BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: Tepezza Products Liability Litigation MDL No. _____

MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407

Pursuant to 28 USC § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Plaintiff Kimberly Exton respectfully moves the Judicial Panel on Multidistrict Litigation ("Panel") for transfer and coordination for pretrial purposes of all currently filed Tepezza cases identified in the Schedule of Actions ("Actions")[1], as well as any Tepezza cases subsequently filed involving similar facts or claims ("tag-along cases"), to the United States District Court for Northern District of California before the Honorable Jon S. Tigar, or alternatively before any available judge in the Northern District of California.

Transfer and centralization of these actions is appropriate for the following reasons:

1. Tepezza is a biologic that is manufactured by Horizon Therapeutics USA, Inc. ("Horizon"). Tepezza was approved by the United States Food and Drug Administration as an "Orphan Drug" in January 2020 for the treatment of thyroid eye disease.

2. To date, Tepezza has generated nearly $5 billion in sales largely achieved through a massive direct-to-consumer and physician-directed marketing campaign.

3. Horizon's clinical trials for Tepezza revealed that the drug is capable of causing hearing impairment, including hearing loss and tinnitus.[2]

[1] Schedule of Actions is attached as Exhibit A to the accompanying Brief filed herewith.
[2] *See Weibel v. Horizon Therapeutics USA, Inc.*, Am. Compl., No. 1:22-cv-04518 (N.D. Ill. Nov. 28, 2022), Dkt. 20 at ¶47.

4. Following Tepezza's approval in 2020, Horizon immediately began to receive hundreds of Adverse Event Reports ("AERs"), detailing injuries associated with the drug, including serious permanent hearing loss and tinnitus, but Defendant did nothing with those AERs.

5. Beginning in or about the spring of 2021, medical reports and findings were published by reputable medical clinics calling the safety of the drug into question. These reports and findings all strongly support that Tepezza use can cause permanent hearing loss and tinnitus.[3]

6. Despite adverse event information obtained during Tepezza's clinical trials, the AERs received after Tepezza was approved by FDA, and the body of research and literature discussed above, Defendant has thus far failed to utilize the Changes Being Effected ("CBE") regulations, 21 C.F.R. § 314.07(c)(3), *as it is required to do. See Merck Sharp & Dohme Corp. v. Albrecht,* 139 S.Ct. 1668, 1673 (2019). Specifically, it has refused to update the Tepezza label to include a warning regarding hearing loss and/or tinnitus or to recommend initial and periodic audiological screening before, during, and following Tepezza use.

7. While Defendant continues to delay amending its label to reflect the dangers associated with Tepezza, it is likely that a label change related to hearing impairment—with or without Defendant's consent—is finally forthcoming. In Horizon's recent Form 10-K filing the company noted the following:

[3] *See e.g.*, Chern A., Gudis DA, Dagi Glass LR. *Teprotumumab and hearing loss: hear the warnings.* Orbit. 2021 Aug;40(4):355-356 (E-pub Feb. 2021); Chern A, Dagi Glass LR, Gudis DA. *Thyroid eye disease, teprotumumab, and hearing loss: an evolving role for otolaryngologists*. Otolaryngol Head Neck Surg. 2021 Dec;165(6):757-758 (E-pub Mar. 30, 2021); Highland J, Gordon S, Reddy D, Patel N. *Ototoxicity and teprotumumab.* Ann. Otol. Rhinol. Laryngol. 2022 Aug; 131(8):910-913) (E-pub Aug. 27, 2021).

> While our post-marketing studies and pharmacovigilance reporting data have shown similar rates of hearing impairment as compared to the TEPEZZA pivotal clinical trials, which is reflected in the FDA-approved label, *there have been third party reports that have purported to show higher rates of hearing impairment*. In addition, *a recent analysis of safety data* as part of our ongoing pharmacovigilance program *indicated a signal of hearing impairment events of greater severity, in limited cases, than those observed in the TEPEZZA pivotal clinical trials*. Based on this analysis, *we are discussing with the FDA potential updates to the TEPEZZA label to further characterize the range of events reported.*[4]

8. Defendant's failure to adequately warn of the potential dangers associated with Tepezza prevented the medical community and the general public from making informed decisions about prescribing and/or using Tepezza, and, as a result, it is believed that thousands of individuals suffered adverse events due to their use of Tepezza. Many of these injured individuals have filed or will file lawsuits against Defendant.

9. To date, there are 18 cases pending across at least five district courts in the country alleging that Tepezza caused permanent hearing loss and/or tinnitus.

10. The Actions and any additional tag-along actions pending against Defendant will involve similar, if not identical, questions of fact, and will involve common discovery and pretrial motion practice. Accordingly, there is the potential for inconsistent pretrial rulings if the cases are not transferred for coordinated or consolidated proceedings under 28 U.S.C. § 1407.

11. Plaintiff seeks to create an MDL with respect to Plaintiffs that have suffered hearing impairment following their use of Tepezza by centralizing all Actions in the Northern District of California along with any subsequent tag-along actions. As explained in more detail in the supporting Brief accompanying this Motion, such centralization will eliminate duplicative

[4] Horizon Therapeutics Form 10-K, p. 75 (submitted Mar. 1, 2023) (available at https://ir.horizontherapeutics.com/static-files/ecd55c43-52e4-4fca-b907-3c2bd81ad985)(emphasis added).

discovery, prevent inconsistent rulings, and conserve judicial resources.

12. The convenience of the courts, witnesses, parties, and counsel will all be served by transferring these cases to the United States District Court for Northern District of California before the Honorable Jon S. Tigar, or alternatively before any available judge in the Northern District of California. For the reasons set forth in the supporting Brief accompanying this Motion, the Northern District of California and Judge Tigar would be excellent choices to shepherd this litigation.

13. In support of this Motion, Plaintiff Kimberly Exton relies upon:

(a) the Brief describing the background of this litigation and Plaintiff's factual and legal contentions:

(b) the Schedule of Actions providing: (1) the complete name of each action involved, listing the full name of each party included; (2) the district court where each action is pending; (3) the civil action number of each action; and (4) the name of the Judge assigned to each action;

(c) a copy of all complaints (without exhibits) and docket sheets for all actions listed in the Schedule of Actions (attached as Exhibits A-1 through A-18 in the accompanying Brief);

(d) the Statement Regarding Oral Argument; and,

(e) the Proof of Service.

Dated: March 22, 2023

Respectfully submitted,

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