IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFF'S SUR-REPLY IN OPPOSITION TO DEFENDANT'S RENEWED 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

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

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I. ARGUMENT

A. Avadel's new, improperly-raised argument should be disregarded

On August 26, Jazz opposed Avadel's motion under both Jazz's proposed claim construction (methods) and Avadel's proposed construction (computer systems). The parties have fully briefed the "methods" prong of Avadel's basis for delisting.

Avadel's August 28 reply, however, includes a new argument for the "computer systems" prong. In its original Rule 12(c) briefing (D.I. 21 & 47) and opening renewed Rule 12(c) briefing (D.I. 118), Avadel rooted its delisting arguments under Avadel's proposed "computer systems" claim construction on whether Jazz properly listed the '963 patent under 21 U.S.C. § 355(b)(1)(A)(viii)(I-II), § 355(c)(2), and 21 C.F.R. § 314.53(b). *See* D.I. 21 at 2, D.I. 47 at 6, D.I. 118 at 6-9. In its renewed motion, Avadel relied on 21 U.S.C. § 355(j)(5)(C)(ii)(I) and 21 U.S.C. § 355(c)(3)(D)(ii)(I) for "remedy" purposes only, but in reply seeks to use the statutes as the basis for why Avadel is allegedly entitled to that "remedy" in the first place. *See* D.I. 118 at 5, 11. Jazz explained why the former cited provisions did not provide for delisting and, thus, why Avadel's proposed remedy should not be granted. *See* D.I. 153. In reply, however, Avadel changed the statutory foundation of its request by using the language of 21 U.S.C. § 355(j)(5)(C)(ii)(I) and 21 U.S.C. § 355(c)(3)(D)(ii)(I) to argue that delisting must be granted if Avadel's proposed "computer systems" construction is adopted. *See, e.g.*, D.I. 154 at 1. Avadel's new argument is improperly raised in reply and, for the reasons stated in Jazz's Motion for Leave to File a Sur-Reply, the Court may disregard it.

B. Even if the Court were to consider Avadel's new argument on reply, it would not change the unsuccessful outcome for Avadel's motion

Avadel states that 21 U.S.C. § 355(j)(5)(C)(ii)(I) (for ANDAs)—and its related 21 U.S.C. § 355(c)(3)(D)(ii)(I) (for 505(b)(2) NDAs)—"gives Avadel a present right to seek an order

requiring Jazz to delist the '963 patent from the Orange Book." D.I. 154 at 2. But that is the only "right" that those provisions afford Avadel. The provisions do not state, as Avadel seems to imply, that any Orange-Book listed patent that does not claim either "(aa) the drug for which the application was approved; or (bb) an approved method of using the drug" ***must*** be delisted from the Orange Book. Nor would such a reading of the provisions be legally supportable in view of the 2021 Orange Book Transparency Act ("OBTA").

As Jazz explained in opposition, the OBTA for the first time stated what types of patents (other than those previously enumerated in the FDA regulations) "shall not be submitted" for listing in the Orange Book. D.I. 153 at 14-15. Further, controlling precedent dictates that the OBTA shall be applied only prospectively, not retroactively to Jazz's submission of the '963 patent for listing in 2014. *See id.* at 15-17. Avadel provides no legal support for interpreting the OBTA any other way. Nor does Avadel address the admitted "statutory conflict" (D.I. 154 at 5) that arises when one attempts to reconcile Avadel's reading of 21 U.S.C. § 355(j)(5)(C)(ii)(I)/21 U.S.C. § 355(c)(3)(D)(ii)(I)—that all but certain types of patents must be delisted from the Orange Book—with Congress's later explicit instruction that those same types of patents cannot be listed in the Orange Book going forward (but not requiring retroactive delisting).

Although Avadel does not address this "conflict," the case law does. "[S]tatutory provisions enacted at different times should be read as harmoniously as possible, so that each is given effect and the provisions do not conflict." *Com. of Pennsylvania v. Dept. of Health & Hum. Servs.*, 723 F.2d 1114, 1119 (3d Cir. 1983). "Unless Congress clearly indicates which of two statutes is to prevail in event of conflict, [the court's] responsibility is to interpret and apply them 'in a way that preserves the purposes of both and fosters harmony between them.'" *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999) (citation omitted). There is only one

way to read the statutory provisions addressed throughout the briefing in order to give effect to all and to avoid conflict.

First, under 21 U.S.C. § 355(b)(1)(A)(viii)(I-II), when Jazz submitted the '963 patent for listing in the Orange Book in 2014, patents claiming a drug substance, drug product, or a method of using a drug were ***required*** to the be listed in the Orange Book; but, consistent with the FDA regulations, other types of patents (e.g., computers systems) were also ***permitted*** to be listed. *See* D.I. 153 at 14-15.

Second, under 21 U.S.C. § 355(j)(5)(C)(ii)(I)/21 U.S.C. § 355(c)(3)(D)(ii)(I), an ANDA/505(b)(2) applicant can "seek", but is not automatically entitled to, an order requiring correction or deletion of certain patent-related information. As the case law demonstrates, these statutory provisions are applied when a patentee, for example: (1) misrepresents use-code information as covering multiple labeled indications when the patent covers only one such indication (*see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 409-11 (2012)); or (2) improperly lists a patent that nowhere mentions the drug product in the listed claims (*see In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7-8 (1st Cir. 2020)). No such similar conduct exists for the '963 patent.

And third, under 21 U.S.C. § 355(c)(2), beginning in 2021, all patents other than those claiming a drug substance, drug product, or a method of using a drug are no longer permitted to be listed in the Orange Book; but consistent with principles of statutory interpretation, the '963 patent remains properly listed. This reading does not render 21 U.S.C. § 355(j)(5)(C)(ii)(I) "superfluous," as Avadel contends. *See* D.I. 154 at 5. That statutory provision would still provide a proper remedy for the above-discussed conduct that was prohibited in *Caraco* and *Lantus*, and would also provide a statutory remedy for delisting the types of patents ("[p]rocess patents, patents

claiming packaging, patents claiming metabolites, and patents claiming intermediates") that the FDA regulations said "must not be submitted to FDA" for listing in the Orange Book pre-OTBA. *See* 21 C.F.R. § 314.53(b)(1); *see also Mylan Pharms. Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (holding, that pre-21 U.S.C. § 355(j)(5)(C)(ii)(I)/21 U.S.C. § 355(c)(3)(D)(ii)(I), no private cause of action existed for seeking delisting of patent claiming metabolite).

II. CONCLUSION

For these additional reasons, Avadel's partial motion for judgment on the pleadings should be denied.

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
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QUINN EMANUEL URQUHART & SULLIVAN, LLP
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