IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW

MEMORANDUM OPINION

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Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Before the Court is Defendant Avadel CNS Pharmaceuticals LLC's ("Avadel") renewed motion for judgment on the pleadings (the "Renewed Motion") with respect to its counterclaim seeking delisting of Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"). The Renewed Motion has been fully briefed. D.I. 118, 153, 154 & 171.[1] The Court held oral argument on November 15, 2022. For the reasons set forth below, the Motion (D.I. 117) is GRANTED.

I. BACKGROUND

Jazz manufactures and sells a Xyrem®, an FDA-approved drug for treating cataplexy and excessive daytime sleepiness associated with the sleep disorder narcolepsy. The active ingredient in Xyrem® is sodium oxybate, a form of gamma-hydroxybutyrate ("GHB") that has been recognized as a dangerous substance. Given GHB's potential for misuse, the FDA conditioned its approval of Xyrem® on the implementation of a Risk Evaluation and Mitigation Strategy (REMS) to control Xyrem®'s distribution. Jazz's '963 patent is directed toward using a computer-implemented system to address certain FDA-required REMS conditions of using Xyrem® according to its approved labeling. Jazz listed the '963 patent in the Orange Book on the basis that it claims a method of using Xyrem®.[2]

[1] Jazz sought leave to file a sur-reply, which this Court granted (D.I. 169) as Avadel did not oppose. D.I. 155 & 157.

[2] Among the patents Jazz asserts in this litigation, only the '963 patent is listed in the Orange Book.

In December 2020, Avadel submitted an NDA pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to manufacture and sell FT218, its once-nightly formulation of sodium oxybate for the treatment of narcolepsy. In May 2021, Jazz initiated the instant patent infringement action against Avadel arising from Avadel's NDA, asserting five patents including the '963. Avadel counterclaimed, seeking a declaration pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I) that orders Jazz to remove the '963 patent from the Orange Book (Count III) because it does not claim a method of using the approved drug. Thereafter, Avadel filed its first motion for judgment on the pleadings on Count III. The Court denied Avadel's motion concluding in part that Avadel's delisting arguments "depend in no small part on claim construction and the question of whether the claimed 'system' includes methods of using the approved product." D.I. 55 at 5. After the parties exchanged their proposed constructions as well as opening and responsive claim construction briefs, on June 23, 2022, Avadel filed the Renewed Motion "so that the Court may decide this issue as promptly as possible once the Court rules on the proper construction of the '963 patent claims." D.I. 118 at 3-4.

Meanwhile, the FDA required Avadel to certify to the '963 patent. Avadel had not done so, opting to file a statement indicating that its application did not implicate the '963 patent. The FDA concluded otherwise, and within 45 days of Avadel's certification, Jazz, on July 15, 2022, filed another patent infringement suit in this Court asserting the '963 patent against Avadel. C.A. No. 22-00941-GBW. That action triggered the automatic stay of FDA approval for FT218, which remains in place until the '963 patent expires and the related term of pediatric exclusivity ends in June 2023. Avadel sought relief from that certification in the United States District Court for the District of Columbia, commencing an action on July 21, 2022 against the FDA. *See Avadel CNS*

Pharmaceuticals, LLC v. Becerra, C.A. No. 22-02159 (APM). Jazz intervened and opposed Avadel's request.

As the action progressed in this Court, Avadel in September requested expedited consideration of the Renewed Motion (D.I. 162 & 167), which Jazz opposed (D.I. 165). Shortly thereafter, this Court convened a status conference to discuss the Renewed Motion and Avadel's related action pending in the District of Columbia, and scheduled a claim construction hearing for October 25, 2022. D.I. 179. After the claim construction hearing, the Court granted Avadel's request for expedition. D.I. 212.

The Court has issued its Memorandum Opinion on claim construction and concluded that the terms of the '963 patent are directed to systems, not methods. D.I. 229. The United States District Court for the District of Columbia denied Avadel's requested relief, concluding that Avadel has an adequate remedy at law via its delisting counterclaim pending in this Court. *Avadel CNS Pharms., LLC V. Becerra*, No. 22-CV-02159 (APM), 2022 WL 16650467, at *6–7 (D.D.C. Nov. 3, 2022). After obtaining leave of Court, on November 15, 2022, the Federal Trade Commission filed an *amicus curiae* brief in connection with Avadel's Renewed Motion, arguing that "REMS distribution patents as a category do not meet the requirements for Orange Book listing." D.I. 227.

II. LEGAL STANDARD

Pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, a party may move for judgment on the pleadings "[a]fter pleadings are closed – but early enough not to delay trial." FED. R. CIV. P. 12(c). When evaluating a motion for judgment on the pleadings, the Court must "view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most

favorable to the nonmoving party." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290-91 (3d Cir. 1988)).

"The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F.Supp.2d 612, 617 (D. Del. 2008); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (explaining that any documents integral to pleadings may be considered in connection with Rule 12(c) motion). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Burlington Coat Factory*, 114 F.3d at 1420. Ultimately, a motion for judgment on the pleadings can be granted "only if no relief could be afforded under any set of facts that could be proved." *Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991).

III. DISCUSSION

Avadel argues that the '963 patent must be delisted because it claims a "system," not a method of using a drug. D.I. 118 at 6. Jazz argues that, even if the '963 patent claims systems, Jazz was permitted to list it in the Orange Book because 21 U.S.C. § 355(c)(2) of the Orange Book Transparency Act (OBTA) (which forbids "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii)" to be submitted for listing in the Orange Book) does not apply retroactively and, therefore, does not support delisting. D.I. 153 at 14-15.

A. The '963 Patent Does Not Claim a Method of Using a Drug

The "Orange Book" is an FDA database "that contains summary information about active drug patents submitted by patentholders." *Becerra*, 2022 WL 16650467, at *2. The Hatch-Waxman Act identifies two requirements for a patent to be eligible for listing in the Orange Book.

First, the patent must be one for which "infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(A)(viii). Second, the patent must claim one of the following three categories of subject matter: "a drug substance (active ingredient)," "a drug product (formulation or composition)," or "a method of using such drug for which approval is sought or has been granted in the [patent holder's NDA]." *Id.*

The "FDA does not make a determination as to whether particular patents should be listed in the Orange Book." *Bayer Schering Pharma AG & Bayer HealthCare Pharms., Inc. v. Lupin, Ltd.*, 676 F.3d 1316, 1324-25 (Fed. Cir. 2012). Instead, the FDCA creates a unique right of action under which an NDA applicant may "assert a counterclaim seeking an order requiring the [patentholder] to correct or delete" an Orange Book listing blocking the FDA's approval of its application. 21 U.S.C. § 355(c)(3)(D)(ii)(I). The relevant statutory provision applying to NDA applicants provides:

> If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) of this section or this subsection on the ground that the patent does not claim either–
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. § 355(c)(3)(D)(ii)(I); *accord Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408-09 (2012) (explaining 21 U.S.C. § 355(j)(5)(C)(ii)(I), the corollary delisting provision for an ANDA applicant, authorizes an ANDA applicant sued for patent infringement to "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand to the Orange Book] on the ground that the patent does not

claim either '(aa) the drug for which the [brand's NDA] was approved; or "(bb) an approved method of using the drug") (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)).[3]

Here, the '936 patent does not belong in the Orange Book. The parties do not dispute that the '963 patent does not claim a drug for which the application was approved under subsection (aa). With respect to subsection (bb), the '963 patent does not claim "an approved method of using the drug" because the claims of '963 patent are directed to systems, not methods. D.I. 229. As Jazz suggests, the Court's construction of the '963 patent disposes of the inquiry.[4] Also, Jazz advances no theory that the '963 patent, construed as claiming systems, could constitute "an approved method of using the drug."

Jazz contends that granting Avadel's Renewed Motion would impermissibly apply the OBTA retroactively. According to Jazz, the OBTA, enacted in 2021, cannot not reach back to punish Jazz for listing the '963 patent in 2014. D.I. 153 at 14-18. However, Avadel's counterclaim arises under the delisting statute, 21 U.S.C. § 355(c)(3)(D)(ii)(I), affording Avadel a present right to seek delisting under the identified conditions. While 21 U.S.C § 355(c)(2) of the OBTA provides that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph," that provision on its face does not

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[3] Although *Caraco* addressed the delisting counterclaim available to ANDA applicants under 21 U.S.C. § 355(j)(5)(C)(ii)(I), Avadel maintains and Jazz does not dispute that *Caraco's* analysis applies to 21 U.S.C. § 355(c)(3)(D)(ii)(I), which is the parallel provision applicable to 505(b)(2) NDA applicants.

[4] In Jazz's answering brief opposing Avadel's first motion for judgment on the pleadings seeking delisting of the '963 patent, Jazz argued, "Avadel's delisting argument is premised entirely on its theory that the '963 patent claims a 'system' as opposed to a 'method.' This is, plain and simple, claim construction . . . To accept Avadel's arguments and to find that the '963 patent is improperly listed in the Orange Book, the Court would have to construe the claims and hold that the '963 patent covers no methods at all." D.I. 43 at 9-10.

impact an applicant's right to a delisting counterclaim under 21 U.S.C. § 355(c)(3)(D)(ii)(I).[5] As the Supreme Court recognized in *Caraco*, an applicant sued for patent infringement may simply "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subjection (b) or (c) of § 355 on the ground that the patent does not claim either" a "drug" or "an approved method of using the drug." 566 U.S. at 408-09 (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)); *accord In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 4 (1st Cir. 2020). Thus, whether the OBTA applies retroactively is not relevant to Avadel's delisting counterclaim. Moreover, the delisting statute was enacted in 2003—long before Jazz submitted the '963 patent for listing in the Orange Book in 2014. *Becerra*, 2022 WL 16650467 at *6–7.

Jazz also appears to argue that, because it was allegedly "permitted" to list the '963 patent in the Orange Book, it need not delist it now. D.I. 153 at 14-18. But regardless of the propriety of Jazz's initial listing, that assertion is not relevant in view of 21 U.S.C. § 355(c)(3)(D)(ii)(I), which states that patents that do not claim either a drug or method of using a drug may be either "correct[ed] or delete[d]." On its face, the delisting statute does not require inquiring as to whether the NDA holder was authorized to list the patent in the first instance. *See also Caraco*, 566 U.S. at 409 ("The counterclaim [for an ANDA filer under 21 U.S.C. § 355(j)(5)(C)(ii)(I)] thus enables a generic competitor to obtain a judgment directing a brand to 'correct or delete' certain patent information that is blocking the FDA's approval of a generic product.").

Thus, Avadel has satisfied the statutory requirements to seek an order requiring Jazz to correct or delete information in the Orange Book related to the '963 patent.

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[5] The Court takes no position on the retroactive application of 21 U.S.C. § 355(c)(3)(D)(ii)(I).

B. Jazz Must Request the FDA to Delete the '963 Patent from the Orange Book

Because the '963 patent does not claim a drug for which the application was approved or an approved method of using the drug, this Court will issue an order directing Jazz to correct or delete the patent information submitted by Jazz in the Orange Book. 21 U.S.C. § 355(c)(3)(D)(ii)(I). The Code of Federal Regulations further provides:

> If the NDA holder is required by court order to amend patent information or withdraw a patent from the list, it must submit an amendment to its NDA that includes a copy of the order, within 14 days of the date the order was entered, to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. The amendment to the NDA must bear the identification described in paragraph (d)(6) of this section.

21 C.F.R. § 314.53(f)(2)(i). Thus, the Court will issue an accompanying order consistent with these provisions.

Jazz argues that "[u]nder FDA regulations, Jazz has 30 days to correct any patent listing that is affected by order of a District Court, without that correction having any impact on Avadel's patent certification. 21 C.F.R. § 314.94(a)(12)(vi)(A)(3)." D.I. 153 at 18. However, that regulation appears directed to ANDA applicants, which Avadel is not. *See* 21 C.F.R. § 314.94 (titled "Content and format of an ANDA"). Accordingly, this Court will order Jazz to request deletion of the '963 patent from the Orange Book listing for Xyrem® within 14 days of the Court's Order.

IV. CONCLUSION

For the foregoing reasons, Avadel's Renewed Motion is granted. The Court will issue an Order consistent with this Opinion.