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 PHARMACUEITCALS LLC,	)	
	)	
Defendants.	)	

PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

OF COUNSEL:
F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART
& SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules / Statutes / Regulations

I. NATURE AND STAGE OF THE PROCEEDINGS

In this patent infringement suit between Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") and the Avadel Defendants, four of the five patents cover sodium oxybate drug formulations. The other patent—U.S. Patent No. 8,731,963 (the "'963 patent")—claims methods of using a computer-implemented system to safely distribute sodium oxybate for treatment of a narcoleptic patient. Specifically, the independent claims recite a "computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion." Avadel seeks a judgment on the pleadings that the '963 patent is improperly listed in the FDA Orange Book and should be removed therefrom. This is Jazz's answering brief in opposition to that motion.

II. SUMMARY OF ARGUMENT

Avadel's motion fails for each of the following, independent reasons:

First, FDA regulations ***require*** listing the '963 patent in the Orange Book. Particularly, FDA regulations require innovator pharmaceutical companies that file a New Drug Application ("NDA")—like Jazz did—to submit for listing in the Orange Book any patent claiming a method of using the drug that is the subject of the NDA. The regulations explain that method-of-use patents include not only those that claim therapeutic indications, but also those that claim "other conditions of use for which approval is sought or has been granted in the NDA." 21 C.F.R. § 314.53(b)(1). When the FDA first approved Jazz's sodium oxybate drug product (Xyrem®), it expressly conditioned approval on Jazz marketing the drug in accordance with the specific restrictions on distribution and use that are claimed in the '963 patent. Thus, there can be no doubt that the '963 patent claims a condition of use for which approval was granted and that the patent was required to be listed in the Orange Book in connection with Xyrem®.

Second, Avadel's motion is premised entirely on a proposed claim construction that cannot be resolved on the pleadings. Indeed, Avadel's motion is based on its position that the '963 patent claims only a computerized "system" that is ineligible for Orange Book listing. Avadel ignores (and hardly even mentions) that the claims are directed to a "system for treatment." And Jazz pled that the '963 patent claims "methods" that require the use of a computer, which are eligible for listing. In short, the parties have a fundamental disagreement over the meaning of key claim terms, which cannot be decided on the pleadings.

Third and finally, Avadel's patent-delisting counterclaim is not ripe for adjudication because any alleged harm to Avadel is speculative in nature or uncertain to occur. Here, Avadel could only argue that it is affected by an improper listing if FDA approval of its sodium oxybate product were also affected as a result of that listing. But because Avadel has not filed any patent certifications against the '963 patent with the FDA, and because its CEO has publicly stated that the company has no current or future plans to do so, there is no indication that the presence of the '963 patent in the Orange Book has had or will have any impact whatsoever on Avadel or its pending drug application. Accordingly, the delisting counterclaim is not ripe for the Court's adjudication. Further, if Avadel's motion is merely directed to whether Jazz is entitled to relief under the Hatch-Waxman Act, as Avadel's counsel stated during the Rule 16 conference, then the Court need not reach this issue until after the trial scheduled for October 2023 (which will be after the June 2023 expiration of the '963 patent).[1]

[1] Although the '963 patent will expire before trial, Avadel has threatened (and continues to threaten) to launch its product before the patent expires.

III. STATEMENT OF FACTS

A. Xyrem® Was Approved With Mandatory Conditions of Use that Are Covered by the '963 Patent

Jazz developed and manufactures Xyrem®, an FDA-approved drug product for use in the treatment of both cataplexy and excessive daytime sleepiness, which are devastating symptoms associated with the sleep disorder narcolepsy. *See, e.g.*, D.I. 1, Ex. B at 2:51-53.

The active ingredient in Xyrem® is sodium oxybate, which is a specific salt form of gamma-hydroxybutyrate ("GHB"). *Id.* GHB has been recognized by Congress and federal agencies as a dangerous substance, frequently misused as a "date rape drug" in cases of drug-facilitated sexual assault. Because of its high potential for abuse and misuse involving third parties, GHB was classified as a Schedule I controlled substance under the Controlled Substances Act, a designation reserved for drugs with a high potential for abuse and no accepted medical use. *See* 21 U.S.C. § 812(b)(1); 21 C.F.R. § 1308.11(e)(1). At the same time, however, the FDA and Congress recognized that studies had established that GHB might be the basis for a unique treatment for certain symptoms of narcolepsy. *See, e.g.*, D.I. 1, Ex. B at 1:41-58. Thus, approved forms of GHB like Xyrem® were classified as Schedule III controlled substances, acknowledging their legitimate medical uses. *See* 21 U.S.C. § 812(b)(3); 21 C.F.R. § 1308.13(c)(6). In reaching this compromise, however, both Congress and the FDA noted that medical use of a GHB-based drug like Xyrem® must be strictly controlled to ensure that it cannot be illicitly obtained and misused.

Given its unique status, the FDA conditioned approval of Xyrem® on Jazz's development and implementation of a controlled distribution program. Specifically, upon FDA approval of Xyrem® in 2002, the FDA stated that the drug could only be "approved with a Risk Management

Program (RMP) that must include [several specified] components." Ex. A at 2.[2,3] In fact, the FDA stated in Xyrem's approval letter in no uncertain terms that the "[m]arketing of this drug product and related activities are to be in accordance with the substance and procedure of all FDA regulations ***and the specific restrictions on distribution and use described [in the Xyrem Risk Management Program] below***." *Id.* at 1 (emphasis added).

Following approval, the labeling for Xyrem® has specified that "Xyrem is available only through a restricted distribution program called the XYWAV and XYREM REMS because of the risks of central nervous system depression and abuse and misuse." *See, e.g.*, Ex. B at § 5.3.[4] Consequently, distributing and using Xyrem® according to the methods set forth in the FDA-required REMS (which, as explained below, are covered by the '963 patent) are conditions of using the drug.

B. The '963 Patent Covers the Method of Use Required by the Xyrem® REMS

The claims of the '963 patent address the unique problem that the Xyrem® REMS was invented to solve: using GHB for legitimate medical purposes while avoiding the potential for misuse, abuse, or diversion of GHB by or against others. *See* D.I. 1, Ex. A at 1:32-45. The

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[2] A REMS is a form of Risk Management Plan that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. *See, e.g.*, https://www.fda.gov/files/drugs/published/Risk-Evaluation-and-Mitigation-Strategies--Modifications-and-Revisions-Guidance-for-Industry.pdf at 2.

[3] The Court may take judicial notice of the FDA Approval Letter for Xyrem®, as well as the other exhibits cited herein, which are publicly available on the FDA's website. *See, e.g.*, *Desai v. Sorin CRM USA, Inc.*, No. 12-2995, 2013 WL 163298, at *4 (D.N.J. Jan. 15, 2013) (explaining, in context of deciding Rule 12(c) motion, that "[t]his Court takes judicial notice of the FDA's website"); *Freed v. St. Jude Med., Inc.*, No. 17-1128, 2017 WL 4102583, at *2 (D. Del. Sept. 15, 2017) (taking judicial notice of documents "publically available on the FDA's website and [which] are indisputably authentic").

[4] Xywav® is an oxybate product marketed by Jazz that contains 92% less sodium than Xyrem® and is distributed and used according to the methods set forth in the '963 patent. For simplicity's sake, the XYWAV and XYREM REMS is referred to hereafter as the "Xyrem® REMS."

claims cover methods of using a computer-implemented system to safely distribute GHB for treatment of a narcoleptic patient. Specifically, the independent claims recite a "computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion." *See, e.g.*, *id.* at Claim 1. The claimed methods make use of the computerized system to confirm, among other things, that the patient and prescriber are authorized to receive and prescribe the drug, and to identify whether the physician or patient is potentially misusing the drug. *Id.* Claim 6 of the '963 patent is specifically limited to GHB. *Id.* at Claim 6.

As set forth in the table below, the steps of the claimed methods are each required steps of the FDA-approved Xyrem® REMS, and thus are required for the "treatment of a narcoleptic patient" using GHB, as set forth in the claims:

FDA-Approved REMS	**Claimed Method Steps**
"Verify in the Central Database that the patient and prescriber are enrolled." Ex. C at 5.	Identifying "a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug." *See* claim 1.
"Track and verify receipt of each shipment of [Xyrem®] through the processes and procedures established as a requirement of the REMS." *Id.* at 6.	Reconciling "inventory of the prescription drug before the shipments for a day or other time period are sent." *Id.*
"Monitor for all instances of patient and prescriber behavior that give rise to a reasonable suspicion of abuse, misuse, and diversion." *Id.*	Identifying any "indicator of a potential misuse, abuse or diversion by the narcoleptic patient." *Id.*
"Notify prescribers when patients are receiving concomitant contraindicated medications or there are signs of potential abuse, misuse, or diversion." *Id.* at 1.	Notifying "the physician that is interrelated with the narcoleptic patient" if any indicators of misuse are detected. *Id.*
"For patients who request an early refill or if abuse, misuse or diversion is suspected: Discuss the request or concern with the prescriber." *Id.* at 5.	"Selectively block[ing] shipment of the prescription drug to the patient" based upon identification of abuse potential. *See* claim 2.

FDA-Approved REMS	Claimed Method Steps
"Ship … XYREM directly to each patient or a patient-authorized adult designee through the processes and procedures established as a requirement of the REMS." *Id.*	"Shipp[ing] to the narcoleptic patient if no potential misuse, abuse or diversion is found." *See* claim 3.
"Contact the patient's insurance provider to verify … XYREM prescription benefits." *Id.* at 21.	Identifying "an insurer to be contacted for payment for prescription drugs of an associated patient." *See* claim 13.
"Assess the patient for … signs of abuse and misuse including an increase in dose or frequency of dosing, reports of lost, stolen, or spilled medication, and drug-seeking behavior." *Id.* at 2.	Identifying "a current pattern or an anticipated pattern of abuse of the prescription drug." *See* claim 14.

Put simply, the '963 patent claims the FDA-required conditions of using Xyrem® according to its approved labeling, including its REMS. Accordingly, the '963 patent is properly listed in the Orange Book.

C. Avadel's NDA and this Litigation

Avadel describes its infringing sodium oxybate drug product as "an innovative new drug product," which makes this action "[u]nlike the typical pharmaceutical patent infringement case involving a defendant seeking to market a generic version of a brand-name drug." Avadel Br. at 2.[5] To make its argument, Avadel compares its once-nightly sodium oxybate formulation (which it calls "FT218") to Xyrem®, which is currently dosed twice-nightly. *See id.* at 2-3. Avadel omits, however, that although Jazz has yet to bring a once-nightly sodium oxybate formulation to market, it has been developing a once-nightly formulation for years and has obtained several patents that cover its innovations. In fact, four of the five patents-in-suit claim once-nightly sodium oxybate formulations, and Avadel's FT218 infringes them all. *See* D.I. 1, Exs. B-E.

[5] As used herein, "Avadel Br." refers to "Opening Brief in Support of Avadel's Motion for Partial Judgment on the Pleadings" (D.I. 21).

Moreover, despite its claims of innovation, the NDA that Avadel filed with the FDA to seek approval for FT218 largely relies on the clinical studies that Jazz carried out for Xyrem®. Indeed, Avadel did not file a typical NDA but instead submitted a 505(b)(2) NDA. *See, e.g.*, D.I. 1, Ex. F at 13. A 505(b)(2) NDA sponsor is permitted to "rely on clinical studies that were previously submitted to [the] FDA in support of another drug and that were not conducted or licensed by the 505(b)(2) [sponsor]." *Veloxis Pharms., Inc. v. U.S. Food & Drug Admin.*, 109 F. Supp. 3d 104, 108-09 (D.D.C. 2015). In this case, Xyrem® is the Reference Listed Drug ("RLD") for Avadel's 505(b)(2) NDA. *See, e.g.*, D.I. 1, Ex. F at 12; *id.*, Ex. I at 7. The RLD-related clinical studies that a Section 505(b)(2) NDA sponsor relies upon may be submitted to satisfy the sponsor's "entire burden of proving safety and effectiveness" to the FDA. *Veloxis*, 109 F. Supp. 3d at 109. To that end, the 505(b)(2) NDA pathway is "often used when the new drug differs only slightly from the pioneer [or reference listed] drug." *Id.*

And although Avadel filed a 505(b)(2) NDA that relied upon Xyrem® as the RLD, it has refused to file ***any*** patent certification with respect to the Orange Book-listed '963 patent. In fact, Avadel has publicly stated that the company has "not been asked by the agency to certify Paragraph IV against any [Xyrem] Orange Book-listed patents, and we don't believe based on the data and regulatory filing strategy of our FT218 NDA submission, there is any basis to request such a certification." D.I. 1, Ex. F at 3; *see also* D.I. 1, Ex. I at 13. Indeed, Jazz has not received any notice from Avadel of a Paragraph IV certification.

IV. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(c), a judgment on the pleadings "will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (internal quotations and citations omitted). 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." *Id*; *see also, e.g.*, *Aqua Connect, Inc. v. TeamViewer US, LLC*, No. 18-1572 (MN), 2020 WL 5549086, at *1 (D. Del. Sept. 16, 2020) ("In ruling on a Rule 12(c) motion, the Court must accept as true all well-pleaded allegations in the non-movant's pleadings and draw all reasonable inferences in favor of the non-movant").

V. ARGUMENT

A. FDA Regulations Required Jazz to List the '963 Patent in the Orange Book

Under the Hatch-Waxman Act, NDA holders are ***required*** to file with the FDA "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted . . . and that . . . claims a method of using such drug for which approval is sought or has been granted in the [NDA]." 21 U.S.C. § 355(b)(1)(A)(viii). The FDA identifies these patents in the "Orange Book" (*Approved Drug Products with Therapeutic Equivalence Evaluations*). The FDA's Orange Book listing rules specify that, among other things, "[f]or patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA." 21 C.F.R. § 314.53(b)(1). The FDA has also explained that, "if a method of use is described in the labeling for the drug product, and there is a patent claiming that method of use, the patent must be submitted for listing in the Orange Book." *See* 68 Fed. Reg. 36680 (June 18, 2003).

Pursuant to the statute and its attendant regulations, Jazz was required to submit the '963 patent for listing in the Orange Book. As set forth above, the FDA-approved labeling for Xyrem® states that "Xyrem is available ***only*** through a restricted distribution program called the XYWAV and XYREM REMS because of the risks of central nervous system depression and abuse and misuse." Ex. B at § 5.3 (emphasis added). Moreover, the FDA only approved

Xyrem® on the express condition that the drug would be used according to the "specific restrictions on distribution and use described [in the Xyrem Risk Management Program]." *See* Ex. A at 1; *see also id.* at 2 (describing such restrictions on distribution and use). The '963 patent claims the methods "for treatment of a narcoleptic patient" that comprise the FDA-required conditions of use for Xyrem®, which are described in the Xyrem® REMS. *See supra* at § II(B). Accordingly, the method of using Xyrem® according to its approved REMS is not only a "condition of use" as required by the FDA (*see* 21 C.F.R. § 314.53(b)(1)), but also is "described in the labeling for the drug product" (*see* 68 Fed. Reg. 36680). As such, the '963 patent claims "an approved method of using the drug" under both the relevant statute and FDA Rule. *See* 21 U.S.C. § 355(b)(1)(A)(viii); 21 C.F.R. § 314.53(b) (requiring listing of "patents that claim indications or other conditions of use"). Thus, far from this being a case of improper listing, Jazz was legally ***required*** to list the '963 patent in the Orange Book.

Moreover, although FDA regulations expressly set forth the categories of patents that are ***ineligible*** for Orange Book listing, the '963 patent does not fall into any such category. Instead, the FDA makes clear that patents that "must not be submitted to FDA" for listing in the Orange Book are those that are: "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates … ." 21 C.F.R. § 314.53(b)(1). Avadel does not and cannot contend that the '963 patent falls within any of these prohibited categories.

On this basis alone, Avadel's motion should be denied.

B. Avadel's Motion is Based on a Flawed Claim Construction Argument That Cannot Be Adjudicated At This Early Stage of the Case

Avadel's delisting argument is premised entirely on its theory that the '963 patent claims a "system" as opposed to a "method." *See, e.g.*, Avadel Br. at 5. This is, plain and simple, claim construction. As explained below, Avadel's claim construction argument is incorrect, and at the

very least, it cannot be adjudicated on the current record. This is another, independent reason why Avadel's motion should be denied.

Avadel does not dispute that Jazz has pled that the '963 patent claims a method. *See* Avadel Br. at 5 (arguing that "Jazz has incorrectly asserted" that the patent claims recite a "method"); *see also, e.g.*, D.I. 1 at ¶ 27 ("The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of sodium oxybate…"). And yet, at this preliminary stage in the case—and on a motion for judgment on the pleadings—Avadel would have the Court disregard the pleadings and decide the meaning of claim terms based on nothing but six pages of attorney argument. This is improper.

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. Such a determination cannot be made on the pleadings. The Federal Circuit has explained that "it would be inappropriate for a district court to engage in 'claim construction at the pleading stage—with no claim construction processes undertaken.'" *Gestion Proche, Inc. v. Dialight Corp.*, No. 16-00407, 2017 WL 1551606, at *3 (E.D. Tex. May 1, 2017) (quoting *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1343 n.13 (Fed. Cir. 2012)). Accordingly, as this Court recently explained in denying a motion to dismiss, where the moving party's arguments "seem to require claim construction…. [the Court] cannot resolve the claim construction issues on the record [at this early stage of the case]." *Blackbird Tech v. Uber Techs., Inc.*, No. 19-561 (MN), 2020 WL 58535, at *8 (D. Del. Jan. 6, 2020). And other courts within this district routinely decline to resolve claim construction disputes at the outset of a case, well before *Markman* proceedings. *See, e.g., Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 563 (D. Del. 2012) ("The court is not prepared to engage in a claim

construction exercise at this stage of the proceedings, with no context whatsoever provided by discovery or a motion practice."); *Tech. Innovations, LLC v. Amazon.com*, No. 11-690, 2012 WL 1441300, at *2 (D. Del. Apr. 25, 2012).

Avadel nonetheless suggests that the Court need not engage in any sort of claim construction analysis because "Jazz itself" has supposedly "characterized the '963 patent claims as 'system' claims in proceedings before the Patent Trial and Appeal Board." Avadel Br. at 6. Avadel is mistaken. Avadel's argument rests on a selectively (and improperly) cropped quote from a PTAB proceeding involving the '963 patent. There, Jazz described the claims as follows: "computer-implemented systems ***for treating a narcoleptic patient*** with a prescription drug that has a potential for misuse, abuse, or diversion, while preventing that misuse, abuse, and diversion ***by means of various controls***." Avadel Br., Ex. B at 2 (emphasis added); *see also id.* (explaining that "FDA would not have approved Xyrem without a ***method*** of restricting access to the drug that could ensure that its benefits would outweigh the risks to patients and third parties."). In other words, Jazz has consistently described the claims of the '963 patent as covering a method of safely using GHB that relies on the use of a specific, computerized system. And, notably, the PTAB proceeding concerned the alleged obviousness of the claims-at-issue and, thus, had nothing to do with whether the claims were directed towards methods or systems.

To be sure, there is no dispute that the preambles of the independent claims of the '963 patent refer to "a computer-implemented system." But Avadel goes to great lengths throughout its brief to ignore that the claims cover "a computer-implemented system ***for treatment of a narcoleptic patient***." In other words, the '963 patent does not simply claim a computerized system. Rather, the claims describe a method of using GHB through a computer-implemented system "for the treatment of a narcoleptic patient."

Determining whether a patent claims a system, a method, or both is fundamentally a question of claim construction, and so the court should not limit its analysis to the words in the preamble. Instead, the court must consider whether the body of each claim sets forth method steps, regardless of how the preamble may describe the invention. *See, e.g.*, *Lyda v. CBS Corp.*, 838 F.3d 1331, 1339 (Fed. Cir. 2016) (holding that "the purported system claims asserted in this case are, in fact, method claims because the body of the claims require the performance of particular method steps."). Avadel would have the court stop its analysis at the fourth word of the preamble of claim 1, glossing over the fact that the patent claims "[a] computer-implemented system ***for treatment of a narcoleptic patient*** with a prescription drug that has a potential for misuse, abuse or diversion."

The body of claim 1 (and the additional method steps set forth in the dependent claims) illustrate that the claims recite methods. The claimed methods are carried out—and misuse, abuse, and diversion of GHB are avoided—by requiring that, before the drug is dispensed, numerous pieces of information about both the patient and the prescriber are entered into (and analyzed by) the computerized system. For instance and by way of example, the methods comprise:

- Identifying "a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug." *See* claim 1.
- Reconciling "inventory of the prescription drug before the shipments for a day or other time period are sent." *Id.*
- Identifying any "indicator of a potential misuse, abuse or diversion by the narcoleptic patient." *Id.*
- Identifying "an insurer to be contacted for payment for prescription drugs of an associated patient." *See* claim 13.
- Using the computer database to identify "a current pattern or an anticipated pattern of abuse of the prescription drug." *See* claim 14.

- Selecting "one or more controls for distribution … based on the identified pattern." *See* claim 15.

Only if the answers to all inquiries are satisfactory will the methods allow the computer to be "used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database" that the drug may be dispensed. *See* claim 1.[6]

In any event, the pleadings stage is not the appropriate time to resolve this claim construction dispute. *Celgene Corporation v. Lotus Pharmaceutical Company* is instructive. There, a generic drug applicant moved for judgment on the pleadings against several patents that covered aspects of a REMS for a different FDA-approved drug product. No. 17-6842, 2018 WL 6584888, at *1 (D.N.J. Dec. 14, 2018). The court there denied the motion because it could not "determine whether these patents are invalid under [the relevant standard] without construing [several] terms," further explaining that "[j]udgment may only be granted if 'the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" *Id.* at *1-2.

The same result is warranted here. In order to give credence to Avadel's theory, the Court must: (1) ignore the fact that Jazz pled that the '963 patent claims a method, and (2) construe each claim as covering only systems (Avadel's position), and not methods that must

[6] Contrary to Avadel's suggestion (*see* Avadel Br. at 6), the claims of the '963 patent do not improperly claim both a system and a method. Instead, and as "[b]oth common sense and a cursory inspection of relevant authorities demonstrate," a claimed method may be "limited to performance on a particular type of apparatus." *Collaboration Props., Inc. v. Tandberg ASA*, No. 05-1940, 2006 WL 1752140, at *3 (N.D. Cal. June 23, 2006). Accordingly, the Federal Circuit has since "made it clear" that the prohibition on hybrid claiming identified in *IPXL Holdings* (on which Avadel relies) "is not implicated where a method claim 'recite[s] the physical structures of a system in which the claimed method is practiced.'" *Steuben Foods, Inc. v. Oystar USA, Inc.*, No. 10-780, 2021 WL 630906, at *13 (W.D.N.Y. Feb. 18, 2021) (quoting *Microprocessor Enhancement Corp. v. Texas Instruments, Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008)). That is the situation here.

be carried out using a system (Jazz's position). Claim construction determinations cannot be made at the pleadings stage. Instead, where, like here, "the parties vigorously dispute the basic character and meaning of the claims," the court should not attempt "to conjure up all plausible claim constructions at th[e] pleadings stage in the absence of stipulated constructions." *Id.* at *3.

C. Avadel's Delisting Motion Is Not Ripe For Adjudication

In addition to the substantive reasons to deny Avadel's motion set forth above, the Court should also deny the motion for the independent reason that the motion is not ripe for adjudication.

Subject matter jurisdiction in the federal courts requires an Article III case or controversy. *See, e.g.*, *Caraco Pharm. Labs, Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1290 (Fed. Cir. 2008). "A justiciable Article III controversy requires the party instituting the action to have standing and the issue presented to the court to be ripe." *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007). The "ripeness analysis considers whether further factual development would significantly advance [the court's] ability to deal with the legal issues presented, and whether the complained-of conduct has an immediate and substantial impact on the plaintiff." *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1278 (Fed. Cir. 2014) (internal citations and quotations omitted).

Because Avadel has not filed any patent certification against the '963 patent, the listing of that patent in the Orange Book has no impact on Avadel and no Article III controversy exists. Avadel can only be affected by the alleged improper listing if it files a patent certification against the '963 patent. For instance, if the FDA requires Avadel to file a patent certification vis-a-vis the '963 patent, Avadel would have two choices—it could file a Paragraph III or a Paragraph IV certification. If Avadel files a Paragraph III certification, it cannot sell FT218 until the '963 patent expires in June 2023, and if it files a Paragraph IV certification, then the FDA would

have to stay approval of Avadel's NDA for 30-months while this lawsuit is resolved. But unless and until Avadel actually files a patent certification against the '963 patent, the patent's presence in the Orange Book is not immediately or substantially harming Avadel. To the contrary, without any patent certification, the Orange Book listing of the '963 patent has no impact on Avadel whatsoever.

Avadel has made clear in its recent public statements that it has no intention of filing any patent certification against the '963 patent. In fact, the company's CEO recently stated that, "as we sit here today through the [FDA] review process, we've not been asked to certify against any Orange Book-listed patents, and we do not believe there's a reason to do so." D.I. 1, Ex. I at 13; *see also* D.I. 1, Ex. F at 3 ("[W]e still have not been asked by the agency to certify Paragraph IV against any Orange Book-listed patents, and we don't believe based on the data and regulatory filing strategy of our FT218 NDA submission, there is any basis to request such a certification.").

It is well-established that a "claim is not ripe for adjudication if it rests upon contingent ***future*** events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (emphasis added and internal quotations omitted). Therefore, because the '963 patent's presence in the Orange Book is not currently affecting (let alone harming) Avadel in any way, Avadel's counterclaim is not ripe for adjudication.

In addition, during the Rule 16 conference with the Court, Avadel's counsel remarked that Avadel's motion related to Jazz's "claim that they're entitled to an automatic injunction under the Hatch-Waxman Act." D.I. 28 at 16:8-11. But to plead a case under the Hatch-Waxman Act, and thus be entitled to a Hatch-Waxman injunction, Jazz only has to allege that the filing of a 505(b)(2) application infringes one or more of its patents under 35 U.S.C. § 271(e)(2). *See AstraZeneca Pharms. v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012); *Vanda*

Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1124 (Fed. Cir. 2018). In other words, Jazz is entitled to a Hatch-Waxman injunction if it proves infringement of the '963 patent regardless of whether that patent is listed in the Orange Book. Thus, the purported basis that Avadel offered for its motion at the Rule 16 conference fails to create a ripe dispute for the Court. Further, even if Avadel's motion had merit (it does not), given that Avadel's claimed reason for filing its motion goes to Jazz's remedy, the Court will only need to decide the issue if Jazz prevails on the '963 patent after trial on the merits, which is currently scheduled for October 2023 (i.e., after the June 2023 expiration of the '963 patent).

In this case, given that Avadel has publicly and repeatedly stated that it has no intention of filing a patent certification against the '963 patent, and that Jazz may properly seek Hatch-Waxman relief regardless of whether the '963 patent is listed in the Orange Book, Avadel may never be harmed by any alleged improper listing. Accordingly, the claim is not ripe for adjudication and the motion should be denied on this additional, independent basis.

VI. CONCLUSION

For the foregoing reasons, the Court should deny Avadel's partial motion for judgment on the pleadings.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiff Jazz Pharmaceuticals, Inc.

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

August 20, 2021

CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 20, 2021, upon the following in the manner indicated:

Daniel M. Silver, Esquire — *VIA ELECTRONIC MAIL*
Alexandra M. Joyce, Esquire
McCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
Attorneys for Defendants

Kenneth G. Schuler, Esquire — *VIA ELECTRONIC MAIL*
Marc N. Zubick, Esquire
Alex Grabowski, Esquire
Sarah W. Wang, Esquire
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
Attorneys for Defendants

Daralyn J. Durie, Esquire — *VIA ELECTRONIC MAIL*
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111
Attorneys for Defendants

Kira A. Davis, Esquire — *VIA ELECTRONIC MAIL*
Katherine E. McNutt, Esquire
DURIE TANGRI LLP
953 East 3rdStreet
Los Angeles, CA 90013
Attorneys for Defendants

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)