does file suit, however, the effective date of the approval is tied to the outcome of the litigation. If suit is filed, "the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice" of the Patent Certification or "such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action." *Id.* If, however, before the expiration of such period "the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on . . . the date on which the court enters judgment reflecting the decision" or the date a settlement or consent decree is entered by the court. *Id.* § 355(c)(3)(C)(i). If the district court decides that the patent has been infringed but the court of appeals determines otherwise, "the approval shall be made

effective on the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity)" or the date a settlement or consent decree is entered by the court of appeals. *Id.* § 355(c)(3)(C)(ii)(I). And, if the district court finds that the patent has been infringed, and there is no appeal, "the approval shall be made effective on the date specified by the district court in a court order under [S]ection 271(e)(4)(A) of title 35." *Id.* § 355(c)(3)(C)(ii)(II). Section 271(e)(4)(A) in turn provides that "the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). Unlike cases in which a statute is silent on the question of alternative remedies, or in which the existence of an alternative remedy is "doubtful," *see Bowen*, 487 U.S. at 905, Congress has spoken clearly in the FDCA by setting up an alternate remedial scheme via a patent infringement action and counterclaim.

Avadel responds that its delisting counterclaim is not a "real alternative" because the present action and the counterclaim "involve different questions." Pl.'s Reply at 15 (internal quotation marks omitted). That is true. A counterclaim would not, for example, resolve the question of whether the FDA has the authority to reject a Patent Statement and compel a party to file a Patent Certification, as the FDA did here. But the test for determining adequacy of relief is not whether there is perfect alignment of the legal "questions" before the respective courts. Rather, the inquiry centers on the remedies available to the plaintiff and the ability of those remedies to put the plaintiff in the position in which they seek to be placed. *See Garcia*, 563 F.3d at 522 (D.C. Cir. 2009) (affirming dismissal of an APA claim as precluded because the alternative remedy also offered declaratory and injunctive relief to remedy discrimination alleged by the plaintiffs). In this

respect, the adequate remedy inquiry focuses on the outcome sought by the movant rather than the questions they raise in their pleadings. *See id.*

And while an alternative regime that provides for a remedy of a different order—such as one that makes available only monetary damages rather than equitable relief—is inadequate, an independent cause of action "need not provide relief identical to relief under the APA." *Id.*; *Bowen*, 487 U.S. at 904; *CREW*, 846 F.3d at 1246 (courts allow for "some mismatch between the relief sought and the relief available"). Indeed, the outcome available in the alternative cause of action need not even be "as effective as an APA lawsuit" so long as the remedy is of "the same genre." *Garcia*, 563 F.3d at 525 (equitable relief available in both actions); *CREW*, 846 F.3d at 1246 (same).

That test is straightforwardly met here. Before this court, Avadel "seeks to be relieved of the compelled obligation imposed by the Patent Decision to certify." Pl.'s Reply at 31 (emphasis omitted). In its counterclaim in Delaware, Avadel seeks, among other things, to have the '963 patent delisted. *Id.* at 15; *see Jazz Pharms. II*. Both suits enable Avadel to seek relief of the same genre—based on exercise of the respective courts' equitable jurisdiction. And the ultimate import of these two suits is the same because if Jazz's patent is delisted, then Avadel will necessarily "be relieved of the compelled obligation imposed by the Patent Decision to certify." The FDCA is clear: in the absence of a listed patent, Avadel would not be required to complete a Patent Certification. *See* 21 U.S.C. § 355(b)(2). Thus, if Avadel were to prevail on its counterclaim, or Jazz were to fail in its affirmative infringement action, Avadel will be entitled to the ultimate relief it seeks before this court via the specific avenue Congress created for it to do so.

Finally, Avadel maintains that the counterclaim remedy is not adequate because the FDA is not a party to the parallel patent infringement litigation. *See* Pl.'s Reply at 32. This fact is of

no moment. The Circuit has made clear that an independent cause of action need not proceed against the government but instead can proceed against a third party. *See, e.g.*, *Council of and for the Blind of Delaware Cnty. Valley, Inc. v. Regan*, 709 F.2d 1521, 1531–33 (D.C. Cir. 1983) (en banc) (holding that the plaintiff could not maintain an APA action against federal agency even if it might be "more effective," where private third party suit was adequate to address discrimination); *Women's Equity Action League v. Cavazos* (*WEAL*), 906 F.2d 742, 751 (D.C. Cir. 1990); *Garcia*, 563 F.3d at 524–25. A "claim filed directly against the [patentholder] would be adequate to preclude a cause of action under the APA" even where the "plaintiff c[an]not maintain an action . . . against a federal agency for failure" to act in a reasonable manner or for exceeding its authority "where Congress ha[s] provided the plaintiff with a private right of action against the third party." *Garcia*, 563 F.3d at 524–25. Avadel therefore has an adequate remedy of law and relief is foreclosed under the APA.[6]

Before concluding, the court notes that this case does not present the arguably more complicated fact pattern of the NDA applicant *not* having filed the Patent Certification compelled by the FDA. It is only the filing of the Patent Certification that triggers the 45-day period for the patentholder to file suit and, if filed, opens the door for the NDA applicant to file a counterclaim. Whether the FDCA's review scheme would be considered "adequate" if it first *required* the NDA applicant to file a Patent Certification in order to make the counterclaim available to it is not before

[6] It is not clear to the court that Plaintiff's "unreasonable delay" claim can be considered a separate cause of action in this case, rather than merely a remedy Plaintiff seeks. But even if it were a separate cause of action, Plaintiff is not entitled to relief on this claim for two reasons. First, as explained above, the ultimate relief Plaintiff seeks on both the arbitrary and capricious review and unreasonable delay claims is the same: releasing it from the obligation to file a Patent Certification. Thus, removing this identified roadblock to approval of Plaintiff's drug application—through delisting of the patent—will provide Plaintiff an adequate remedy. Second, and more straightforwardly, Plaintiff fails to state a claim on this count. Once the Patent Certification was filed, the statutory trigger of the counterclaim and attendant mandatory stay period went into effect, so there is no statutory basis on which Plaintiff may assert an unreasonable delay claim. This claim is thus either subsumed under the umbrella of relief that the counterclaim's alternative adequate remedy provides or it falls away for failure to state a claim.

the court. Avadel here filed the Patent Certification *before* it brought this action, triggering the 45-day period that led Jazz to file suit, thus making the statutorily created counterclaim available to Avadel. In that circumstance, there can be no doubt that Avadel has an alternative adequate remedy at law.

VI.

For the foregoing reasons, the court grants Federal Defendants' and Intervenor-Defendant's Cross-Motions for Summary Judgment, ECF Nos. 25 and 27, and denies Plaintiff's Motion for Preliminary Injunction or Summary Judgment, ECF No. 2. A final, appealable order accompanies this Memorandum Opinion.

Dated: November 3, 2022

Amit P. Mehta
United States District Court Judge