

**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-MN

**RESPONSE TO PLAINTIFF'S MOTION FOR LEAVE TO FILE SUR-REPLY**

Jazz's contention that a sur-reply is warranted because "Avadel changed the statutory foundation of its request" is wrong. More importantly, Jazz's sur-reply provides no more basis for denying Avadel's motion than any of Jazz's three prior briefs. While Avadel disputes that further briefing is necessary, it offers the following to aid the Court in resolving the motion, and respectfully requests that the Court consider it if the Court considers Jazz's sur-reply.

Avadel's counterclaim seeks "a declaration pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I) ordering Jazz to remove the '963 patent from the Orange Book." D.I. 11 at 42, ¶ 31. Avadel's opening brief stated that it sought "partial judgment on the pleadings for its *counterclaim seeking delisting*" pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I). D.I. 118 at 1, 11 (all emphasis added). Jazz was on notice that the delisting provision was the predicate for Avadel's motion as well as the substantive basis for the requested remedy. *Id.* at 1, 5-7, 9, 11; *see generally* D.I. 154. Avadel's opening brief explained how the provisions of 21 U.S.C. § 355(b)(1)(A)(viii) (requirements for Orange Book listing) and § 355(c)(3)(D)(ii)(I) (requirements for delisting) work congruously such that any patent that does not fall into the categories enumerated in § 355(b)(1)(A)(viii) may be delisted under § 355(c)(3)(D)(ii)(I)—the logical reading of the Hatch-Waxman Act. Indeed, the most sensible way to "harmonize" the listing and delisting provisions is to give proper import to the word "shall" in § 355(b)(1)(A)(viii), as the Supreme Court did in *Carciari v. Salazar*, 555 U.S. 379, 391-92 (2009), to identify an *exclusive* list of patents suitable for Orange Book listing such that patents not falling within this list are subject to delisting. D.I. 154 at 4.

Jazz's contention that the delisting statute only affords Avadel a right to "seek" delisting of an improperly-listed patent but does not "entitle" Avadel to delisting, is nonsensical. D.I. 155, Ex. A at 3. A statutory construction that grants a non-enforceable right is not logical, and "it is a venerable principle that a law will not be interpreted to produce absurd results." *KMart Corp. v.*

*Cartier, Inc.*, 486 U.S. 281, 324 n. 2 (1988) (Scalia, J., concurring in part and dissenting in part).

Finally, Jazz’s theory that “the OBTA stated for the first time what types of patents (other than those previously enumerated in the FDA regulations) ‘shall not be submitted’ for listing in the Orange Book” is flatly inconsistent with precedent. D.I. 155, Ex. A at 2. Jazz’s assertion is predicated on the notion that the delisting statute allows delisting solely of the patents that the FDA regulations said “must not be submitted to FDA” for listing in the Orange Book prior to the OBTA: “[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates.” *Id.* at 3-4 (citing 21 C.F.R. § 314.53(b)(1)). That assertion cannot be squared with Judge Stark’s decision in *Avanir* or the First Circuit’s decision in *Lantus*. In *Avanir*, the Court held that “[d]efendants are entitled to an order requiring Plaintiffs to delete the ’115 patent from the Orange Book” on the basis that it did not claim “*the drug* for which the application was approved.” D.I. 118, Ex. C at 1; *see also* Ex. D. The Court in *Lantus* refused to dismiss the Defendant’s delisting counterclaim for a patent to a drive mechanism for an injector pen, finding that “[u]nder the plain wording” of the Hatch-Waxman Act the proper listing of a patent “would require not only that it be a patent that claims *a drug*; it must be a patent that claims the drug (or method of using the drug) ‘for which the applicant submitted’ the sNDA.” *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8 (1st Cir. 2020). Both of these cases—which predate the OBTA—found the asserted patents eligible for delisting, even though they did not fall into the categories enumerated in the FDA regulation Jazz relies upon. Thus, courts already have harmonized the statutes at issue as urged by Avadel’s Reply. D.I. 154 at 6.

Although Avadel disagrees there is any basis for Jazz’s request to file a sur-reply, in the interest of expeditiously resolving this dispute, Avadel does not oppose Jazz’s motion and respectfully requests that Avadel’s delisting motion be decided as promptly as practicable.

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