IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION This Document Relates to: CONSUELO EGGER, Plaintiff, vs. HORIZON THERAPEUTICS USA, INC., Defendant.	No. 23 C 3568 **MDL No. 3079** Civil Action No.: **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**

Consuelo Egger ("Plaintiff"), by and through Plaintiff's undersigned counsel, hereby submits this Complaint against Defendant and alleges as follows:

A. PRELIMINARY STATEMENT

1. This is an action for damages related to Defendant's wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of teprotumumab as Defendant's prescription drug Tepezza® (hereinafter "Tepezza").

2. Defendant manufactures, promotes, and sells Tepezza as a prescription drug that treats thyroid eye disease. Tepezza is manufactured as an infusion treatment given by physicians intravenously.

3. Tepezza injured Plaintiff by causing permanent bilateral hearing loss and tinnitus.

4. Defendant knew or should have known that Tepezza, when used as prescribed and intended, causes harmful hearing loss and other symptoms including tinnitus.

5. Numerous patient reports, including significant newly acquired reports immediately following Horizon's launch of Tepezza, scientific studies, and even Defendant's post-

marketing studies established that Tepezza causes hearing loss and tinnitus.

6. Nevertheless, Defendant failed to warn, instruct, advise, educate, or otherwise inform Tepezza users, Tepezza prescribers, or United States governmental regulators about the risk of hearing loss or tinnitus, or the need for medical and/or audiological monitoring. At all relevant times, the U.S. label for Tepezza contained no warning of permanent hearing loss or tinnitus.

7. As a proximate result Defendant's wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff's use of Tepezza.

8. Plaintiff therefore demands judgment against Defendant and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

B. PARTIES

1. PLAINTIFF

9. Plaintiff, Consuelo Egger, at all times relevant hereto, was a resident and a citizen of Imperial, California, which is located in Imperial County, California. Plaintiff suffered severe injuries as a direct result of Plaintiff's infusion of the biological product Tepezza.

10. Plaintiff was diagnosed with thyroid eye disease and/or Graves' Disease and received Tepezza infusions from Plaintiff's physician from approximately March 2022-August 2022.

11. During the relevant time periods, Plaintiff and Plaintiff's physicians were given no warning and had no knowledge of the serious risk of permanent hearing loss and/or tinnitus posed by Tepezza. As discussed more fully below, there was no warning or indication that Tepezza could, and in fact does, cause permanent hearing loss and tinnitus at the time Plaintiff used Tepezza. Nor were physicians directed to conduct base-line audiology testing prior to treatment with Tepezza or monitor hearing acuity during treatment while Plaintiff used Tepezza.

12. Subsequent to her Tepezza use, and as a result of the Tepezza infusions she received, Plaintiff now suffers from permanent hearing loss and tinnitus.

13. As a proximate result of Defendant's acts and omissions, Plaintiff suffered the injuries described above due to Plaintiff's infusions of Tepezza. Plaintiff accordingly seeks

damages associated with these injuries.

2. DEFENDANT

14. Defendant Horizon Therapeutics USA, Inc. f/k/a Horizon Pharma USA, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 1 Horizon Way, Deerfield, IL 60015.

15. Horizon Therapeutics USA, Inc. is a wholly owned subsidiary of Horizon Therapeutics PLC organized under the laws of Ireland with a principal place of business located at 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland.

16. Defendant, together with its parent company Horizon Therapeutics PLC (hereinafter collectively "Horizon") were responsible for the sales and marketing in the United States of the drug Tepezza from their US headquarters in Deerfield, Illinois.

17. Horizon held the Biologic License Application ("BLA") for Tepezza from approximately January 2020 to present.

18. At all times relevant and material hereto, Horizon was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Tepezza, in Illinois and throughout the United States.

19. Defendant was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Tepezza, and controlling the Tepezza BLA.

20. At all times alleged herein, the term Defendant shall include any and all named or un-named parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

C. JURISDICTION AND VENUE

21. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and

because there is complete diversity of citizenship between the parties.

22. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

23. Venue in this Court is proper pursuant to 28 U.S.C § 1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, Defendant is a resident of this District and Defendant is subject to personal jurisdiction in this District.

D. NATURE OF THE CASE

24. Plaintiff brings this case against Defendant for damages associated with Plaintiff's use of the biologic product, Tepezza, which was designed, manufactured, marketed, sold and/or distributed by Defendant. Specifically, Plaintiff suffered various injuries, serious physical pain, emotional distress and medical expenses as a direct result of Plaintiff's use of Tepezza.

25. At all relevant times, Defendant was in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell and/or distribute Tepezza for the treatment of thyroid eye disease.

26. Defendant's unlawful conduct with respect to Tepezza caused hundreds, if not thousands of individuals, including Plaintiff, to develop severe and permanent hearing loss and/or tinnitus.

E. RELEVANT FACTUAL BACKGROUND

A BRIEF HISTORY OF TEPEZZA

27. Thyroid eye disease ("TED") (including conditions also called Graves' eye disease, Graves' Ophthalmopathy or Graves' Orbitopathy) is a condition in which the eye muscles, eyelids, tear glands and fatty tissues behind the eye become inflamed. This can cause the eyes and eyelids to become red, swollen, and uncomfortable and the eyes can push forward looking bulging ("proptosis"). Notwithstanding Horizon's marketing materials suggesting double vision is common amongst person diagnosed with TED, that outcome is, in fact, exceedingly rare—impacting a mere three to five percent of persons impacted with TED. On information and belief, Horizon was aware of these facts at all times, but nonetheless, promoted Tepezza's use for anyone

diagnosed with TED and early treatment of disease.

28. TED is an autoimmune disease usually associated with hyperthyroidism. The exact mechanism of the disease is not fully understood.

29. The signs and symptoms of TED can vary greatly from one person to another. Eye symptoms can range from mild to severe. Initial symptoms include redness, irritation, and discomfort of the eyes and eyelids. Dry eyes and pain when moving the eyes may also occur. Eyelid retraction is also common which is when the upper eyelid is positioned too high and/or the lower eyelid too low thus exposing the eye. The most noticeable symptom can be exophthalmos or proptosis, which means that the eyes bulge or protrude outward out of the eye socket. Bulging of the eyes can cause a person to appear as if they are constantly 'staring'. Additional symptoms and signs can include blurred vision, double vision (diplopia), misalignment of the eyes (strabismus), chronic bloody eyes, white area of eye inflamed, constant, watery eyes due to the excess formation of tears, swelling near the upper and lower eyelids, an intolerance of bright lights and difficulty moving the eyeballs.

30. TED is divided into 2 stages: the "active phase," which involves a progressive worsening of symptoms and visible inflammation followed by an "inactive phase" that is characterized by no further deterioration in patients' conditions

31. In affected individuals who have underlying Graves' disease, treatment includes reversing hyperthyroidism. Some individuals with mild TED may be treated with supportive measures such as dark sunglasses to treat sensitivity to light, ointments, artificial tears, and/or prisms that are attached to glasses. Individuals with moderate-to-severe disease may receive corticosteroids, which are drugs that reduce inflammation and swelling, but do not affect diplopia and proptosis.

32. Some individuals with moderate-to-severe disease may eventually require surgery. Surgery is also used to treat individuals with severe disease. Generally, it is recommended to avoid surgery until after the active phase of the disease has ended. Surgical options include orbital decompression, motility, and lid surgery. During orbital decompression surgery, a surgeon takes out the bone between the eye socket (orbit) and the sinuses. This allows the eye to fall back into

its natural position within the eye socket. Surgical options can also help to improve bulging eyes (proptosis) and the position of the eyelids. Motility surgery involves repositioning certain muscles around the eyes to reduce or eliminate double hearing.

33. Upon approval of Tepezza, the FDA Risk Assessment and Risk Mitigation Review notes:

> Severity of TED is distinct from, but related to, disease activity. Severity of TED is best defined by functional or cosmetic impairment, which can be assessed by various criteria, such as is the Clinical Measures of Severity based on the European Group on Graves' Orbitopathy (EUGOGO) Consensus Statement. Clinical activity of TED is commonly measured by the Clinical Activity Score (CAS). Both activity and severity should be considered in the treatment of TED, as the 2 measurements are not interchangeable and don't follow a linear relationship.

34. According to the 2008 Consensus Statement of the European Group on Graves' Orbitopathy (EUGOGO) on Management of Graves' Orbitopathy, the disease is often mild and self-limiting, and probably declining in frequency, with only 3–5% of cases posing a threat to eyesight.

35. Other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED.

36. On May 6, 2013, FDA granted Orphan Drug designation for the compound. The Orphan Drug Act defines drugs used for treatment in rare diseases and conditions, with populations of patients under 200,000 people as orphan drugs, and provides a separate pathway for approval of the drug with incentives for manufacturers.

37. On March 9, 2015, FDA granted a Fast Track designation for the compound.

38. On July 29, 2016, FDA granted Breakthrough Therapy Designation for active TED.

39. On approximately July 6, 2019, Defendant submitted the original BLA for teprotumumab-trbw (BLA: 761143).

40. In January 2020 the U.S. Food and Drug Administration (FDA) approved Tepezza, the first approved drug indicated to treat TED.

41. Tepezza acts by inhibiting (or blocking) the activity of the protein insulin-like growth factor-1 ("IGF-1"), which is believed to a play as significant role in the development of

the disorder.

42. In 2021, the EUGOGO issued clinical practice guidelines for the medical management of Graves' orbitopathy, which included first and second line treatments for disease based on severity. The guidelines recommend that Tepezza be considered *only as a second-line treatment for moderate to severe and active Graves' Orbitopathy*. In making Tepezza a second-line treatment recommendation, the 2021 EUGOGO guidelines note, "although teprotumumab has become the first drug approved by the US Food and Drug Administration for the treatment of adult GO, its incorporation into routine clinical practice is currently limited by the lack of comprehensive long-term efficacy and safety data, absence of head-to-head comparison with i.v. glucocorticoids, restricted geographical availability, reimbursement (outside the US), and costs."

DEFENDANT'S FAILURE TO TEST TEPEZZA

43. According to the Tepezza label, "Teprotumumab-trbw's mechanism of action in patients with Thyroid Eye Disease has not been fully characterized. Teprotumumab-trbw binds to IGF-1R and blocks its activation and signaling." However, Defendant failed to conduct tests to determine the mechanism of action of the drug.

44. Further, the Tepezza label admits "[n]o formal pharmacodynamic studies have been conducted with teprotumumab-trbw."

45. Tepezza was submitted to FDA for approval using less than one hundred patients enrolled in clinical trials. Tepezza "was evaluated in 2 randomized, double-masked, placebo-controlled studies in 171 patients with Thyroid Eye Disease: Study 1 (NCT01868997) and Study 2 (NCT03298867)." Of those patients, "[a] total of 84 patients were randomized to Tepezza and 87 patients were randomized to placebo.

46. The label for Tepezza contains warnings for Infusion Reactions, Exacerbation of Pre-existing IBS, and Hyperglycemia.

47. Until very recently, the only warning on the label relating to hearing loss was noted in Section VI of the label (Post-Marketing Adverse Events) and included in the Clinical Trial Experience included hearing impairment occurring in 10% of Tepezza users (n=8) vs. 0 in placebo. Hearing impairment was noted to include deafness, eustachian tube dysfunction, hyperacusis,

hypoacusis, and autophony. No warning appeared in Section V of the label and the label did not indicate whether hearing loss may be permanent.

48. There is no warning in the product labeling concerning tinnitus occurring with or being caused by Tepezza use.

THE DANGERS OF TEPEZZA – POSTMARKETING INFORMATION

49. Despite study after study providing clear evidence of the dangers of Tepezza, Defendant failed to adequately investigate the threat that Tepezza poses to patients' ears and hearing or warn patients of the risk that they would suffer ear injury and permanent hearing impairment.

50. According to Defendant's 2021 Annual Report, they "delayed the start of an FDA-required post-marketing study to evaluate safety of TEPEZZA in a larger patient population and retreatment rates relative to how long patients receive the medicine." The FDA-required post-marketing study was initiated in the fourth quarter of 2021.

51. On February 22, 2022, Defendant issued a press release announcing results from a new post-marketing safety analysis of hearing events associated with Tepezza for the treatment of TED.

52. These findings were also presented at the 48th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS 2022), Feb. 12-17, in Austin, Texas.

53. Thousands of patients were included in this 19-month analysis and demonstrated approximately 10% of all cases reported to the safety database have included a hearing-related event.

54. The most frequently reported hearing event was hypoacusis (reduction in hearing), followed by tinnitus (ringing in the ears).

55. Defendant continues to represent the majority of hearing-related adverse events in the pivotal trials and post-approval have been mild to moderate and reversible.

56. In contrast to the public statements, almost immediately after the FDA approved Tepezza, patients and doctors began reporting serious complications relating to ear and permanent hearing problems in patients taking Tepezza.

1. **Adverse Events Reported to FDA**

57. As noted above, Plaintiff was treated with Tepezza between March 2022 and August 2022. Prior to completion of Plaintiff's treatment, Horizon received the following relevant adverse event reports, but took no action to seek a label change pursuant to FDA's Changes Being Effected ("CBE") regulation (21 CFR § 314.70(c)(3)):

a. May 2020 – 1 report of tinnitus;
b. June 2020 – 4 reports of tinnitus and 2 reports of hypoacusis (hearing loss);
c. July 2020 – 1 report of tinnitus and 1 report of deafness;
d. August 2020 – 5 reports of hypoacusis; 2 reports of tinnitus; 1 report of deafness; and 2 reports of bilateral deafness;
e. September 2020 – 10 reports of hypoacusis; 3 reports of tinnitus; 2 reports of deafness; 1 report of unilateral deafness; and 1 report of conductive deafness;
f. October 2020 – 1 report of hypoacusis and 3 reports of deafness;
g. November 2020 – 2 reports of hypoacusis; 2 reports of tinnitus; and 1 report of deafness; and 1 report of neurosensory deafness;
h. December 2020 – 2 reports of hypoacusis; 1 report of tinnitus; 1 report of deafness; and 1 report of neurosensory deafness;
i. January 2021 – 3 reports of hypoacusis; 1 report of tinnitus; and 1 report of deafness;
j. February 2021 – 1 report of hypoacusis;
k. March 2021 – 1 report of hypoacusis and 1 report of tinnitus;
l. April 2021 – 2 reports of deafness;
m. May 2021 – 6 reports of hypoacusis; 3 reports of tinnitus; 3 reports of deafness; 2 reports of neurosensory deafness; and 1 report of unilateral deafness;
n. June 2021 – 1 report of deafness;
o. July 2021 – 1 report of hypoacusis; 1 report of tinnitus; 2 reports of deafness;
p. August 2021 – 14 reports of hypoacusis; 5 reports of tinnitus; 6 reports of deafness; 2 reports of neurosensory deafness; 1 report of unilateral deafness;

and 1 report of conductive deafness;

q. September 2021 – 1 report of hypoacusis; 1 report of tinnitus; 2 reports of deafness; and 1 report of unilateral deafness;

r. October 2021 – 2 reports of hypoacusis; 3 reports of tinnitus; 5 reports of deafness; 1 report of neurosensory deafness; 1 report of unilateral deafness;

s. November 2021 – 17 reports of hypoacusis; 9 reports of tinnitus; 2 reports of deafness; and 2 reports of neurosensory deafness;

t. December 2021 – 2 reports of hypoacusis; 2 reports of tinnitus; 1 report of deafness; and 1 report of bilateral deafness;

u. January 2022 – 1 report of hypoacusis; 2 reports of tinnitus; and 1 report of neurosensory deafness;

v. February 2022 – 5 reports of hypoacusis; 6 reports of tinnitus; 1 report of deafness; and 1 report of deafness unilateral;

w. March 2022 – 5 reports of hypoacusis; 2 reports of tinnitus; 1 report of deafness neurosensory; 1 report of deafness bilateral; and 1 report of deafness;

x. April 2022 – 2 reports of hypoacusis; 1 report of tinnitus; 1 report of deafness neurosensory; 3 reports of deafness; 1 report of deafness unilateral; and 1 report of conductive deafness;

y. May 2022 – 12 reports of hypoacusis; 4 reports of tinnitus; 7 reports of deafness neurosensory; 2 reports of deafness bilateral; and 7 reports of deafness;

z. June 2022 – 1 report of hypoacusis; and 2 reports of tinnitus; and

aa. July 2022 – 2 reports of hypoacusis; 2 reports of deafness, and 2 reports of tinnitus;

58. Upon information and belief, many of the adverse event reports outlined in paragraph 57 contained causal attributions to Tepezza use by the reporting physicians.

59. These adverse event numbers have been reported, although based on well-established reporting principles, these numbers vastly underestimate the true number of these events occurring in Tepezza users.

2. **Reports in the Published Medical Literature**

60. The FDA has established reporting categories for post-approval changes to a drug's label. Specifically, the Changes Being Effected supplement ("CBE") (21 CFR § 314.70(c)(3)) allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA. The manufacturer may make these changes based on "Newly Acquired Information" which can include re-evaluation of prior clinical trials, post-marketing adverse event reports, and peer-reviewed literature. The manufacturer is, at all times, responsible for the content of their label and may execute a CBE to the label *with or without FDA approval.*

61. The CBE process allows for drug manufacturers to change a drug label more quickly than the sNDA process based on newly acquired information about the drug.

62. Prior to completion of Plaintiff's treatment, the peer-reviewed literature, coupled with the mounting adverse event reports, and Horizon's own clinical trial data, required Defendant to implement a CBE warning physicians and consumers of the risk of irreversible hearing loss and tinnitus. To date, Horizon has failed to utilize the CBE process to modify the label to warn of risks associated with long term hearing loss and tinnitus and/or impose a base-line testing regime to monitor patients for hearing loss.

63. The peer-reviewed literature independently establishes that Defendant possessed Newly Acquired Information sufficient to trigger its CBE obligations prior to Plaintiff's diagnosis with hearing loss and tinnitus. For example:

a. In April 2021, an e-publication of a pooled analysis *from the clinical trials* was funded and published by Horizon. Kahaly GJ, Douglas RS, Holt RJ, Sile S, and Smith TJ. *Teprotumumab for patients with active thyroid eye disease: a pooled data analysis, subgroup analyses, and off-treatment follow-up results from two randomised, double-masked, placebo-controlled, multicentre trials.* Lancet Diabetes Endocrinol 2021; 9: 360–72 (E-pub April 15, 2021). These data were available to Horizon at all times prior-to and during Plaintiff's treatment. The authors include Horizon employee Saba Sile. The article notes Horizon funded

the study and played a pivotal role in constructing the analysis plan, study design, data collection, data analysis, data interpretation, and writing of the report. The paper reported the hearing events in the clinical trials as: "[h]earing impairment events, reported as deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, or autophony, were all classified as non-serious and all patients continued in the study without event worsening. No patients discontinued treatment because of these events. One hearing event continued but improved and was lost to follow-up, while another patient with a history of loud noise-induced tinnitus continued at the time of last-post study follow-up report." In other words, the authors' reanalysis of the clinical trial data could not rule out ongoing hearing issues following discontinuation of treatment.

b. In October 2021, Douglas et al., published a follow-up open-label extension clinical trial report of the OPTIC-X study. Douglas RS, Kahaly, GJ, Ugradar S, Elflein H, Ponto KA, Fowler BT, Dailey R, Harris, GJ, Schiffman J, Tang R, Wester S, Patel Jain A, Marcocci C, Marinò M, Antonelli A, Eckstein A, Führer-Sakel D., Salvi M, Sile S, Francis-Sedlak M, Holt RJ, Smith TJ. *Teprotumumab efficacy, safety, and durability in longer-duration thyroid eye disease and re-treatment: OPTIC-X*. Ophthalmology 2022;129:438-449 (E-pub Oct 2021). As with the April 2021 publication all of the data from the study existed prior to Plaintiff's treatment and/or discontinuation of use. The authors include three Horizon employees: Saba Sile, Megan Francis-Sedlak, and Robert J. Holt. The authors reported four patients experiencing hearing loss or tinnitus, *one of which continued through the last visit*. On information and belief, Horizon failed to conduct any additional follow-on investigation for the patient with ongoing hearing loss at the time of the clinical trials and failed to propose a CBE in light of this newly acquired information.

c. Teprotumumab (Tepezza) is an insulin-like growth factor I receptor (IGF-IR) inhibitor. Upon information and belief, it was known at the time of development

of Tepezza that it was an IGF-IR inhibitor.

d. It has been known since the early 2000s that IGF-1 is associated with mammalian hearing and deficiencies result in hearing loss. Upon information and belief, it was well known in the medical literature that IGF-1 plays a central role in hearing and low levels of IGF-I had been shown to correlate with human syndromes associated with hearing loss. *See e.g.,* Murillo-Custa, S et al., *The role of insulin-like growth factor-I in the pathophysiology of hearing*. Front. Mol. Neurosci. 2011; 4:11; Varela-Nieto I, Murillo-Cuesta S, Rodriguez de la Rosa L, Lassatetta L, Contreras J. *IGF-1 deficiency and hearing loss: molecular clues and clinical implications*. Pediatr. Endocrinol. Rev. 2013 Jul; 10(4): 460-72; Varela-Nieto I, Morales-Garcia JA, Vigil P, Diaz-Casares A, Gorospe, I, Sanchez-Galiano S, Canon S, Camarero G, Contreras J, Cediel R, Leon Y. *Trophic effects of insulin-like growth factor-I (IGF-I) in the inner ear*. Hear Res. 2004 Oct; 196 (102):19-25; Cediel R, Riquelme R, Contreras J, Diaz A, Varela-Nieto I. *Sensorineural hearing loss in insulin-like growth factor I-null mice: a new model of human deafness*. Eur J. Neurosci. 2006 Jan; 23(2): 587-90.

e. Inhibition of IGF-1R is a mechanism for teprotumumab-induced ototoxicity has been reported in the medical literature. *See e.g.* Winn BJ, Kersten RC. *Teprotumumab: interpreting the clinical trials in the context of thyroid eye disease pathogenesis and current therapies*. Ophthalmology. 2021 Nov; 128 (11): 16-27-1651 (E-pub April 28, 2021); Teo HM, Smith TJ, Joseph SS. *Efficacy and safety of teprotumumab in thyroid eye disease*. Ther. Clin. Risk. Manag. 2021 Nov 25; 17: 1219-1230; 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; Girnita L, Smith TJ, Janssen JAML. *It takes two to tango: IGF-I and TSH receptors in thyroid eye disease*. J. Clin. Endocrinol. Metab. 2022 Aug 8;

107(Supplement _1):S1-S12.

f. In August 2021, Chern et al. published an editorial article noting a relationship between IGF-1 R inhibition and hearing loss and recommending clinicians prescribing teprotumumab consider monitoring patients in conjunction with an audiologist and otolaryngologist. Chern A., Gudis DA, Dagi Glass LR. *Teprotumumab and hearing loss: hear the warnings*. Orbit. 2021 Aug;40(4):355-356 (E-pub February 2021).

g. In August 2021, Highland et al. published an article titled *Ototoxicity and teprotumumab* reporting a case of a 61-year-old female with "one of the first descriptive cases of ototoxicity resulting in irreversible sensorineural hearing loss in the setting of treatment with teprotumumab." The authors suggested audiologic evaluations should be recommended to patients on teprotumumab. 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).

h. In September 2021, Yu et al. reported a case series of 2 cases of subjective and objective hearing function changes associated with teprotumumab treatment for thyroid eye disease, including hearing loss and tinnitus. The authors noted that the potential for a risk of long-term irreversible hearing loss may exist. Yu CY, Correa T, Simmons BA, Hansen MR, Shriver EM. *Audiology findings in patients with teprotumumab associated otologic symptoms*. Am J. Ophthalmol Case Rep. 2021 Sep 16;24:101202 (E-pub September 16, 2021).

i. Chern et al. also published an article in December 2021 stating, "clinicians who prescribe teprotumumab should strongly consider monitoring patients' hearing with an audiologist and otolaryngologist." 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).

64. These data, coupled with the fact that IGF-1Rs are well known to adversely impact cochlear development and maintenance triggered Horizon's obligation to implement a CBE to warn of the risks of long-term hearing loss and tinnitus. To date, Horizon has yet to execute a CBE warning patients and their doctors of ongoing hearing loss and tinnitus following discontinuation of use and/or completion of treatment.

65. Beyond the information set forth above, there is mounting evidence in the peer-reviewed literature establishing that long-term hearing loss can occur following discontinuation of Tepezza treatments.

66. In February 2022, another case report was published noting that while hearing loss was noted as a side effect in clinical trials, no formal audiometric investigations of these patients were reported and the manufacturer offered no formal guidelines for audiometric monitoring. The authors conclude that given guidelines exist for other known ototoxic medications, they encouraged similar audiometric monitoring for patients undergoing treatment with Tepezza. Ding AS, Mahoney NR, Campbell AA, Creighton FX. *Sensorineural hearing loss after teprotumumab therapy for thyroid eye disease: a case report.* Otol Neurotol. 2022 Feb 1;43(2):e148-e152.

67. In February 2022, Sears et al. reported on a prospective observational case series. In this series, twenty-seven patients were analyzed (24 females, 3 males, average 56.3 years old). Twenty-two patients (81.5%) developed new subjective otologic symptoms. The results revealed three of the five patients with teprotumumab-related hearing loss had persistent subjective hearing loss at last follow-up. The authors also concluded screening, monitoring, and prevention guidelines are needed for clinicians. Sears CM, Azad AD, Amarikwa L, Pham BH, Men CJ, Kaplan DN, Liu J, Hoffman AR, Swanson A, Alyono J, Lee JY, Dosiou C, Kossler AL. *Hearing dysfunction after treatment with teprotumumab for thyroid eye disease.* Am J Ophthalmol. 2022 Aug;240:1-13 (E-pub Feb 25, 2022).

68. In March 2022 the e-publication of an Expert Consensus on the use of teprotumumab was released. Douglas RS, Kossler AL, Abrams J, Briceño,CA, Gay D, Harrison A, Lee M, Nguyen J, Joseph SS, Schlachter D, Tan J, Lynch J, Oliver L, Perry R, Ugradaron, S.

Expert consensus on the use of teprotumumab for the management of thyroid eye disease using a modified-Delphi approach. J Neuro-Ophthalmol 2022; 42: 334-339 (E-pub March 24, 2022). The authors reported the results of three rounds of surveys taken between October 2020 and February 2021. Nine of the fifteen authors reported being consultants, speakers or owners of Defendant in the publication. The consensus recommendations include: 1) a medical history including history of hearing loss *must be* completed before initiation of treatment (emphasis in original) because conditions can worsen during treatment; and 2) baseline audiogram and patulous eustachian tube testing *may be* conducted before the initiation of treatment with teprotumumab to ensure patients undergo minimal adverse events (emphasis in original); and 3) hearing impairment adverse effects *should be* discussed with patients before initiating treatment (emphasis in original).

69. In April 2022 Chow and Silkiss published a case report of a woman in her 50s who developed tinnitus after the third dose, followed by frank hearing loss after the fifth dose. Repeat audiogram six weeks later showed no improvement in the hearing loss. The authors concluded "[g]iven potentially irreversible sensorineural hearing loss, we recommend close monitoring with regular audiometric testing before, during and after teprotumumab therapy and propose potential treatment to reverse its effects in the ear." Chow A, Silkiss RZ. *Teprotumumab-associated chronic hearing loss screening and proposed treatments*. BMJ Case Rep. 2022 Apr 13;15(4):e248335.

70. In April 2022, an additional case report of a woman with tinnitus and hearing loss was published by Najjar and Yu. The woman reporting tinnitus after the second infusion and hearing loss by the fifth infusion. Audiograms after discontinuation revealed no improvement. The authors recommend a new prospective clinical trial should be performed with comprehensive pretreatment audiologic testing and ongoing audiologic monitoring. Najjar W, Yu J. *Audiologic demonstration of ototoxicity from teprotumumab treatment in a patient with thyroid eye disease*. OTO Open. 2022 Apr 29;6(2):2473974X221097097.

71. In July 2022, Bartalena, Marino, Marcocci, and Tanda continued the publication of reports in an article titled *Teprotumumab for Graves' orbitopathy and ototoxicity: moving problems from eyes to ears?* Bartalena L, Marino M, Marcocci C, and Tanda ML. *Teprotumumab for Graves' orbitopathy and ototoxicity: moving problems from eyes to ears?* J. Endocrinol. Invest.

2022 Jul; 45(7): 1455-1457 (E-pub April 11, 2022).

72. Against this backdrop of data linking hearing impairment to Tepezza use, Defendant, in its March 2023 10k Statement, admitted the following:

> 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.*

73. In fact, in July 2023 Defendant added the following Warning to its labeling for Tepezza:

> 5.4 Hearing Impairment Including Hearing Loss
>
> TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients.

74. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that Tepezza causes, is linked to, and is associated with permanent hearing loss and/or tinnitus.

75. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that patients receiving Tepezza should undergo regular audiological testing to detect hearing loss.

76. At all relevant times, the labeling for Tepezza failed to provide adequate warnings and instructions, failed to caution that patients should be closely monitored, failed to adequately inform patients and physicians that permanent hearing loss and/or tinnitus is associated with Tepezza use.

77. At all relevant times, Defendant also failed to alert patients to the need for audiological monitoring while receiving Tepezza or whether risks for hearing related injuries increase with higher doses or longer durations.

78. The American Speech-Language-Hearing Association 2020 guidelines—available to Horizon prior to completion of Plaintiff's treatment—also suggest that baseline audiological monitoring should occur when using ototoxic medications. Specifically, the guidelines state:

> When possible, the baseline record should include (1) an audiologic hearing test focused on your ability to hear very high-pitched sounds; (2) word recognition tests; and (3) other tests. This information can help you and your doctor make any important decisions to stop or change the medication therapy before your hearing is affected.

79. As noted above, FDA has established reporting categories for post-approval changes to a drug's label. The Changes Being Effected supplement ("CBE") (21 CFR § 314.70(c)(3)) allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA. The CBE process allows for drug manufacturers to change a drug label more quickly than the sNDA process based on newly acquired information about the drug.

80. Defendant should have changed the Tepezza label to include warnings and instructions addressing the risk of injury associated with the drug as soon as they had notice of adverse reports relating to the same. As noted above, Horizon possessed this newly acquired information prior to Plaintiff completing treatment with Tepezza. In fact, a reanalysis of the clinical trial data—*by Horizon employees*—reported in 2022, "One hearing event continued but improved and was lost to follow-up, while another patient with a history of loud noise-induced tinnitus continued at the time of last-post study follow-up report." *Infra* at ¶ 63(a). Despite this knowledge of ongoing hearing loss following discontinuation of use, Horizon failed to file a CBE alerting patients and physicians of the risk of on-going (permanent) hearing loss following discontinuation of use.

81. By failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians, of the risk of permanent hearing loss associated with using Tepezza, Defendant acted in a gross and flagrant character, evincing reckless disregard of human life, and of the safety of persons exposed to its dangerous drug.

82. Additionally, by failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians, of the risk of permanent hearing loss and/or tinnitus associated with using Tepezza, Defendant showed wantonness, recklessness, or a grossly careless disregard for the public's safety and welfare.

HORIZON'S AGGRESSIVE MARKETING CAMPAIGN FOR TEPEZZA

83. As noted above, less than 5% of all persons with TED suffer *any* form of vision impairment. In this sense, Tepezza was, and is, a drug in search of a disease given more than 95% of all users will experience *no benefit* related to vision impairment. As a drug in search of a disease, Horizon launched an aggressive marketing campaign to fuel sales in an effort to build its' block-buster drug. For example, according to Horizon's 2021 Annual report, "Our comprehensive post-launch commercial strategy for TEPEZZA aims to enable more TED patients to benefit from TEPEZZA. We are doing this by: (i) facilitating continued TEPEZZA uptake in the treatment of TED through continued promotion of TEPEZZA to treating physicians; (ii) continuing to develop the TED market by increasing physician awareness of the disease severity and the urgency to diagnose and treat it, as well as the benefits of treatment with TEPEZZA; (iii) driving accelerated disease identification and time to treatment through our digital and broadcast marketing campaigns; (iv) enhancing the patient journey with our high-touch, patient-centric model as well as support for the patient and site-of-care referral processes; and (v) pursuing more timely access to TEPEZZA for TED patients."

84. Similarly, Horizon's 2021 Annual Report noted, "It bears repeating: 2021 was a record-breaking year for Horizon. Full-year 2021 net sales were $3.23 billion, representing year-over-year growth of 47 percent, and our full-year 2021 adjusted EBITDA was $1.28 billion, representing year-over-year growth of 33 percent. Driving much of this growth was TEPEZZA®, which boasted one of the most successful rare disease medicine launches in history, and had full-year 2021 net sales of $1.66 billion, representing year-over-year growth of 103 percent."

85. Additionally, in the wake of the Global COVID pandemic, Horizon launched an aggressive campaign to convert physician use. On May 14, 2021, PM360 reported the following:

> Within three months of its launch, 95% of target physicians were aware of the brand and more than 65% said they were highly likely to prescribe TEPEZZA. Due to COVID, the team also had to find ways to reach HCPs without an in-person sales force. **The team developed a booth (TEPEZZAexperience.com) for virtual medical congresses that allows visitors to take a quiz about TED, tour the TEPEZZA data, hear real patient stories, and connect with a Horizon representative.** In just the month of November, the booth received over 2,800 visits and over 550 unique HCP engagements.
>
> As TEPEZZA is an infusion medication and the core prescriber base did not have infusion experience, a new field team was also developed to build a site of care network. The marketing team developed customized materials for the infusion center clinical and administrative staff to support rapid uptake at launch.

See *https://www.pm360online.com/elite-2021-marketing-team-tepezza-marketing-team/* (last visited November 16, 2022) (emphasis in original).

86. On information and belief, this aggressive marketing campaign drove, in part, the astonishing sales associated with Tepezza.

87. But that was not all. At the same time, Horizon launched a massive Direct to Consumer campaign whose sole purpose was to build brand awareness and promote sales. Specifically, PM360 reported:

> On the patient front, the team launched a DTC campaign that spotlighted the extremely challenging symptoms of TED that cannot be ignored. Within a month, TEPEZZA achieved 82% aided awareness among patients, an increase of 68% prior to the campaign. Combined communication efforts also drove 157K unique visitors to TreatTED.com, a page created for the TEPEZZA.com website.

88. The DTC campaign included the development of websites masquerading as support-groups for persons suffering from TED, promotion of the drug in Grave's Disease websites, the creation of "more than 1,000 infusion centers," and a massive unbranded and branded televised DTC advertisement campaign directed towards consumers. *See generally*https://www.fiercepharma.com/marketing/horizon-uses-eye-catching-animation-for-ted-ads (last visited November 16, 2022).

89. At the time of approval, a spokesperson for the company said teprotumumab will cost $14,900 per vial, with full treatment over 6 months approximately 23 vials, and that the wholesale acquisition cost for that amount is $343,000, with an annual net realized price of

$200,000. As a result, the cost of a course of treatment of the drug is hundreds of thousands of dollars per patient.

90. As a direct result of these efforts annual sales of Tepezza soared. According to Horizon's April 28, 2022 Proxy Statement, the company's "excellence in commercial execution" continued for this dangerous drug, evidenced by "more than doubl[ing] the full-year net sales of TEPEZZA … to $1.7 billion in its second year post-launch, representing impressive growth of 103 percent."

91. In that 2022 Proxy Statement, Horizon continued to tout its "initiatives to drive increased awareness of TEPEZZA and TED…" and reported that it has "generated cumulative net sales of $2.5 billion, despite the negative impact of the COVID-19 pandemic, representing exceptional value creation for our shareholders" and sees "opportunities for continued growth for TEPEZZA, projecting peak global annual net sales of more than $3.5 billion."

92. Yahoo Finance recently reported that Horizon's anticipated 2022 sales will likely exceed $3.6 billion. In short, Horizon's collective marketing efforts worked, resulting in nearly $6 billion in sales in less than three years.

DEFENDANT HAD A DUTY TO PROTECT U.S. CONSUMERS, BUT DID NOT

93. At all relevant times, Defendant had a duty to craft an adequate label with respect to Tepezza.

94. At all relevant times, Defendant had a duty to ensure that the warnings in the Tepezza label were adequate for as long as the drug remained available for sale in the United States.

95. At all relevant times, Defendant had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Tepezza, after the Tepezza BLA was approved, for as long as the drug remained available for sale in the United States.

96. At all relevant times, Defendant had a duty to revise the Tepezza label to include a warning regarding the risk of serious hearing-related injuries as soon as there was reasonable evidence of a causal association between hearing-related injuries and Tepezza use.

97. Upon information and belief, despite understanding Tepezza could cause hearing-related injuries, Defendant knowingly withheld and/or misrepresented information required to be submitted under FDA BLA regulations, concerning the safety and efficacy of Tepezza, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Tepezza users suffering hearing-related injuries as a result of their Tepezza use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious hearing-related injuries as a result of taking Tepezza.

DEFENDANT'S MISCONDUCT ENDANGERED PLAINTIFF AND OTHER U.S. CONSUMERS

98. Had Defendant exercised reasonable care in testing and studying Tepezza, they would have discovered prior to seeking FDA approval, that Tepezza use can cause serious and irreversible hearing loss and/or tinnitus.

99. Despite post-approval adverse event reports and other clinical evidence, Defendant failed to continue to test and study the safety and efficacy of Tepezza.

100. From the date Defendant received FDA approval to market Tepezza in the United States, Defendant made, distributed, marketed, and sold Tepezza without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Tepezza was associated with and/or could cause serious hearing loss and/or tinnitus in patients who used it, and that all Defendant had not adequately conducted complete and proper testing and studies of Tepezza with regard to hearing loss and/or tinnitus.

101. Defendant concealed and/or failed to completely disclose their knowledge that Tepezza was associated with and/or could cause hearing loss and/or tinnitus as well as their knowledge that they had failed to fully test or study said risk.

102. Defendant ignored the association between the use of Tepezza and the risk of developing permanent hearing loss and tinnitus.

103. Defendant failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of hearing damage with Tepezza.

104. Defendant failed to provide adequate instructions to U.S. healthcare

professionals and patients regarding how to safely monitor and identify signs of potentially serious audiological complications associated with Tepezza infusions.

105. Defendant failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious hearing complications associated with Tepezza infusions.

106. Defendant failed to warn and/or to provide adequate instructions to U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop receiving Tepezza in the event that potentially serious hearing complications developed while using Tepezza.

107. Defendant failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of auditory damage to patients receiving Tepezza as to compared to other similarly efficacious pharmaceutical products.

108. Defendant's failures to provide adequate instructions and/or disclose information—which Defendant possessed regarding the failure to adequately test and study Tepezza for the risk of serious hearing complications—further, rendered the Tepezza Package Insert, and other educational and/or promotional materials inadequate.

109. Despite adverse event reports from healthcare professionals and consumers around the world, Defendant never adequately warned of the risk of serious and irreversible hearing loss, including, but not limited to, hearing loss and tinnitus, associated with Tepezza.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

110. Defendant willfully, wantonly and intentionally withheld information from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, Tepezza.

111. Defendant willfully, wantonly withheld safety-related warnings from Plaintiff, Plaintiff's family members, and the general public concerning the known hazards associated with the use of, and exposure to, Tepezza.

112. Defendant willfully, wantonly withheld instructions from Plaintiff, Plaintiff's family members, and the general public concerning how to identify, mitigate, and/or treat known

hazards associated with the use of, and exposure to, Tepezza.

113. Defendant willfully, wantonly ignored relevant safety concerns and deliberately did not properly study the safety and efficacy of Tepezza.

114. Defendant failed to disclose a known defect and, instead, affirmatively misrepresented that Tepezza was safe for its intended use. Defendant disseminated labeling, marketing, promotion and/or sales information to Plaintiff, Plaintiff's healthcare providers, and the general public regarding the safety of Tepezza knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with Tepezza use. It did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Tepezza's safety.

115. Further, Defendant actively concealed the true risks associated with the use of Tepezza, particularly as they relate to the risk of serious hearing-related injuries, by affirmatively representing in numerous communications that there were no hearing loss warnings required to safely prescribe and take Tepezza and no permanent hearing-related adverse side effects associated with use of Tepezza. These communications were disseminated to Plaintiff, Plaintiff's healthcare providers, and the general public and included, without limitation, the Package Insert.

116. Due to the absence of any warning by Defendant as to the significant permanent health and safety risks posed by Tepezza, Plaintiff and her prescribing physician were unaware that Tepezza could cause serious hearing-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

117. Due to the absence of any instructions for how to identify and/or monitor Tepezza patients for potential hearing-related complications, Plaintiff and her prescribing physician were unaware that Tepezza could cause serious hearing-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

118. Given Defendant's conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public with respect to the safety and efficacy of Tepezza, Defendant is estopped from relying on any statute of limitations defenses.

COUNT ONE: STRICT LIABILITY – FAILURE TO WARN

119. Plaintiff incorporates the factual allegations set forth above as if fully set forth herein and further alleges as follows:

120. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Tepezza and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

121. Defendant, as a manufacturer and distributer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Tepezza were inadequate.

122. Plaintiff did not have the same knowledge as Defendant, and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

123. Defendant had a duty to provide adequate warnings and instructions for Tepezza, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their product.

124. Defendant had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Tepezza as it became or could have become available to Defendant.

125. Defendant marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Tepezza, to health care providers empowered to prescribe and dispense Tepezza to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendant misled the medical community about the risk and benefit balance of Tepezza, which resulted in injury to Plaintiff.

126. Defendant knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, and their own post-marketing studies, that Tepezza created a risk of serious and potentially irreversible hearing issues, and/or could interfere with normal hearing.

127. Despite the fact that Defendant knew or should have known that Tepezza caused unreasonable and dangerous side effects, they continued to promote and market Tepezza without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

128. Defendant knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendant's failures.

129. The Tepezza supplied to Plaintiff by Defendant was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendant also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Tepezza. Despite this knowledge and information, Defendant failed and neglected to issue adequate warnings that Tepezza causes serious and potentially irreversible hearing issues and/or instructions concerning the need for audiological monitoring and potential discontinuation of use of Tepezza.

130. Defendant's failure to provide adequate warnings or instructions rendered Tepezza unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by Defendant, and in that the risk of danger outweighs the benefits.

131. Defendant failed to provide timely and adequate warnings to physicians, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the following ways:

a. Defendant failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Tepezza including, among other things, potentially irreversible hearing issues;

b. Defendant failed to provide adequate post-marketing warnings and

instructions after Defendant knew or should have known of the significant risks of, among other things, potentially irreversible hearing issues; and

c. Defendant continued to aggressively promote and sell Tepezza, even after they knew or should have known of the unreasonable risks of potentially irreversible hearing issues from the drug.

132. Defendant had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Tepezza, and/or that there existed safer and more or equally effective alternative drug products.

133. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Tepezza, and/or that there existed safer and more or equally effective alternative drug products, Defendant breached their duty of reasonable care and safety.

134. By failing to adequately test and research harms associated with Tepezza, and by failing to provide appropriate warnings and instructions about Tepezza use, patients and the medical community, including Plaintiff and Plaintiff's prescribing doctors, were inadequately informed about the true risk-benefit profile of Tepezza and were not sufficiently aware that serious and potentially irreversible hearing issues might be associated with use of Tepezza. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially irreversible hearing issues might be a side effect of Tepezza and should or could be reported as an adverse event.

135. The Tepezza designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendant knew or should have known of the risks and severe and permanent hearing injuries from receiving Tepezza, they failed to provide adequate warnings to users or consumers of the product and continued to improperly advertise, market and/or promote Tepezza.

136. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendant had exercised all possible care in its preparation and sale.

137. The foreseeable risk of serious and potentially irreversible hearing issues caused by Tepezza could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers had Defendant provided reasonable instructions or warnings of these foreseeable risks of harm.

138. Defendant's actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

139. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Tepezza, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount which will compensate Plaintiff for Plaintiff's injuries.

COUNT TWO: STRICT LIABILITY – DESIGN DEFECT

140. Plaintiff incorporates the factual allegations set forth above as if fully set forth herein and further alleges as follows:

141. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Tepezza, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

142. Defendant, as a manufacturer, designer, distributer, marketer, and promoter of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

143. Defendant breached this duty by designing Tepezza in such a way that posed an unreasonable risk of permanent hearing injuries and by placing and keeping Tepezza on the market despite in a defective condition.

144. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended, and foreseeable use. Defendant knew or should have known that the Tepezza they developed, manufactured, labeled, marketed, sold, and/or promoted was defectively designed in that it posed a serious risk of severe and permanent hearing injuries.

145. Defendant had a continuing duty to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor their product.

146. Defendant breached that duty when they created a product unreasonably dangerous for its intended and foreseeable use.

147. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendant are therefore strictly liable for the injuries sustained by Plaintiff.

148. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and a defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant, posing a risk of serious and potentially irreversible hearing damage to Plaintiff and other consumers.

149. The Tepezza ingested by Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

150. The Tepezza ingested by Plaintiff was in a condition not contemplated by Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent hearing loss.

151. Tepezza is a medication prescribed primarily for TED.

152. Tepezza in fact causes serious and potentially irreversible hearing issues, and/or could interfere with the normal health and hearing, harming Plaintiff and other consumers.

153. Plaintiff, ordinary consumers, and prescribers would not expect a TED drug designed, marketed, and labeled for eye disease treatment to cause irreversible hearing loss.

154. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible hearing issues to Plaintiff and other consumers.

155. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation in that its limited and unproven effectiveness and low efficacy did not outweigh the risks of serious and potentially irreversible hearing issues posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of the Tepezza drug makes the product unreasonably dangerous.

156. The design defects render Tepezza more dangerous than other drugs and therapies designed to treat TED and causes an unreasonable increased risk of injury, including but not limited to potentially irreversible hearing loss.

157. Defendant knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, their own post-marketing studies, or otherwise, that Tepezza created a risk of serious and potentially irreversible hearing loss and/or could interfere with the normal health and hearing.

158. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Tepezza use could result in permanent hearing loss, Defendant failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on hearing, the potential effects and risks of long-term use, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

159. Defendant knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Tepezza's defective design.

160. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendant had exercised all possible care in the preparation and sale of Tepezza.

161. Defendant's actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

162. As a direct and proximate result of Defendant's conduct, including the lack of adequate testing and research and the defective and dangerous nature of Tepezza, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount which will compensate Plaintiff for Plaintiff's injuries.

COUNT THREE: NEGLIGENCE

163. Plaintiff incorporates the factual allegations set forth above as if fully set forth herein and further alleges as follows:

164. At all times material herein, Defendant had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, development, testing, and post-sale warnings to assure the safety of Tepezza when used as intended or in a way that Defendant could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Tepezza.

165. Defendant's duty of care was that a reasonably careful designer, manufacturer, seller, importer, distributor and/or supplier would use under like circumstances.

166. Defendant had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Tepezza's dangers and serious side effects, including serious and potentially irreversible hearing loss, as it was reasonably foreseeable to Defendant that Tepezza could cause such injuries.

167. At all times material herein, Defendant failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Tepezza had inadequate instructions and/or warnings.

168. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendant, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

a. Failing to accompany their product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Tepezza and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;

b. Disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

d. Failing to adequately test and/or warn about the use of Tepezza, including, without limitations, the possible adverse side effects and health risks caused by the use of Tepezza;

e. Failure to adequately warn of the risks that Tepezza could interfere with the normal health and hearing;

f. Failure to adequately warn of the risk of serious and potentially irreversible hearing loss and tinnitus;

g. Failure to adequately warn and advise of adverse reactions involving hearing, tinnitus, and other audiologic symptoms;

h. Failure to instruct patients, prescribers, and consumers of the need for audiological monitoring when receiving Tepezza;

i. Failing to provide instructions on ways to safely use Tepezza to avoid injury;

j. Failing to explain the mechanism, mode, and types of adverse events associated with Tepezza;

k. Failing to provide adequate training or information to medical care providers for appropriate use of Tepezza and patients receiving Tepezza; and

l. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

m. Failing to use due care in developing, testing, designing, and manufacturing Tepezza so as to avoid the aforementioned risks to individuals when Tepezza was being used for treatment;

n. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Tepezza; and

o. Designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff.

169. Tepezza was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks associated with Tepezza, including but not limited to the risk of serious and potentially irreversible hearing loss and tinnitus despite Defendant's knowledge of the risk of these injuries over other TED therapies available.

170. Tepezza was defective due to inadequate post-marketing warnings and instruction because Defendant knew or should have known of the risk and danger of serious bodily harm from the use of Tepezza but failed to provide an adequate warning to patients and prescribing physicians of the product, including Plaintiff and Plaintiff's prescribing physician, knowing the product could cause serious injury.

171. Plaintiff was prescribed and used Tepezza for its intended purpose.

172. Plaintiff could not have known about the dangers and hazards presented by Tepezza.

173. The warnings given by Defendant were not accurate, clear, or complete and/or were ambiguous.

174. The warnings, or lack thereof, that were given by Defendant failed to properly warn prescribing physicians, including Plaintiff's prescribing physician, of the risk of serious and potentially irreversible hearing loss and tinnitus, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

175. The warnings that were given by Defendant failed to properly warn Plaintiff and prescribing physicians of the prevalence of permanent hearing loss.

176. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendant. Defendant had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Tepezza. Had Plaintiff received adequate warnings regarding the risks of Tepezza, Plaintiff would not have used Tepezza.

177. Defendant's failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Tepezza was a proximate cause of Plaintiff's injuries and damages.

178. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

179. As a direct and proximate result of Defendant's negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount which will compensate Plaintiff's injuries.

COUNT FOUR: PUNITIVE DAMAGES

180. Plaintiff incorporates the factual allegations set forth above as if fully set forth herein and further alleges as follows:

181. The acts and omissions of Defendant described herein consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendant's officers, directors, and/or managing agents.

182. Defendant actions amounted to actual malice or reckless indifference to the likelihood of harm associated with their acts and omissions.

183. Defendant misled both the medical community and the public, including Plaintiff and Plaintiff's physicians, by making false representations about the safety and effectiveness of Tepezza and by failing to provide adequate instructions and training concerning its use.

184. Defendant downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Tepezza despite available information demonstrating that drug could interfere with the normal health and hearing and cause potentially irreversible hearing loss and tinnitus.

185. Defendant were or should have been in possession of evidence demonstrating that Tepezza use could interfere with the normal health and hearing; cause irreversible damage to hearing; and cause tinnitus. Nevertheless, Defendant continued to market Tepezza by providing false and misleading information with regard to its safety and effectiveness.

186. Defendant failed to provide warnings that would have dissuaded health care professionals from using Tepezza, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Tepezza.

187. As a proximate result of Defendant's acts and omissions, Plaintiff suffers from hearing loss, tinnitus and other auditory symptoms resulting from Plaintiff's receiving Tepezza.

188. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering, has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

189. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured.

190. Defendant's actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

191. Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

192. Defendant's conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

193. Consequently, Defendant is liable for punitive damages in an amount to be determined by the jury.

DAMAGES

194. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Exemplary and Punitive Damages;

h. Reasonable and necessary attorneys' fees, costs, pre-judgement interest; and

i. Such other relief to which Plaintiff may be justly entitled

WHEREFORE, Plaintiff demands judgment of and from Defendant in an amount for compensatory damages against Defendant for pain and suffering actual damages; consequential damages; exemplary damages, interest on damages (pre- and post-judgment) in accordance with the law; Plaintiff's reasonable attorney's fees, as well as costs of court and all other costs incurred; and such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Respectfully submitted,

Dated: 10/25/2023

/s/ Brandon L. Bogle
Brandon L. Bogle, Esq. FL Bar #52624
Levin, Papantonio, Rafferty, Proctor,
Buchanan, O'Brien, Barr & Mougey, P.A.
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Attorney for Plaintiff

ILND 44 (Rev. 08/23)

CIVIL COVER SHEET

The ILND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(See instructions on next page of this form.)*

I. (a) PLAINTIFFS
CONSUELO EGGER

(b) County of Residence of First Listed Plaintiff Imperial County, CA
(Except in U.S. plaintiff cases)

(c) Attorneys *(firm name, address, and telephone number)*
Brandon L. Bogle, Esquire; Levin Papantonio Rafferty; 316 South Baylen Street, Suite 600, Pensacola, FL 32502; 850-435-7043

DEFENDANTS
HORIZON THERAPEUTICS USA, INC.

County of Residence of First Listed Defendant Lake County, IL
(In U.S. plaintiff cases only)
Note: In land condemnation cases, use the location of the tract of land involved.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Check one box, only.)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government not a party.)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate citizenship of parties in Item III.)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(For Diversity Cases Only.)*

(Check one box, only for plaintiff and one box for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business in This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Check one box, only.)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excludes Veterans)
- ☐ 153 Recovery of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

PROPERTY RIGHTS
- ☐ 820 Copyright
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729 (a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Arts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 445 Amer. w/ Disabilities-Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus – Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAXES
- ☐ 870 Taxes (U.S. Plaintiff or Defendant
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Check one box, only.)*

- ☐ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 USC 1332 Diversity Product Liability Action Tepezza

VII. PREVIOUS BANKRUPTCY MATTERS

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

VIII. REQUESTED IN COMPLAINT:

☐ Check if this is a **class action** under Rule 23, F.R.CV.P.

Demand $

CHECK Yes only if demanded in complaint:
Jury Demand: ☒ Yes ☐ No

IX. RELATED CASE(S) IF ANY *(See instructions):*

Judge Thomas M. Durkin

Case Number MDL 3079, No. 23 C 3568

X. Is this a previously dismissed or remanded case?

☐ Yes ☐ No **If yes, Case #** **Name of Judge**

Date: 10/25/2023

Signature of Attorney of Record /s/ Brandon L. Bogle

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority for Civil Cover Sheet

The ILND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use
(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the
(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.