

**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-GBW

ORDER AND JUDGMENT

WHEREAS, the Court has reviewed the parties' filings related to Defendant Avadel CNS Pharmaceuticals LLC's ("Avadel") renewed motion for judgment on the pleadings (the "Renewed Motion", D.I. 117) with respect to its counterclaim seeking delisting of Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"); and

WHEREAS, the Court issued a Memorandum Opinion concluding that Avadel is entitled to an Order requiring Jazz to delete the patent information from the Orange Book because the '963 patent does not claim either "the drug for which the application was approved" or "an approved method of using the drug" consistent with 21 U.S.C. § 355(c)(3)(D)(ii)(I).

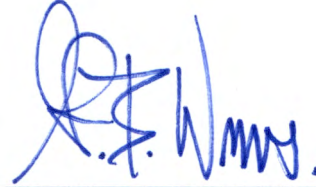
THEREFORE, IT IS HEREBY ORDERED, that Avadel's Renewed Motion is GRANTED.

IT IS FURTHER ORDERED that, within fourteen (14) days from the date of this Order, Jazz is directed by mandatory injunction under 21 U.S.C. § 355(c)(3)(D)(ii)(I) to submit to the

FDA a request enclosing this Order to delete the '963 patent from the Orange Book entry for Xyrem®;

IT IS FURTHER ORDERED AND ADJUDGED that judgment is entered in favor of Avadel and against Jazz on Count III of Avadel's Answer to Complaint for Patent Infringement, Defenses, and Counterclaims (D.I. 11).

SO ORDERED this 18th day of November, 2022.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE