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

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	No. 1:23−cv−03568 MDL No. 3079
This Document Relates to: No. 1:23-cv-02659 (*Stern*) No. 1:23-cv-02703 (*Ford*) No. 1:23-cv-03033 (*Chryssos*) No. 1:23-cv-03585 (*Meyers*) No. 1:23-cv-15306 (*Egger*)	Judge Thomas M. Durkin Magistrate Judge M. David Weisman

DEFENDANT HORIZON THERAPEUTICS USA, INC.'S MEMORANDUM IN SUPPORT OF ITS OMNIBUS MOTION TO DISMISS THE FRAUDULENT MISREPRESENTATION CLAIMS IN FIVE INITIAL BELLWETHER DISCOVERY COMPLAINTS PURSUANT TO FED. R. CIV. P. 9(b) & 12(b)(6)

Horizon Therapeutics USA, Inc. ("Horizon") moves this Court to dismiss the fraudulent misrepresentation claims asserted in the First Amended Complaints ("FACs") filed by five of the Initial Bellwether Discovery plaintiffs: *Chryssos*, *Egger*, *Ford*, *Meyers*, and *Stern*.[1] Plaintiffs' claims, as alleged, fail to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6) because they do not meet the heightened pleading standard in Federal Rule of Civil Procedure 9(b), which requires plaintiffs to state with particularity the circumstances constituting fraud or mistake. *See* Fed. R. Civ. P. 9(b); *Ashcroft v. Iqbal*, 556 U.S. 662, 686 (2009).

Plaintiffs' conclusory allegations are nothing more than repackaged failure-to-warn claims, without the particularized facts required to support this type of serious claim. Nowhere in their FACs do plaintiffs allege any specific false statements, let alone the requisite "who, what, where,

[1] *See* FAC: Claim 5, *Chryssos*, No. 1:23-cv-03033 (ECF No. 12); FAC: Claim 5, *Egger*, No. 1:23-cv-15306 (ECF No. 3); FAC: Claim 5, *Ford*, No. 1:23-cv-02703 (ECF No. 11); FAC: Claim 5, *Meyers*, No. 1:23-cv-03585 (ECF No. 6); FAC: Claim 6, *Stern*, No. 1:23-cv-02659 (ECF No. 14). The remaining Initial Bellwether Discovery cases do not assert claims for fraudulent misrepresentation.

when or how" required by Rule 9(b). Plaintiffs' pleadings fail to allege when and how their prescribers relied upon any alleged misrepresentations, or to allege a specific injury that resulted due to the allegedly fraudulent misrepresentation. The proper remedy for such inadequately pled, spurious fraud claims is dismissal.

BACKGROUND

Tepezza® (teprotumumab) is the first FDA-approved medication indicated to treat thyroid eye disease ("TED"), a rare autoimmune disease "characterized by progressive inflammation in the tissues around the eyes," resulting in symptoms such as bulging eyes, "bloody eyes," redness and immense pain. *See, e.g.*, FAC ¶¶ 28, 31, 42 (Ex. A).[2] Plaintiffs allege that they were prescribed Tepezza® and "now suffer[] from permanent hearing loss and/or tinnitus as a result of [their] infusions of Tepezza," but do not allege any specified injuries or diagnoses. *Id.* ¶ 12.

All twelve Initial Bellwether Discovery plaintiffs assert failure-to-warn and design defect claims related to their Tepezza® use. Plaintiffs *Chryssos*, *Egger*, *Ford*, *Meyers*, and *Stern* additionally assert fraudulent misrepresentation claims, alleging that Horizon made "fraudulent, intentional and material misrepresentations and omissions regarding the safety and efficacy of Tepezza" to plaintiffs and their physicians. *Id.* ¶ 259; *see id.* ¶¶ 258-80 (Claim 5: Fraudulent Misrepresentation). Plaintiffs allege in vague terms that these misrepresentations were contained in unspecified "promotional materials [and] advertising," as well as in product inserts and the product monograph, "with the intent that Plaintiff[s] use Tepezza." *Id.* ¶ 259. Plaintiffs allege that these unspecified misrepresentations were made "with the intent that such misrepresentations would result in Tepezza being prescribed and administered to Plaintiff[s]," that Horizon knew the

[2] Horizon refers to the FAC in *Chryssos*, No. 1:23-cv-03033, ECF No. 12, as Exhibit A. The allegations set forth in the *Chryssos* FAC are representative of the FACs of all the Initial Bellwether Discovery plaintiffs subject to this motion.

misrepresentations were false, and that plaintiffs and their prescribing physicians "would rely upon such material misrepresentations." *Id.* ¶¶ 259-62. Plaintiffs further allege that the "'adverse reactions' section of the label has at all times been false as it relates to the occurrence of hearing loss and tinnitus" because it "indicated that these conditions occurred in less than 10% of clinical trial patients. However, as noted above, these conditions occurred in as many as 40% of clinical trial patients receiving Tepezza." *Id.* ¶ 267.

The alleged "misrepresentations and omissions" include:

- "Defendant failed to disclose or actively concealed data demonstrating that Tepezza increased the risk of hearing loss and/or tinnitus and related sequelae." *Id.* ¶ 269;
- "Defendant failed to include or provide adequate warnings along with Tepezza regarding potential and established risks, and the nature, scope, severity, and duration of any serious side effects of Tepezza use . . . ." *Id.* ¶ 270;
- "Since receiving FDA approval, Horizon has encouraged endocrinologists and neuro-ophthalmologists to switch their patients to Tepezza, purporting to offer greater clinical benefit and reduction in symptoms with little to no long-term data on the sustained improvement in symptoms." *Id.* ¶ 271;
- "Defendant failed to issue a safety communication like a Dear Healthcare Professional Letter or otherwise timely update its product labeling upon receipt of post-marketing adverse event reports . . . . In addition to misreporting the safety data from the clinical trials, Horizon has misled healthcare providers and the public by consistently downplaying the frequency at which hearing loss adverse events have occurred in patients treated with Tepezza." *Id.* ¶ 272.
- "[T]he company's clinical-trial data and internal analysis or reanalysis of those data, including but not limited to Study 401 (EAP) [Expanded Access Protocol]—which ClinicalTrials.gov reports was completed in March of 2020 *three months post launch*—indicated a higher rate of hearing impairment than was initially reported. Defendant, however, continued to minimize the risks (including the rate of hearing impairment as an adverse event) and represent that the majority of hearing-related adverse events in the pivotal trials and post-approval have been mild to moderate and reversible. Study 401 EAP data suggested a much higher incidence rate of 40%." *Id.* ¶ 263.
- "To date, Horizon has refused to publish or make available to Healthcare providers the results of Study 401 EAP." *Id.* ¶ 264.

The crux of plaintiffs' fraudulent misrepresentation claim appears to be that Horizon did not include data from the "Study 401 EAP"[3] in Tepezza®'s FDA-approved label. *Id.* ¶¶ 120, 263. "Study 401 EAP" refers to an Expanded Access Protocol, a compassionate use program that provides access to a breakthrough drug still in the investigational stage for patients who could not otherwise access it due to ineligibility or lack of access to a clinical trial, here for twenty-two patients.[4] Plaintiffs allege that Study 401 EAP was complete in March 2020—two months after FDA approved the Tepezza® label in January 2020. *See id.* ¶¶ 42, 60, 120, 263. Plaintiffs do not allege that Study 401 EAP was a randomized controlled trial similar to the two pivotal randomized controlled trials relied on by FDA in assessing the safety and efficacy of Tepezza® for its approval in January 2020. *See id.* ¶¶ 52, 67. Plaintiffs do not allege that Horizon was required to disclose the results of Study 401 EAP in the label or elsewhere. Nor do plaintiffs allege that the results of the Study 401 EAP would have changed the percentage of hearing impairment adverse events reported in the label.

[3] Nat'l Libr. Med., *Expanded Access Protocol of Teprotumumab (HZN-001) for Patients With Active Thyroid Eye Disease (EAP)*, ClinicalTrials.gov, https://clinicaltrials.gov/study/NCT04040894 (last updated June 20, 2024) (Ex. B). *See also* Horizon's concurrently filed Request for Judicial Notice ("RJN") asking that the Court take judicial notice of the Exhibits that are referenced in the FACs or are matters of public record. When deciding a motion to dismiss, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007); *see also Jackson v. Kane Cnty.*, No. 09 C 4154, 2010 WL 4719713, at *2 n.2 (N.D. Ill. Nov. 9, 2010) ("In ruling on a 12 (b)(6) motion to dismiss, the court may take judicial notice of matters of public record.") (citing *Cancer Found., Inc. v. Cerberus Cap. Mgmt.*, 559 F.3d 671, 675, n.2 (7th Cir. 2009)); Fed. R. Evid. 201(b).

[4] *See* FAC ¶ 120 (Ex. A); *Expanded Access | Information for Physicians*, U.S. Food & Drug Admin. (Nov. 29, 2023), https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians (Ex. C).

LEGAL STANDARD

A complaint is insufficient under Rule 12 where it does not contain sufficient factual allegations to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim for fraud must be dismissed pursuant to Rule 12(b)(6) when it does not satisfy the additional, heightened requirements of Rule 9(b), which requires a party to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also Iqbal*, 556 U.S. at 686 (discussing the heightened Rule 9(b) pleading standard). Rule 9(b) specifically requires that plaintiff allege with particularity: "the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." *U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharm., Inc.*, 772 F.3d 1102, 1106 (7th Cir. 2014). Simply put, a plaintiff must include "the who, what, when, where, and how: the first paragraph of any newspaper story." *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (quotation omitted).

"[T]he particularity requirement of Rule 9(b) is designed to discourage a 'sue first, ask questions later' philosophy." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 441 (7th Cir. 2011); *see also U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776-77 (7th Cir. 2016) (emphasizing the importance of Rule 9(b) in protecting defendants against spurious fraud claims and fishing expeditions); *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 924 (7th Cir. 1992) ("Rule 9(b) ensures that a plaintiff have some basis for his accusations of fraud before making those accusations and thus discourages people from including such accusations in complaints simply to gain leverage for settlement or for other ulterior purposes."). When a complaint fails to meet such requirements, defendants are entitled to "riposte swiftly and effectively if the claim is groundless" and courts are required to dismiss those

claims. *Fid. Nat'l Title Ins. Co. of N.Y. v. Intercounty Nat'l Title Ins. Co.*, 412 F.3d 745, 749 (7th Cir. 2005).

ARGUMENT

Plaintiffs fail to adequately plead the elements of their fraudulent misrepresentation claims under each relevant state law with the particularity required by Rule 9(b). To state a claim for fraud under any of the applicable state laws[5]—California (*Egger*), New York (*Chryssos* and *Stern*), Pennsylvania (*Ford*), Utah (*Meyers*)—each plaintiff must allege: (1) a false statement or material omission of fact, (2) knowledge of falsity by the party making it, (3) intention to defraud, *i.e.*, to induce the other party to act, (4) action by the other party in reliance on the truth of the statements, and (5) damage to the other party resulting from such reliance.[6]

[5] Plaintiffs have conceded that the law of the state where each plaintiff resides applies to that plaintiff's claims. *See* Email from T. Becker to C. Thurman (June 27, 2024) (Ex. D) (plaintiffs agreed to dismiss strict liability failure-to-warn and design defect claims where the states of injury did not recognize such claims). Illinois choice-of-law rules yield the same result, given the "*strong* presumption" in Illinois that the law of the place of the injury applies. *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 904-05 (Ill. 2007) (emphasis in original); *see also Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941) (stating that federal courts sitting in diversity apply the choice-of-law rules of the forum state). Applying Illinois choice-of-law principles, MDL courts in the Northern District of Illinois have repeatedly applied the law of the place of injury to a plaintiff's fraudulent misrepresentation claims in a product liability action. *See, e.g.*, *Paulsen v. Abbott Lab'ys*, No. 15-cv-4144, 2018 WL 1508532, at *10-13, 17 (N.D. Ill. Mar. 27, 2018) (applying Georgia law to fraudulent misrepresentation claim where plaintiff is a Georgia resident, injected the product in Georgia, and suffered injury in Georgia); *In re Testosterone Therapy Prods. Liab. Litig. Coordinated Proc.*, 430 F. Supp. 3d 516, 546-47 (N.D. Ill. 2019) (applying Minnesota law to Minnesota plaintiff's fraudulent misrepresentation claim in product liability action).

[6] The required elements of fraudulent misrepresentation are similar under each relevant state's law, as well as Illinois law. *See, e.g.*, **California:** *Bekins v. Zheleznyak*, No. CV15-4478, 2016 WL 1091057, at *8 (C.D. Cal. Mar. 21, 2016) (quoting *Lazar v. Superior Ct.*, 909 P.2d 981, 984 (Cal. 1996)); **New York:** *Oden v. Bos. Sci. Corp.*, 330 F. Supp. 3d 877, 897-98 (E.D.N.Y. 2018) (quoting *Premium Mortg. Corp. v. Equifax, Inc.*, 583 F.3d 103, 108 (2d Cir. 2009)); **Pennsylvania:** *Petruska v. Gannon Univ.*, 462 F.3d 294, 310 (3d Cir. 2006) (quoting *Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992)); **Utah:** *Heaton v. Am. Brokers Conduit*, No. 2:11-CV-531, 2011 WL 3734201, at *4 (D. Utah Aug. 24, 2011) (quoting *Armed Forces Ins. Exch. v. Harrison*, 70 P.3d 35, 40 (Utah 2003)); *see also* **Illinois:** *In re Boeing 737 Max Pilots Litig.*, 638 F. Supp. 3d 838, 864 (N.D. Ill. 2022) (quoting *Weidner v. Karlin*, 932 N.E.2d 602, 605 (Ill. App. 2010)).

Plaintiffs fail to plead with particularity the "who, what, when, where, and how" of any alleged misrepresentation. *Lusby*, 570 F.3d at 854. Plaintiffs additionally fail to plead with particularity that plaintiffs relied on any alleged misrepresentation or that the reliance resulted in any specified injury.

I. Plaintiffs Fail to Plead Any Specific Misrepresentation with the Particularity Required by Rule 9(b).

Absent particularized facts about the alleged misrepresentations, plaintiffs' claim for fraudulent misrepresentation simply repeats plaintiffs' failure-to-warn claim. Rule 9(b) requires more detail to "operate as a screen against spurious fraud claims" and protect defendants against baseless but serious accusations of fraud. *Fid. Nat'l Title Ins. Co.*, 412 F.3d at 749. Plaintiffs' fraudulent misrepresentation claims fail because they do not plead the "who, what, when, where, and how" of any alleged misrepresentation. *Lusby*, 570 F.3d at 853.

What. Significantly, plaintiffs fail to allege the "what"—the content of the misrepresentations—with the requisite particularity required by Rule 9(b). "The paradigmatic example of a fraudulent misrepresentation is a false statement rather than an omission." *In re Boeing 737 Max Pilots Litig.*, 638 F. Supp. 3d at 864 (quoting *Pactiv LLC v. Perez*, No. 20 CV 01296, 2020 WL 7123070, at *8 (N.D. Ill. Dec. 4, 2020)). An omission can only give rise to a fraudulent misrepresentation claim if defendants had "a duty to disclose" due to a "special or fiduciary relationship." *Hair Relaxer Mktg. Sales Pracs. & Prods. Liab. Litig.*, -- F. Supp. 3d --, 2023 WL 7531230, at *7 (N.D. Ill. Nov. 13, 2023) (quoting *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 571 (7th Cir. 2012); *Cohen v. Am. Sec. Ins. Co.*, 735 F.3d 601, 614 (7th Cir. 2013)).

Plaintiffs allege in a conclusory fashion that Horizon made "fraudulent, intentional, and material misrepresentations and omissions regarding the safety and efficacy of Tepezza and of Tepezza's side effects." FAC ¶ 259 (Ex. A). Plaintiffs support this vague conclusion with

essentially one allegation: that Horizon misrepresented "the occurrence of hearing loss and tinnitus" in the "'adverse reactions' section of the label" by "indicat[ing] that these conditions occurred in less than 10% of clinical trial patients," while Study 401 EAP data suggested that "these conditions occurred in as many as 40% of clinical trial patients receiving Tepezza." *Id.* ¶¶ 263, 267.

Plaintiffs' allegation that the information in the January 21, 2020, FDA-approved Tepezza® label is "false," *id.* ¶¶ 260, 267, is nothing but a legal conclusion based upon a series of impermissible inferences. As plaintiffs admit, the 10% rate of hearing impairment adverse events disclosed in the FDA-approved Tepezza® label accurately reported the rate of hearing impairment observed in the two pivotal, randomized controlled trials that the FDA relied on in deciding to approve Tepezza®'s Biologics License Application ("BLA"). *See id.* ¶ 52 (alleging that the label listed the incidence of hearing impairment adverse reactions in the experimental group (8) versus control group (0) in the clinical trials); *id.* ¶ 67 (alleging that the rate of hearing impairment in the label was based on two TED studies, and that a higher rate was only revealed in later studies).

Nowhere do plaintiffs allege that Horizon had a duty to disclose the results of Study 401 EAP—an open label, compassionate use program to provide Tepezza® to twenty-two patients who could not otherwise access Tepezza®.[7] *See In re Hair Relaxer*, 2023 WL 7531230, at *7 (dismissing fraudulent misrepresentation claims based upon an alleged omission without alleging

[7] *See Vanda Pharms., Inc. v. Food & Drug Admin.*, No. 1:22-CV-01432, 2023 WL 6035663, at *3 (D.D.C. Aug. 2, 2023) (explaining expanded access programs); *Expanded Access | Information for Industry*, U.S. Food & Drug Admin. (Jan. 19, 2023), https://www.fda.gov/news-events/expanded-access/expanded-access-information-industry (Ex. E) ("[E]xpanded access treatment generally occurs outside a controlled clinical setting."). It is very rare for adverse event information from EAP to contribute to safety information reflected in the FDA-approved labeling for a biologic—"FDA is not aware of instances in which adverse event information from expanded access has prevented FDA from approving a drug," in part because it is "difficult to link an expanded access treatment to a particular adverse event." *See Expanded Access | Information for Industry*, *supra.*

a duty to disclose). Nor do plaintiffs allege how the results of Study 401 EAP would have changed the frequency of hearing impairment adverse events observed in the two pivotal clinical trials that formed the basis of FDA's approval of Tepezza®. Plaintiffs' allegation that there was a higher rate of hearing impairment detected in a later, less scientifically rigorous study of only twenty-two patients does not support any inference that the rate of hearing impairment on the label was fraudulently misrepresented. *See Iqbal*, 556 U.S. at 678 (explaining that facts merely consistent with a defendant's liability, without more, do not support a reasonable inference of liability). Plaintiffs' allegations that Horizon "concealed data demonstrating that Tepezza increased the risk of hearing loss and/or tinnitus and related sequelae," FAC ¶ 269 (Ex. A); "failed to include or provide adequate warnings along with Tepezza regarding potential and established risks," *id.* ¶ 270; and "failed to issue a safety communication like a Dear Healthcare Professional Letter or otherwise timely update its product labeling upon receipt of post-marketing adverse event reports involving hearing loss, tinnitus, and related sequalae," *id.* ¶ 272, likewise cannot support a fraudulent misrepresentation claim because they amount to an allegation of fraud on FDA, preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).[8]

To the extent plaintiffs allege fraud in Horizon's promotional materials and advertising, they allege *no* facts—much less particular facts—as to *what* false statements were made. Plaintiffs vaguely allude to Horizon "purporting to offer greater clinical benefit and reduction in symptoms

[8] FDA requires the approved label to be used; any materials with information contrary to the label is mislabeled. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997) ("To the extent that this [fraud] allegation is based on the labeling of the product in conformity with . . . requirements of the FDA, the claim is preempted. . . . The sufficiency of this information has been approved explicitly by the FDA."). Because plaintiffs' fraudulent misrepresentation claims are based on the product labeling, they are preempted because it would have been impossible for Horizon to change Tepezza®'s label and remain in compliance with federal law. *See* Horizon's Mem. Supp. Mot. Dismiss Nine Bellwether Compls. Pursuant to Fed. R. Civ. P. 12(b)(6), *In re Tepezza Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 1:23-cv-03568 (ECF No. 178).

with little to no long-term data on the sustained improvement in symptoms," FAC ¶ 271 (Ex. A); "downplaying the frequency at which hearing loss adverse events have occurred in patients treated with Tepezza," *id.* ¶ 272; and misrepresenting the hearing risks through "[unidentified] public statements," as well as "advertising, . . . promotional materials, or other marketing resources and materials," *id.* ¶¶ 275, 277.[9] These allegations all fail to specify the "what" required by Rule 9(b).

Who. Plaintiffs fail to allege any specific "individuals," *id.* ¶ 279, who allegedly made any of these alleged fraudulent misrepresentations. Instead, plaintiffs vaguely allude to unidentified "individuals" that purportedly were in a "position of knowledge of the true facts." *Id.*; *see also id.* ¶ 268 (referring to unidentified "agents and/or their employees" of Horizon); *id.* ¶ 273 (referring to unidentified "sales representatives, employees, distributors, agents, and/or detail persons"). Plaintiffs must do more than simply point to unidentified employees of Horizon. *See Edalatdju v. Guaranteed Rate, Inc.*, 748 F. Supp. 2d 860, 864 (N.D. Ill. 2010) (allegations of fraud that failed to clearly state *who* at the defendant company made the fraudulent assertions failed to satisfy Rule 9(b)); *Cardenas v. Abbott Lab'ys*, No. 11 C 4860, 2011 WL 4808166, at *5 (N.D. Ill. Oct. 7, 2011) (allegations that defendants, "with or through others, their agents, servants and/or employees, the

[9] The lack of required particularity in the FACs is exemplified by the fact that plaintiffs' allegations are almost verbatim copies of the fraudulent misrepresentation allegations asserted by another plaintiff represented by the Johnson Becker firm in an entirely different litigation involving an entirely different biologic. *See* Excerpted Compl. ¶¶ 98-133, *Frye v. Novartis Pharms. Corp.*, No. 4:21-cv-01173 (E.D. Ark. Dec. 2, 2021) ("*Frye* Compl.") (Ex. F) (nearly verbatim allegations, substituting the product name, defendant, and injury). The Initial Bellwether Discovery plaintiffs, however, fail to include the specific factual allegations additionally included in the *Frye* Complaint. *See Frye* Compl. ¶¶ 103-13, 117-25. The *Frye* Complaint contains twenty unique factual allegations, while the FACs here include a mere *four* unique factual allegations. *See* FAC ¶¶ 263-66 (Ex. A). Those sparse allegations are that: "Study 401 EAP data suggested a much higher incidence rate [than the pivotal clinical trials] of 40%," *id.* ¶ 263; "Horizon has refused to publish . . . the results of Study 401 EAP," *id.* ¶ 264; "At all times, Horizon was aware that the 401 EAP data established the reported incidence rate was seriously flawed" because "upon his arrival, and after reviewing Study 401 EAP data,"—in 2023, three years *after* Study 401 EAP was allegedly completed—"Dr. Liu informed his superiors that the reported incidence rate for hearing impairment was incorrect," *id.* ¶ 265; and "Horizon did re-adjudicate certain clinical trials [b]ut in doing so intentionally excluded Dr. Liu from that process and subsequently terminated him in September 2023," *id.* ¶ 266.

companies they own, control, and for whose actions are responsible" include numerous unnamed actors and actions and thus fail to plead the required "who").

When. Plaintiffs fail to allege "when" the allegedly false statements were made. *See Grenadvor*, 772 F.3d at 1106 (requiring particularized facts as to the time of the misrepresentation); *Rosenstern v. Allergan, Inc.*, 987 F. Supp. 2d 795, 806 (N.D. Ill. 2013) (dismissing plaintiff's fraud claims for failure to state with particularity the circumstances constituting fraud because plaintiff's "general allegations" did not detail, *inter alia*, "when" allegedly fraudulent statements occurred); *Paulsen v. Abbott Lab'ys*, No. 15-cv-4144, 2018 WL 1508532, at *17 (N.D. Ill. Mar. 27, 2018) (allegation that defendants made misrepresentations "beginning in the 1990's and continuing into the 2000's" was insufficient to satisfy the "when" under Rule 9(b)). Plaintiffs here allege false representations were made in unidentified "promotional materials, advertising," FAC ¶ 259 (Ex. A), and "public statements," *id.* ¶ 275, but fail to specify with particularity *when* they were made. Plaintiffs' claims of misrepresentations made in the label likewise fail to plead the "when" with particularity, and plaintiffs fail to allege even basic facts such as when Tepezza® was prescribed and when they or their prescribing physicians read the label. *See Gray v. Abbott Lab'ys, Inc.*, No. 10-cv-6377, 2011 WL 3022274, at *5 (N.D. Ill. July 22, 2011) (dismissing plaintiff's fraudulent misrepresentation claim for failing to establish when plaintiff encountered the allegedly false promotional materials).

Where. Rule 9(b) also requires that plaintiffs state with particularity the location where the alleged false statements were made. Plaintiffs do not allege where the promotional materials and advertisements were distributed or where the public statements were made. *Compare Paulsen*, 2018 WL 1508532, at *17 (allegation that defendant made misrepresentations in Georgia and elsewhere insufficient to satisfy the "where" under Rule 9(b)), *with Hefferman v. Bass*, 467 F.3d

596, 601-02 (7th Cir. 2006) (complaint satisfied Rule 9(b)'s requirement of alleging "the time, the place, and the content of the misrepresentation" because it alleged a misrepresentation was made in late August or early September, after midnight, at plaintiff's home in Chicago).

How. Plaintiffs also fail to allege with particularity "how" the alleged misrepresentations were communicated to plaintiffs. Plaintiffs allege that they and their prescribers relied on misrepresentations in the label and promotional materials in deciding to prescribe or take Tepezza®, *e.g.*, FAC ¶¶ 268-72 (Ex. A), but fail to allege particularized facts to support this allegation, including any *specific* advertisement communicated to any *specific* prescribing physician and where and when any such statements were viewed. The failure to identify, at a minimum, how Horizon communicated specific statements to plaintiffs warrants dismissal of these claims for lack of the requisite particularity under Rule 9(b). *See Foge, McKeever LLC v. Zoetis Inc.*, 565 F. Supp. 3d 647, 657 (W.D. Pa. 2021) (dismissing plaintiffs' fraudulent misrepresentation claim alleging that defendant represented the drug as "safe and effective" and actively concealed known risks and danger, and information from labels and promotional materials because "[t]here are no allegations as to the specific advertisement relied upon by an unspecified, prescribing physician"); *George v. Amgen, Inc.*, No. 18 C 6421, 2019 WL 10893813, at *7 (N.D. Ill. June 6, 2019) (dismissing fraudulent misrepresentation claim because the allegations failed "to identify the time, place, or content of the alleged misrepresentations, specify which publications she relied upon or was defrauded through, or state when she viewed any specific publications"). Plaintiffs' vague references to "promotional materials, advertisements," and "other public statements," FAC ¶¶ 259, 275, 277 (Ex. A), are too vague to pass muster under Rule 9(b).

* * *

Plaintiffs failed to meet the heightened pleading requirements of Rule 9(b) because they

do not identify any particularized "misrepresentation". The Court should reject plaintiffs' attempt to impermissibly elevate their failure to warn claims as spurious claims for fraud. *See, e.g.*, *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 545-46 (E.D. Pa. 2021) (dismissing fraudulent misrepresentation claim that amounted to a "dressed-up failure to warn claim[]").[10]

II. Plaintiffs Fail to Plead Any Alleged Reliance with the Particularity Required by Rule 9(b).

Plaintiffs' fraudulent misrepresentation claim additionally fails because they do not plead reliance with the particularity required by Rule 9(b). Plaintiffs cannot merely assert in a conclusory fashion that they "relied on" inaccurate information; rather, they must include particularized facts such as "when [they] viewed these promotional items" and "which particular statements [they] relied on." *Gray*, 2011 WL 3022274, at *5 (dismissing plaintiff's fraudulent misrepresentation claim in product liability action for failure to plead particularized facts as to when and which statements were relied on to support justifiable reliance); *Oden*, 330 F. Supp. 3d at 898 (holding plaintiff's fraudulent misrepresentation claim "cannot proceed" absent facts indicating whether and when plaintiff and his physicians "actually read" and relied on the allegedly false statements on the website and justifiably relied on those materials prior to the prescribing decision).

Here, plaintiffs allege that they and their prescribing physicians "were misled by this in accurate [sic] information and detrimentally relied on this inaccurate information in deciding to prescribe and use Tepezza," FAC ¶ 269 (Ex. A); "relied on these lack of warnings to conclude that Tepezza did not pose these risks when compared to other available therapies to treat TED," *id.* ¶ 270; and "used Tepezza without an understanding that these events had been reported in the post-

[10] The fraudulent misrepresentation claims in *Ford* fail under Pennsylvania law for an additional reason. Pennsylvania law bars claims brought under a failure-to-warn theory because the Pennsylvania Supreme Court has held that negligence is the only recognized basis of liability where a failure to adequately warn is at issue. *See Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996).

marketing setting and therefore prescribed and used the drug without possessing this knowledge," *id.* ¶ 272. Plaintiffs do not state when they relied on allegedly fraudulent promotions, advertising, or even the label, nor what specific statements they relied on in deciding to use Tepezza®. Such allegations do not meet the heightened pleading requirements under Rule 9(b) to plead *particularized facts* about plaintiffs' reliance. *See Gray*, 2011 WL 3022274, at *5.

III. Plaintiffs Fail to Plead Any Alleged Injury with the Particularity Required by Rule 9(b).

Finally, plaintiffs *Chryssos*, *Meyers*, *Stern*, and *Ford* further fail to allege a specific injury that resulted from the allegedly fraudulent misrepresentation, a required element of fraudulent misrepresentation under under all of the applicable states' laws. *E.g.*, *In re Boeing*, 638 F. Supp. 3d at 864. Plaintiffs allege that they "now suffer[] from permanent hearing loss **and/or** tinnitus as a result of" Tepezza® infusions. FAC ¶ 12 (Ex. A) (emphasis added).[11] Plaintiffs are silent as to each of their *specific* injuries, dates of diagnoses, and how their injuries were allegedly caused by the allegedly fraudulent misrepresentations. Plaintiffs' allegation of "permanent hearing loss and/or tinnitus" is the type of generalized pleading that fails to meet the heightened pleading requirements of Rule 9(b).[12] *See In re Generac Solar Power Sys. Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 23-MD-3078, 2024 WL 2519778, at *5 (E.D. Wis. May 24, 2024) (finding that an allegation using "and/or" statements as to the elements of fraud "is perhaps a perfect example

[11] Plaintiff *Egger*, in contrast, alleged that he "now suffers from permanent hearing loss and tinnitus." FAC ¶ 12, *Egger*, No. 1:23-cv-15806, ECF 3.

[12] Plaintiffs likewise fail to adequately plead the element of causation, which requires plaintiffs to allege that the false statement caused plaintiffs' injuries. Plaintiffs do not allege that plaintiffs suffered injury as a result of Horizon's alleged fraud or allegedly defective promotional materials; instead, plaintiffs allege that as "a direct and proximate result of the *dangerous and defective nature* of Tepezza®," they suffered injury. FAC ¶ 280 (Ex. A) (emphasis added). This allegation reveals the deficiency of plaintiffs' fraudulent misrepresentation claims—namely, that they are not fraud claims at all, but merely repackaged failure-to-warn claims.

of how not to plead fraud with particularity"); *cf. Lyons v. Leatt Corp.*, No. 4:15-CV-17, 2015 WL 7016469, at *4 (N.D. Ind. Nov. 10, 2015) (allegation that false representations were made through "marketing, advertising, and/or promotion" was too "generalized" to satisfy Rule 9(b)).

CONCLUSION

For the foregoing reasons, the Court should grant this motion and dismiss the fraudulent misrepresentation claims asserted in the First Amended Complaints of plaintiffs *Chryssos*, *Egger*, *Meyers*, *Stern*, and *Ford* because they do not meet the heightened pleading standards required by Federal Rule of Civil Procedure 9(b).

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Respectfully Submitted,

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