IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	Case No. 21-691-MN
v.	)	
	)	
	)	
AVADEL PHARMACEUTICALS PLC, ET AL.,	)	
	)	
	)	
Defendants.	)	

REPLY BRIEF IN SUPPORT OF AVADEL'S MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

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I. INTRODUCTION

Jazz's opposition to Avadel's Rule 12(c) motion makes clear that there is no genuine dispute that Jazz improperly listed the '963 patent in the Orange Book. Jazz brazenly asks the Court to ignore plain English and interpret claims that are unmistakably directed to ***computer systems*** as method claims. In order to do so, Jazz does not construe the claim terms but instead ***rewrites*** the claims to add verbs and omit nouns—a ploy that only serves to highlight the lack of any "method steps" in the claimed computer systems. Jazz doubles down on this facially absurd argument by insisting that the Court must undertake a full claim construction analysis before it can resolve whether the claims are directed to a system or a method. Not so—courts in this district have routinely ruled on Rule 12 motions where, as here, there was no plausible claim construction dispute. Finally, as a last ditch effort to avoid an order requiring it to correct its facially improper Orange Book listing, Jazz attempts to convince the Court that the parties' dispute is somehow not ripe for adjudication, despite Supreme Court precedent to the contrary.

Jazz's arguments underscore that the only plausible viewing of the facts is that the '963 patent is improperly listed, and this Court should grant Avadel's delisting motion on the pleadings.

II. ARGUMENT

A. The '963 Patent Is Improperly Listed Because It Does Not Claim a "Method of Using [a] Drug"

As Avadel explained in its opening brief, the '963 patent is unmistakably directed to a "computer-implemented ***system***."[1] D.I. 21 at 3-6. Because it does not claim a drug substance, drug product, or method of using a drug, the Hatch-Waxman Act and attendant regulations do not permit its listing in the Orange Book. *See* 21 U.S.C. § 355(b)(1)(A)(viii) (requiring that listed

[1] All emphases added except where otherwise noted.

patents are those (1) "for which a claim of patent infringement could reasonably be asserted;" ***and*** (2) claim "a drug substance (active ingredient)," "drug product (formulation or composition)," or "a ***method*** of using such drug); 21 C.F.R. § 314.53(b) (the patents to be listed "***consist*** of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents").

Method claims "consist[] of doing something, and therefore ha[ve] to be carried out or performed." *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002); *NTP, Inc. v. Rsch. in Motion, Ltd.*, 418 F.3d 1282, 1322 (Fed. Cir. 2005) ("The invention recited in a method claim is the ***performance*** of the recited steps."). Thus method claims have certain hallmarks, including the use of the word "method"; verbs describing actions to be performed; and steps to be taken in performing the claimed method. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204-05 (Fed. Cir. 2010) (determining that claims to a "system for execution by a server that serves as a gateway to a client . . ." were not method claims because they "[did] not require the performance of any method steps" and instead "recite[d] software components with specific purposes," such as "a logical engine for *preventing* execution") (emphasis in original). Not only do the claims of the '963 patent fail to recite "methods," they are entirely devoid of verbs describing actions to be performed or steps to be taken. They thus plainly fail to display any of the commonsense indicia of method claims.

Jazz's arguments to the contrary are unavailing. First, Jazz rewrites the unambiguous language of the claims to include "method steps" that do not exist. Jazz goes so far as to chart the purported "methods steps" found in the '963 patent claims. *See* D.I. 43 at 5. But even a cursory review of the actual claim language reveals that Jazz arrives at the "method steps" for the '963 patent by ***omitting*** the recitation of components of the "computer-implemented system" from the

claim language (*e.g.*, "prescriber fields" and "data processor") and ***substituting*** verbs describing method steps in place of the adjectives describing the system components (*e.g.*, "to identify," "to . . . reconcile," "to notify"). Thus, in Jazz's brief, the system element of "a ***data processor*** configured to . . . reconcile inventory of the prescription drug" is recast as an alleged method step of "***reconciling*** 'inventory of the prescription drug . . . .'" *See* D.I. 43 at 5 (*citing* claim 1). Similarly, "the system of claim 1, wherein the data processor selectively blocks shipment of the prescription drug" is contorted to the alleged method step of "block[ing] shipment of the prescription drug." *See Id.* (*citing* claim 2); *see also id.* at 5-6 (*citing* claims 1, 3, 13, 14).) But the claims are plain on their face and cannot be rewritten as Jazz suggests. *See Bio-Rad Labs, Inc. v. Int'l Trade Comm'n*, 998 F.3d 1320, 1331 (Fed. Cir. 2021) (rejecting patentee's argument because "it is premised on rewriting the claims" and patentee's "summary of the claim is not remotely close to what the claim says"); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed, Cir. 2001) ("A patent may not, like a nose of wax, be twisted one way to avoid [invalidity] and another to find infringement.") (citations and internal quotation marks omitted).

Second, Jazz ignores entirely the fact that the preambles of claims 1 and 23 (the independent claims at issue) expressly state that the claims are directed to a "computer-implemented system." *See* '963 patent at Claims 1, 23. Instead, Jazz cites language from the preamble stating that the "computer-implemented system" is intended for the "treatment of a narcoleptic patient." *See* D.I. 43 at 11-12. But courts have repeatedly rejected similar attempts to rely on such isolated claim fragments describing the intended use of a physical device or system to transform a non-method claim into a method-of-use claim. Thus, in *In re Lantus Direct Purchase Antitrust Litig.*, 950 F.3d 1 (1st Cir. 2020), the Court reversed the trial court and found that it was improper to list a patent to a "<u>device</u> ***intended for use in an injector pen***," because it

neither "claim[ed] the pertinent drug or a method of using the drug." *In re Lantus*, 950 F.3d at 1, 7. Other courts have made it clear that language describing a particular use must be read in the full context of the claims, and the recitation of a therapeutic use to describe a system or device does not transform such non-method claims into method claims. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Microspherix LLC*, 814 F. App'x 575, 577 (Fed. Cir. 2020) (characterizing claims to a brachytherapy device ***for use in radiation treatment*** as "devices for treating cancers"); *Purdue Pharm. Prods. L.P. v. Actavis Elizabeth, LLC*, No. 12-5311 (JLL), 2014 WL 2624787, at *7-8 (D.N.J. June 11, 2014) (treating claims to "[a] solid unit dosage composition ***for the treatment of MOTN insomnia***" as "composition" claims); *Pacific Biosciences Labs, Inc. v. Nutra Luxe MD, LLC*, No. 2012 WL 12845607, at *3, *10 (W.D. Wash. Mar. 21, 2012) (describing a claim to "[a]n apparatus ***for treatment of acne***" as an "apparatus" claim).[2] The Court should reject Jazz's attempt to rely on select phrases to transform claims directed to "computer systems" that can be used for a specific application into claims "covering a method of safely using GHB." D.I. 43 at 11, *see also id.* at 1, 4-5, 13-14.

Third, Jazz's attempts to walk back its prior characterization of the '963 patent before the PTAB as "system" claims are unavailing. *See* D.I. 43 at 11.[3] Jazz's first example—in which Jazz stated that the claims were directed to "computer-implemented systems for treating a narcoleptic

[2] *Lyda v. CBS Corp.*, 838 F.3d 1331 (Fed. Cir. 2016) is not to the contrary. D.I. 43 at 12. The method claims at issue were construed as such because the body of the claims recited "the performance of particular method steps." *Lyda*, 838 F.3d at 1339. Here, the claims of the '963 patent require components of a computers system, *e.g.*, a "computer database," "computer memories," and a "data processor," not actions to be performed.

[3] Jazz's contention that Avadel "suggest[ed]" that the '963 patent was directed to both a method and a system misunderstands Avadel's argument. D.I. 43 at 13 n.6. As Avadel explained in its opening brief, patent claims may either be method claims or composition claims, but not both. D.I. 21 at 6. Having repeatedly represented to the PTAB that the claims of the '963 patent were system claims, it cannot now take the position that they are method claims.

patient"—simply repeats the claim language which, on its face, describes a "computer-implemented *system*," not a method of use. D.I. 43 at 11. Jazz's remaining example—that Jazz explained that the "FDA would not have approved Xyrem without a method of restricting access to the drug" fares no better. *See id.*; *see also id.* at 8-9 (citing the fact that FDA approval of Xyrem required a system for controlling access to the drug). The FDA's requirement that Xyrem's use be regulated has no bearing on whether Jazz has patent claims covering its use.

Fourth, Jazz's arguments are flatly contradicted by the fact that it obtained six other patents relating to the REMS system, all of which included method claims. Notably, all six were also listed in the Orange Book, and all six were invalidated in their entirety by the PTAB. D.I. 21 at 3. Those patents provide a stark counterpoint to Jazz's contention that the '963 patent is directed to a method of use: when Jazz intended to claim methods of using GHB (including in connection with a computer system), it did so clearly and unequivocally, using claims that carry the hallmarks of method claims: expressly reciting a "method"; using verbs describing specific actions; and identifying steps to be performed in carrying out the method. *See, e.g.*, Ex. 1, U.S. Patent No. 7,765,106, cl. 1 ("A therapeutic ***method for treating a patient*** . . . comprising . . . ***receiving***, only into an exclusive central computer system, all prescriptions."); Ex. 2, U.S. Patent No. 8,457,988, cl. 1 ("A ***method of treatment*** of a narcoleptic patient . . . comprising . . . ***receiving*** in a computer processor all prescription requests"). But now that those claims are invalidated, Jazz is attempting to recover those invalidated method claims through the wholesale rewriting of the computer system claims of the '963 patent. The Court should reject these tactics.

Because the claims of the '963 patent are directed to computer systems, rather than methods of use, Jazz's contention that the FDA regulations "required Jazz to list the '963 patent in the Orange Book," is entirely unfounded. D.I. 43 at 8. Further, as explained in Avadel's opening brief

(D.I. 21 at 2), the FDA does not police whether particular patents should be listed in the Orange Book—"it simply lists those patents that are submitted by patent holders." *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324-25 (Fed. Cir. 2012) (finding non-infringement on the pleadings because defendants did not seek approval for the use protected by the listed method-of-use patent). Thus, the fact that Jazz listed the '963 patent is irrelevant to the question of whether it ***should*** have been listed, and Jazz cannot hide behind an FDA regulation that purportedly required such a listing.

Finally, Jazz contends that the '963 patent claims (even if they are not method-of-use claims) may be eligible to be listed in the Orange Book because they do not "fall[] within any of the[] prohibited categories" as set forth in 21 C.F.R. § 314.53(b)(1) (prohibiting listing of "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates"). D.I. 43 at 9. But Jazz ignores that, as described above, both the statute and attendant regulations require that the patent be "to a method of using the drug." 21 U.S.C. § 355(b)(1)(A)(viii); *see also* 21 C.F.R. § 314.53(b)(1). Jazz's interpretation would eviscerate such a requirement, and thus cannot be correct. *See Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 401-02 (2008) (rejecting interpretation of regulation that would be in "tension with the structure and purpose" of the authorizing statute). The regulations simply state that process patents (such as methods of manufacturing) are not methods of ***using*** the drug.

B. There Is No Genuine Claim Construction Dispute That Would Preclude Judgment on the Pleadings

Jazz next argues that Avadel is precluded from a ruling on the pleadings because there is an outstanding claim construction dispute. D.I. 43 at 14. Jazz thus attempts to create a *per se* rule that as soon as a party alleges a claim construction dispute, this Court cannot grant Rule 12(c) relief. *Id.* No such rule exists, and courts have routinely rejected such arguments where the

purported claim construction issue is facially implausible. *See, e.g.*, *Ottah v. Fiat Chrysler*, 884 F.3d 1135, 1141-42 (Fed. Cir. 2018) (affirming dismissal because claims to a "'book holder' cannot plausibly be construed to include or be the equivalent of a camera holder, in view of the specification and the prosecution history"); *Cumberland Pharms. Inc. v. Sagent Agila LLC*, No. 12-825-LPS, 2013 WL 5913742, at *2 (D. Del. Nov. 1, 2013) (granting a motion to dismiss because "[n]o claim construction is necessary in order to determine that 'free from a chelating agent' means that a claimed composition may not include a chelating agent").

That is exactly the situation here. As discussed above, while Jazz asserts that there is a "claim construction dispute," it does not identify any specific term in need of construction, nor identify the construction that it would advocate for any such term, nor identify any factual evidence that the Court would need to evaluate in order to resolve the meaning of it. The Court is not required to entertain Jazz's facially implausible arguments. *See, e.g.*, *Max v. Republican Comm. of Lancaster Cnty.*, 587 F.3d 198, 200 (3d Cir. 2009) (to survive motion to dismiss, non-movant must "state a claim to relief that is plausible on its face") (citation omitted); *Wolfington v. Reconstructive Orthopaedics Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019) (analyzing Rule 12(c) motions "under the same standards that apply to a Rule 12(b)(6) motion"). Were the case otherwise, a plaintiff could simply manufacture a claim construction dispute, no matter how frivolous, and preclude a court from granting Rule 12(c) relief. Thus, while Jazz pled that the '963 patent claims are "method claims," it offers no legitimate reading of the claims in which they would be understood to be "method claims," nor does such a legitimate reading exist. In these circumstances, where there is no material issue of fact to be resolved, Avadel is entitled to judgment as a matter of law. *See Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1178 (Fed. Cir. 2020) (applying Third Circuit law to find that judgment on the pleading was

appropriate when proffered expert testimony "was merely 'an attempt to manufacture a factual dispute'").

C. This Issue Is Ripe for Adjudication

Finally, Jazz argues that this motion is not ripe for adjudication because (1) Avadel has not filed any patent certifications against the '963 patent; and (2) Jazz can assert the '963 patent under 35 U.S.C. § 271(e)(2) regardless of whether it is listed in the Orange Book (D.I. 43 at 15-16).

First, Avadel is not required to have filed a certification against the '963 patent in order to bring a motion for judgment on the pleadings for its delisting counterclaim. The Supreme Court addressed an analogous situation in *Caraco* when it considered whether an applicant could seek a counterclaim against a branded company to force correction of an improper method of use code without first certifying against the patent. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012). The Court explained that in order 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 a brand has submitted to the FDA. *Id.* at 408. Further, this 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.* While Avadel is not a generic applicant, it has been sued by Jazz on an improperly listed patent, and the Court's holding in *Caraco* applies here with equal force. That is a cognizable harm. Avadel's motion for judgment is not precluded by the lack of a certification against the '963 patent and is ripe for adjudication.

Second, Jazz argues that it could assert the '963 patent under the Hatch-Waxman Act regardless of its listing status. Yet, Jazz's own cases are inapposite, because in both cases, the

asserted patents ***had*** been listed. Thus, in *AstraZeneca*, the patentee alleged that the Defendants' "ANDA filings infringed its ***listed*** patents under § 271(e)(2), and nothing more was required to establish the district court's subject matter jurisdiction pursuant to § 1338(a)." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (determining that the district court had subject matter jurisdiction when patentee asserted listed patents against ANDA filers). Similarly, in *Vanda*, the asserted patent was listed in the Orange Book, and the dispute was whether relief under § 271(e)(4)(A) was available when the patent issued and was listed only after the ANDA was filed. *See Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1121, 1123 (Fed. Cir. 2018). Finally, that assertion is irrelevant in any event – Congress has prescribed a remedy for an improperly-listed patent, and Avadel has demonstrated that it is entitled to the very relief Congress has afforded under the statute.

Avadel's delisting counterclaim does not require a certification against the '963 patent, and nothing precludes the Court from deciding Avadel's Rule 12(c) motion for judgment on the pleadings.

III. CONCLUSION

In light of the foregoing, Avadel respectfully requests that the Court decide on the pleadings that Jazz's '963 patent was improperly listed and that it be removed from the Orange Book.

Dated: September 3, 2021

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