IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (MN)
	)	
AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION and AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

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October 19, 2021
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

Before the Court is the motion of Defendants Avadel Pharmaceuticals PLC, Avadel US Holdings, Inc. Avadel, Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation and Avadel CNS Pharmaceuticals LLC (collectively "Defendants") for judgment on the pleadings with respect to its counterclaim seeking de-listing of Plaintiff, Jazz Pharmaceuticals, Inc.'s ("Plaintiff"), U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"). For the reasons set forth below, Defendants' motion (D.I. 20) is DENIED.

I. BACKGROUND

Plaintiff manufactures and sells a product called Xyrem®, which is FDA-approved for use in the treatment of 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, frequently misused as a "date rape drug" in cases of drug facilitated sexual assault. Give this, the FDA conditioned approval on the implementation of a Risk Evaluation and Mitigation Strategy (REMS) that controlled distribution of the product and minimized the possibility of abuse. The '963 Patent purportedly covers using a computer-implemented system that addresses certain FDA-required REMS conditions of using Xyrem® according to its approved labeling.

Defendants have submitted an NDA pursuant to section 505(b)(2) seeking approval to manufacture and sell their own sodium oxybate product. According to the Complaint, Defendants have acknowledged that a REMS will be required for Avadel's product. (D.I. 1 ¶ 34). Plaintiff sued Defendants for infringement of five patents, only one of which – the '963 Patent – is listed in the Orange Book. (D.I. 1). Defendants answered and asserted a number of counterclaims,

including Count III, alleging required delisting of the '963 Patent. Thereafter Defendants' filed the instant motion seeking judgment on the pleadings on Count III of its counterclaims.

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

Defendants argue that the '963 Patent must be delisted because it claims a "system," not a drug product, or method of using a drug, as required by statute to be listed. Plaintiff does not

dispute that the claims of the patent are directed to a "computer-implemented system for treatment of a narcoleptic patient with a prescription drug . . . ," comprising, *inter alia*, "a [] computer database," "computer memories," and "a data processor." Instead, Plaintiff asserts that 1) Defendants' counterclaim is not ripe because Defendants have not filed a certification against the '963 patent and 2) there are at least factual issues regarding whether it was required to list the patent in the Orange Book. The Court addresses each in turn.

1. Ripeness

For a federal court to exercise jurisdiction over a case, the case must be ripe for review. *See Thompson v. Borough of Munhall*, 44 Fed. App'x. 582, 583 (3d Cir. 2002). "Ripeness is a separate doctrine from standing, but both doctrines originate from the same Article III requirement of a case or controversy." *Free Speech Coalition, Inc. v. Attorney Gen. U.S.*, 825 F.3d 149, 167 n.15 (3d Cir. 2016). "The ripeness doctrine serves 'to determine whether a party has brought an action prematurely and counsels abstention until such time as a dispute is sufficiently concrete to satisfy the constitutional and prudential requirements of the doctrine.'" *Khodara Envtl., Inc. v. Blakey*, 376 F.3d 187, 196 (3d Cir. 2004) (quoting *Peachlum v. City of York, Pennsylvania*, 333 F.3d 429, 433 (3d Cir. 2003)). The purpose of the doctrine "is to prevent the courts . . . from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967).

Here, Plaintiff argues that Defendants' "motion is not ripe for adjudication"[1] because Defendants have not filed a certification against the '963 Patent. (D.I. 43 at 14). The Court disagrees. The Supreme Court addressed an analogous situation when it considered whether an applicant could counterclaim against a branded company to force correction of an improper use code in the Orange Book without first certifying against the patent. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012). The Supreme Court explained that to curb abuses associated with improper listings with the FDA, Congress "create[d] a mechanism, in the form of a legal counterclaim" for parties to challenge patent information submitted to the FDA. *Id.* at 408. Such a counterclaim was available regardless of whether the defendant had certified against the listed patent. *Id*. The alternative, the Court noted, would mean that "the only option for generic manufacturers [challenging a listing] was to file a paragraph IV certification (triggering an infringement suit) and then wait out the usual 30-month period before the FDA could approve an ANDA." *Id*. Although Avadel is not a generic applicant, it has been sued by Jazz on the '963 Patent. And following the Supreme Court's reasoning in *Caraco*, adjudication of Avadel's counterclaim for delisting the '963 Patent is not precluded by the lack of a certification against that patent.

2. Propriety of the Orange Book Listing

The Hatch-Waxman Act recites 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

[1] The Court understands this argument to mean that Count III – seeking delisting of the '963 Patent – is not ripe for adjudication.

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]." It is the second of these requirements that Defendants' delisting counterclaim contests. Viewing the facts and the inferences to be drawn therefrom in the light most favorable to Plaintiff, however, the Court agrees with Plaintiff that questions regarding whether Plaintiff was required to list the '963 Patent in the Orange Book preclude entry of judgment on the pleadings.

First, there is a question as to whether Jazz was required to submit the '963 Patent for listing in the Orange Book because the FDA-approved labeling for Xyrem® states that "Xyrem is available only through a restricted distribution program called the . . . XYREM REMS because of the risks of central nervous system depression and abuse and misuse." Moreover, Defendants' arguments depend in no small part on claim construction and the question of whether the claimed "system" includes methods of using the approved product. During the claim construction process, "[t]he court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995). As such, the vast majority of courts have held claim construction to be inappropriate on a motion under Rule 12. *See, e.g., Nalco*, 883 F.3d at 1349; *In re Bill of Lading*, 681 F.3d at 1343 n.13; *Encore Dermatology Inc. v. Glenmark Pharms. Ltd.*, No. CV2002509KMESK, 2020 WL 7586958, at *3 (D.N.J. Dec. 22, 2020); *Deston Therapeutics LLC v. Trigen Laboratories Inc.*, 723 F. Supp. 2d 665, 670 (D. Del. 2010); *Yangaroo Inc. v. Destiny Media Techs.*, No. 09–462, 2009 WL 2836643, at *3, (E.D. Wis. Aug. 31, 2009). "To engage in the claim construction process upon review of a motion to dismiss [or, here, a motion for judgment on the pleadings] would be to go beyond the scope of a court's

traditional gatekeeping role in reviewing such a motion; it would instead amount to a more in-depth evaluation of the merits of a plaintiff's case." *Pragmatus AV, LLC v. Yahoo! Inc.*, No. 11-902-LPS-CJB, 2012 U.S. Dist. LEXIS 161874, at *22 (D. Del. Nov. 13, 2012). The Court agrees with these cases and will decline to engage in claim construction at this early stage of the case.

IV. CONCLUSION

For the reasons set forth above, Defendants' motion for judgment as a matter of law on Count III of its counterclaims (D.I. is denied. An appropriate order will follow.

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	)	
Defendants.	)	

ORDER

At Wilmington, this 19th day of October 2021, for the reasons set forth in the Memorandum Opinion issued on this date, IT IS HEREBY ORDERED that Defendants' Motion for Partial Judgment on the Pleadings (D.I. 20) is DENIED.

The Honorable Maryellen Noreika
United States District Judge