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

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION,	No. 23 C 3568 MDL No. 3079 Judge Thomas M. Durkin

MEMORANDUM OPINION AND ORDER

Presently before the Court is a multidistrict litigation arising out of alleged permanent hearing loss and tinnitus associated with the use of the drug TEPEZZA®. In one of the underlying cases, Defendant Horizon Therapeutics USA, Inc. ("Horizon") moved to dismiss Plaintiff Cynthia Williams's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). At the case management conference on July 31, 2023, it was decided that the Court would use the *Williams* motion to dismiss briefing to evaluate the sole issue of whether the design defect claims are preempted. The Court allowed each side to file an additional brief and heard oral argument on that issue on September 29, 2023. For the reasons that follow, Williams's pre-approval design defect claims are not preempted. The Court takes no position on whether Williams's (or any other plaintiff's) design defect claims warrant dismissal on any other ground.

Background

The following facts are taken from Williams's complaint. *Williams v. Horizon Therapeutics USA, Inc.*, Case No. 1:22-cv-06838, Dkt. No. 1 ("Compl."). 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. *Id.* ¶ 28. Symptoms can vary greatly from one person to another, and may include redness, irritation, discomfort, eyelid retraction, and blurred or double vision. *Id.* ¶ 30. The most noticeable symptom is exophthalmos or proptosis, which refers to the bulging or protrusion of the eyes out of the eye socket. *Id.*

In January 2020, the FDA approved TEPEZZA® ("Tepezza"), the first approved drug to treat TED. *Id.* ¶ 41. Horizon, the pharmaceutical company involved in the manufacture, research, development, marketing, distribution, and sale of Tepezza, has held the Biologic License Application ("BLA") for the drug since that time. *Id.* ¶¶ 18–19. Tepezza acts by inhibiting the activity of the protein insulin-like growth factor-1 ("IGF-1"), which is believed to play a significant role in the development of the disorder. *Id.*

Williams was diagnosed with TED and/or Graves' eye disease and received Tepezza infusions from her physician from November 2020 through June 2021. *Id.* ¶ 10.[1] Williams alleges that as a result of her infusions of Tepezza, she now suffers from permanent hearing loss and/or tinnitus. *Id.* ¶ 12. Among other claims, Williams brings a strict liability design defect claim (Count II) and a negligent design claim (Count IV) under state law. *Id.* ¶¶ 140–62.

[1] There is some inconsistency in Williams's complaint about the dates of her infusions. *Compare* Compl. ¶ 10 (November 2020 to June 2021) *with id.* ¶ 56 (July 2021 to December 2021). That issue does not affect the merits of whether Williams's design defect claims are preempted.

Discussion

Horizon moves to dismiss Williams's design defect claims on impossibility preemption grounds. Horizon contends that any change in Tepezza's design to conform with state tort law would conflict with federal law, which precludes any change in formulation without FDA approval. Williams conceded at oral argument that the post-approval design defect claim, i.e., that Horizon should have re-designed Tepezza *after* it was approved by the FDA, is preempted. But Williams argues that her pre-approval design defect claim, i.e., that Horizon should have designed Tepezza differently *before* it sought FDA approval, is not preempted.

Impossibility preemption is a "demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). The inquiry for impossibility preemption "is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (citing *Wyeth*, 555 U.S. at 572). Neither the Supreme Court nor the Seventh Circuit has addressed whether federal law preempts a claim that a brand-name manufacturer should have designed and sought FDA approval for a different, safer drug. Though *Mut. Pharm. Co. v. Bartlett*, comes close, the Supreme Court in that case addressed a claim that a generic manufacturer should have redesigned a drug after FDA approval. 570 U.S. 472, 484–85 (2013). Central to the Court's reasoning was the fact that after a drug, whether generic or brand-name, is approved by the FDA, a manufacturer is not permitted to unilaterally change its formulation. *Id.* at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)). But the fact "that a brand-name manufacturer cannot market a redesigned version of an approved drug without

first seeking additional FDA approval does not address whether the 'manufacturer was required to use the allegedly defective design in the first place.'" *Holley v. Gilead Scis., Inc.*, 379 F. Supp. 3d 809, 825 (N.D. Cal. 2019) (quoting *Trahan v. Sandoz, Inc.*, No. 3:13-cv-350-J-34MCR, 2015 WL 2365502, at *6 n.5 (M.D. Fla. Mar. 26, 2015)). Here, Horizon "has cited no federal law that restricts a brand-name drug manufacturer from designing a reasonably safe product *prior* to FDA approval." *Sullivan v. Aventis, Inc.*, No. 14-CV-2939- NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015). More specifically, Horizon has not cited any federal law that dictates the manner in which a manufacturer must design a drug in the first place or that dictates which compositions among available alternatives a manufacturer must submit for approval. *Id.* Thus, to the extent that Horizon had a duty under state law to create a safer alternative design,[2] Horizon could have satisfied that duty without coming into conflict with any federal requirement.

Numerous district courts presented with this precise question have reached the same conclusion. *See, e.g.*, *Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 344 (D.N.J. 2021) (denying motion to dismiss pre-approval design defect claim for drug on preemption grounds and citing *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1009–10 (7th Cir. 2020)); *Holley*, 379 F. Supp. 3d at 825 (same); *Young v. Bristol-Myers*

[2] The parties disagree as to whether Virginia or Illinois law applies to Williams's claims. Because there is no federal law that dictates Horizon's design of the drug before seeking FDA approval, the preemption argument fails regardless of the state law in question. Whether there is a duty to create a safer alternative design pre-approval is dependent on the state law that applies and is thus a separate basis for dismissal not addressed in this opinion.

Squibb Co., No. 4:16-cv-00108, 2017 WL 706320, at *8 (N.D. Miss. Feb. 22, 2017) (same); *Guidry v. Janssen Pharm., Inc.*, 206 F. Supp. 3d 1187, 1209 (S.D. La. 2016) (same); *Sullivan*, 2015 WL 4879112, at *6 (same); *see also In re Zostavax Prod. Liab. Litig.*, MDL No. 2848, 2021 WL 5235225, at *4 (E.D. Pa. Nov. 10, 2021) (denying summary judgment on the same grounds); *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. MDL 2592, 2017 WL 3188456, at *6 (E.D. La. July 21, 2017) (same); *Estate of Cassel v. Alza Corp.*, No. 12-CV-771-WMC, 2014 WL 856023, at *2–6 (W.D. Wis. Mar. 5, 2014) (same).

What's more, such a conclusion follows from the Seventh Circuit's decision in *Kaiser*. In that case, a patient sued Ethicon, the manufacturer of the mesh medical device she alleged permanently injured her, as part of a multidistrict litigation. 947 F.3d at 1002. Ethicon argued that the plaintiff's design defect claim was preempted because it was impossible for Ethicon to independently redesign the device to satisfy its duties under the Indiana Product Liability Law ("IPLA") since the federal regulatory scheme under § 510(k) required it to seek FDA clearance before making any substantive change to the device. *Id.* at 1009. The Seventh Circuit held that "nothing in the § 510(k) clearance process prevented Ethicon from complying with IPLA's standard of care *before* seeking § 510(k) clearance for [the device]." *Id.* (emphasis added). Because Ethicon had "complete and independent control over [the device's] design before it sought § 510(k) clearance . . . [i]t was not impossible to simultaneously comply with federal and state law." *Id.* at 1010.

Even though *Kaiser* involved a federal regulatory scheme for a medical device, its reasoning applies with equal force in this context. As alleged, Horizon had "complete and independent control" over the design of Tepezza before it sought FDA approval for the drug. *Id.*; *see also* Compl. ¶¶ 141; 181. And Horizon points to no federal law that would have prohibited it from making changes to Tepezza's design before it sought FDA approval.[3] As such, there is no conflict between Horizon's obligations under federal and state law, and the pre-approval design defect claim is not preempted.

Horizon urges this Court to follow the Sixth Circuit's decision in *Yates v. Ortho-McNeil-Janssen Pharms., Inc.* instead. 808 F.3d 281 (6th Cir. 2015). In *Yates*, a consumer sued the manufacturers and designers of a birth control patch that allegedly caused her to suffer a stroke as part of a multidistrict litigation. *Id.* at 287. The plaintiff argued that her design defect claim was not preempted because there was no federal law that prohibited defendants from designing a reasonably safe product prior to FDA approval. *Id.* at 299. The Sixth Circuit disagreed and concluded that the design defect claim was preempted for two reasons. Respectfully, this Court finds neither reason persuasive, and the second reason runs counter to *Kaiser*.

[3] Horizon's counsel indicated at the July 31, 2023 case management conference that Tepezza was designed in the first instance by a different entity. The extent to which Horizon had control over the design and/or the ability to modify the design is a matter for discovery. For now, the Court accepts as true Williams's allegation that at all times relevant, Horizon was "involved in the manufacturing, research, [and] development" of Tepezza. Compl. ¶ 19.

First, the Sixth Circuit found the plaintiff's argument "too attenuated," because it would require the court to "speculate" that if the defendants designed the drug differently, the FDA would have approved the alternative design, the plaintiff would have taken that alternative drug, and the alternative drug would not have caused the plaintiff to suffer a stroke. *Id.* But those issues relate to causation rather than whether it was impossible to comply with both federal and state law. *See Gaetano*, 529 F. Supp. 3d at 343 ("These are, of course, weighty concerns, but they go primarily to causation; the specific connection to preemption is less clear."). Indeed, "every defective design claim requires consideration of hypothetical scenarios—what different steps *could have* been taken that *may have* prevented the plaintiff's injury." *Guidry*, 206 F. Supp. 3d at 1208 ("[T]he Sixth Circuit merely outlines the requisite assumptions for *all* defective design claims under [state law]."") (emphasis in original). "It is not too attenuated to assume that the FDA would approve a safer, alternative design of a drug that it has already approved." *Id.* Discovery may reveal that there was no safer, alternative design, or that the FDA would not have approved an alternative design. But the lack of proof at this stage does not warrant dismissal on preemption grounds.

Second, the Sixth Circuit pointed to *Bartlett*'s rejection of the rationale that a manufacturer can comply with both federal and state law by pulling an approved drug off the shelves and seeking the approval of a different one. *Yates*, 808 F.3d at 300 (citing *Bartlett*, 570 U.S. at 475). The Sixth Circuit reasoned that the plaintiff "essentially argued that defendants should never have sold [the product] in the first

place," and that "never-start selling rationale" was no different than the "stop-selling rationale" rejected in *Bartlett*. *Id.*

Yet, as several courts have observed, *Yates* misapplies the "stop-selling" rationale in this context. *See, e.g.*, *Gaetano*, 529 F. Supp. 3d at 344; *Holley*, 379 F. Supp. 3d at 825; *Young*, 2017 WL 706320, at *8. *Bartlett* held that "an actor seeking to satisfy both federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." 570 U.S. at 488. The pre-approval theory, however, "does not argue that a manufacturer should have stopped acting, just that it should have acted *differently*." *Young*, 2017 WL 706320, at *8 (emphasis in original). Williams's pre-approval claim is not that Horizon should have complied with federal and state law by not selling Tepezza. *See Gaetano*, 529 F. Supp. 3d at 344 ("[The pre-approval theory] does not require a manufacturer to abandon its investment and marketing efforts with respect to an efficacious drug that the FDA has approved."). Rather, the claim is that Horizon should have submitted to the FDA a formulation that did not cause permanent hearing loss and tinnitus. "That state-law directive to act 'differently' applies pre-approval, at the development stage, when the manufacturer is choosing among alternatives and the choice is not dictated by federal law." *Id.* Indeed, in *Kaiser*, the Seventh Circuit held that the defendant's reliance on the *Bartlett*'s rejection of the "stop selling" theory was "misplaced" because there was no direct conflict between federal and state laws. 947 F.3d at 1011.

Horizon cites other district court cases holding that pre-approval design defect claims are preempted. Several of those courts were bound by *Yates* or otherwise rely

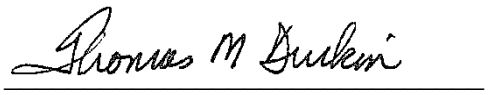
on its reasoning. *See, e.g.*, *Fleming v. Janssen Pharms.*, 186 F. Supp. 3d 826, 833 (W.D. Tenn. 2016). In addition to this Court's disagreement with the reasoning of *Yates*, the Seventh Circuit's decision in *Kaiser* counsels against preemption here.

Horizon further argues that the pre-approval design defect claim is preempted because Tepezza, as a biologic, is scientifically incapable of being redesigned. Horizon cites *Bartlett*, where the Supreme Court stated that the defendant "cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." 570 U.S. at 484. But unlike *Bartlett*, the Court does not yet have the benefit of discovery to examine whether Horizon's argument that there is no safer alternative design is supported by evidence. Relatedly, whether a plaintiff must allege or offer proof of a safer alternative design is a matter of state law and is entirely separate from the question of whether a design defect claim is preempted by federal law. *See Kaiser*, 947 F.3d at 1011. The Court thus declines to address that argument, and Horizon may renew that argument at the appropriate juncture.

Conclusion

For the foregoing reasons, the Court grants dismissal of Williams's post-approval design defect claims but denies dismissal of Williams's pre-approval design defect claims on preemption grounds.

ENTERED:



Honorable Thomas M. Durkin
United States District Judge

Dated: November 3, 2023