UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS

DANIEL WEIBEL

Plaintiff.

Civil Action No. 1:22-cv-4518

v.

Judge Harry D. Leinenweber Magistrate Judge Gabriel A. Fuentes

HORIZON PHARMACEUTICALS, INC.,

Defendant.

HORIZON THERAPEUTICS USA, INC'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

Defendant Horizon Therapeutics USA, Inc. ("Horizon"), incorrectly named as Horizon Pharmaceuticals, Inc., hereby moves to dismiss Plaintiff's claims alleging a hearing impairment injury from his use of TEPEZZA® to treat his symptoms of Thyroid Eye Disease. Plaintiff asserts negligence and strict liability claims for failure to warn and design defect. All of Plaintiff's claims fail as preempted by federal law. Plaintiff's warning-based claims are preempted because he fails to allege facts that, if proven, would be sufficient to demonstrate that Horizon could have added desired warnings consistent with the "changes being effected" regulation, which is the only way that Horizon could have unilaterally changed the TEPEZZA® label after the FDA approved it. See 21 C.F.R. § 314.70(c)(6)(iii). Plaintiff's design defect claims are preempted because any change to TEPEZZA®'s design to conform with state tort law obligations as advocated by Plaintiff would conflict with federal law, which precludes any change in formulation absent prior FDA approval.

¹ Horizon Therapeutics USA, Inc. does not waive defenses relating to insufficiency of process and insufficiency of service of process over the proper entity by filing this Motion.

As separate grounds for dismissal, Plaintiff fails to state plausible claims for failure to warn and design defect under Arizona law, which applies to this case. Simply put, the Complaint does not allege facts sufficient to render his negligent warnings and design claims plausible under the *Twombly-Iqbal* standard. Finally, punitive damages are not allowed under Arizona law because TEPEZZA® is FDA-approved. Further grounds and support for this Motion are set forth in the attached Memorandum of Law.

Respectfully Submitted,

/s/Daniel W. McGrath

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CERTIFICATE OF SERVICE

I certify that a copy of this Motion was filed via the Court's E-Filing System and sent electronically on October 25, 2022, which will send an electronic copy to e-filers.

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