Maze v. Bayer Healthcare Pharmaceuticals, Inc. (TV3) Doc. 39

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE

REAGAN MAZE, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS INC., Defendant.	)	No.: 4:18-CV-21-TAV-CHS

MEMORANDUM OPINION

Plaintiff Reagan Maze claims that the name-brand birth-control pill Yaz, manufactured by defendant Bayer Healthcare Pharmaceuticals, Inc., caused her stroke and failed to adequately warn her of that potential outcome on its label. But because the FDA-approved Yaz warning label contained several warnings about the risk of a stroke, and because Maze has pointed to no new information—or a new interpretation of old information—suggesting that the included warning was inadequate, Maze's failure-to-warn claims are preempted by federal law. In the absence of any non-preempted claim, Bayer's motion to dismiss the complaint must be granted.

I. Background

Yaz is a birth-control pill produced, marketed, and sold by defendant Bayer [Doc. 19, at ¶ 15]. It is a combination oral contraceptive (COC), the use of which, in addition to preventing pregnancy, treats acne and the symptoms of premenstrual dysphoric disorder

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[Doc. 19-1, at 3]. The Food and Drug Administration first approved Yaz for marketing and sales in 2006 [Doc. 19, at ¶ 19].

On July 1, 2015, Maze, who was then a sixteen-year-old girl, suffered a massive ischemic stroke after taking Yaz as prescribed [Doc. 19, at ¶¶ 9–10, 41–42]. The effects were debilitating [Doc. 19, at ¶¶ 43–51]. In her complaint Maze alleges that her stroke was caused when, "[a]s a direct and proximate result of ingesting Yaz . . . a thrombus came to block the middle cerebral artery of [her] brain" [Doc. 19, at ¶¶ 41–42].

At the time of Maze's stroke, the warning label and prescribing information for Yaz (exhibit 1 to the amended complaint),[1] which as of that time had not been updated since 2012, provided the following warnings of stroke:

(1) "Use of COCs also increases the risk of arterial thromboses such as strokes" [Doc. 19-1, at 8];
(2) "COCs have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes)" [Doc. 19-1, at 8];
(3) "COCs also increase the risk for stroke in women with other underlying risk factors" [Doc. 19-1, at 8];
(4) Lists "Serious cardiovascular events and stroke" as one of three "serious adverse reactions" from the use of COCs [Doc. 19-1, at 10];
(5) Places vascular disorders, including "stroke," at the top of a list of adverse reactions that are "ordered by frequency" [Doc. 19-1, at 12];
(6) Includes the risk of stroke in a prominent boxed warning for women who smoke and also use oral contraceptives [Doc. 19-1, at 22];
(7) Warns that women who have ever had a stroke "should not take Yaz" [Doc. 19-1, at 28];

[1] Although at the motion-to-dismiss stage "review is typically limited to the complaint's allegations," the Court "may look outside the four corners of the complaint and consider materials attached to a motion to dismiss if they are referred to in the complaint and central to the claim." *Berry v. United States Dep't of Labor*, 832 F.3d 627, 637 (6th Cir. 2016). Because the Yaz warning label was attached as an exhibit to both the complaint and Bayer's motion to dismiss [Docs. 19-1, 22-1], and because it is essential to Maze's claims, considering it is proper.

(8) States that it "is possible to die or be permanently disabled from a problem caused by a blood clot, such as a heart attack or a stroke" [Doc. 19-1, at 30].

In her complaint Maze admits that "Bayer devoted substantial . . . space in its Yaz prescribing information . . . to warning of the risk of venous thromboembolism associated with the medication," but maintains that those warnings were "still inadequate" [Doc. 19, at ¶ 21].

Bayer has moved to dismiss Maze's claims, arguing that she has asserted no claim that is not preempted by federal law [Docs. 21, 22]. Maze responded [Doc. 24], and Bayer replied [Doc. 25]. For the reasons that follow, the motion will be granted and Maze's complaint will be dismissed.

II. Legal Standard

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires merely "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the [opposing party] fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks and citation omitted). In ruling on a Rule 12(b)(6) motion to dismiss, a court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and draw all reasonable inferences in favor of the plaintiff. *Id.* at 555, 570. Detailed factual

allegations are not required, but a party's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." *Id.*

In short, the Court's task is to determine whether the amended complaint here contains "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570; *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007) (citation omitted). A complaint must contain enough factual allegations to state a plausible claim, or else it cannot survive a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 663, 678 (2009).

As one district court explained, "It is well-established that preemption may be analyzed and decided at the motion to dismiss stage." *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672 (S.D.N.Y. 2017) (citations omitted). Thus, when a complaint does not plausibly allege any non-preempted claim, it must be dismissed under Rule 12(b)(6). *See, e.g.*, *Mitchell v. Boehringer Ingelheim Pharms., Inc.*, 2017 WL 5617473, at *1 (W.D. Tenn. Nov. 21, 2017) (granting in part defendants' motion to dismiss Tennessee product liability claims on preemption grounds); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42-43 (1st Cir. 2015) (affirming dismissal for failure to state a claim on preemption grounds).

III. Analysis

Maze's two Tennessee state-law tort claims, one based on negligence and one based on strict liability, are preempted because they conflict with federal law. Conflict

preemption is based on the Supremacy Clause, which states that federal law "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. It exists where (1) "it is impossible for a private party to comply with both state and federal law," and (2) the state law is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000). Here, Maze's tort claims seek to hold Bayer liable because the FDA-approved label for Yaz failed to warn strongly enough about the risk of stroke. To avoid the state-law liability that Maze's complaint seeks to impose, then, Bayer would need to change Yaz's label. Unsurprisingly, federal law has something to say about that.

Wyeth v. Levine, 555 U.S. 555 (2009), is the leading Supreme Court case addressing the intersection between federal name-brand labelling requirements and state products-liability lawsuits. The holding of *Wyeth* was that the plaintiff's state-law failure-to-warn claim, which was based on an inadequate brand-name drug label, was not preempted merely because the FDA had approved that label. *See id*. at 569–72. Rather, so the Court held, state law can still hold a manufacturer liable for failing to update the drug's label based on "newly acquired information" or even a "new analyses of previously submitted data." *Id*. at 571. Such updates are authorized by the so-called Changes Being Effected regulation (CBE), 21 C.F.R. § 314.70(c)(6)(iii), which allows brand-name drug

manufacturers to make changes without prior FDA approval if those changes "reflect newly acquired information," *id.*; *see also id.* § 314.3(b) (defining "newly acquired information"), and, as relevant here, "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling," *id.* Changes not based on new information—and thus necessarily based on the same information already considered by the FDA—require prior FDA approval. 21 C.F.R. § 314.70(b)(2)(v)(A).

Wyeth thus draws a line that balances the regulatory expertise of the FDA with a state's general police power. As the First Circuit explained, "the line so drawn lets the FDA be the exclusive judge of safety and efficacy based on information available at the commencement of marketing, while allowing the states to reach contrary conclusions when new information not considered by the FDA develops." *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015). Similarly, the Sixth Circuit has framed the *Wyeth* rule in this way: "As a general matter, plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal law." *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 294 (6th Cir. 2015) (citing *Wyeth*, 555 U.S. 555).

It follows from the above that any claim asserted by Maze and based on information known to the FDA as of April 2012—when the label at issue here was approved—is plainly

preempted by federal law. Maze's complaint states, "In 2012 . . . pharmaceutical research indicated the risk of stroke in individuals taking Yaz was 500% greater than the risk of stroke in individuals not taking birth control medication" [Doc. 19, at ¶ 31]. Assuming this is true, which is disputed by Bayer and unclear on the record, to impose state-law tort liability based on information known to the FDA at the time of approval is strictly prohibited under the Supremacy Clause and *Wyeth*.

What is more, Maze's complaint cannot plausibly be read to contain any "newly acquired information," or even a "new analyses of previously submitted data," on the basis of which Bayer could have changed the Yaz label using the CBE process, at sometime between 2012 and Maze's stroke in 2015. Maze submits that "in the years following the April 2012 Yaz label change there emerged more medical evidence in support of the contention that birth control pills containing drospirenone (DRSP) are associated with higher rates of side effects caused by blood clots" [Doc. 24, at 5]. No such evidence is included in the complaint, and no further detail is provided about this asserted new medical consensus. Maze also states, "A search of the FDA Adverse Event Reporting System indicates numerous adverse incidents suffered by Yaz users that postdate the FDA approval of the 2012 label change." This reference is once again neither cited nor explained. These blanket statements are merely conclusory allegations and do not count as a sufficient

"showing" that the plaintiff is entitled to relief.[2] *See McElroy v. Amylin Pharms., Inc.*, 2013 WL 12099073, at *4 (E.D. Tenn. Aug. 5, 2013).

Finally, and what seals the deal here, is that the label in effect during the entire relevant time repeatedly warned about the risk of stroke. *Supra* at 2–3. Thus, even assuming the science marshaled by Maze is newly acquired and says anything at all about the risk of stroke (as stated above, it is not and does not), nothing indicates that the risk is any higher than what is reflected in the Yaz label that the FDA approved in 2012. This crucial point distinguishes the facts here from those in *Wyeth*, where the plaintiff argued that a drug's warning label was inadequate for not telling healthcare providers to use a low-risk method of administering the drug, rather than the high-risk method that injured the plaintiff.[3] *See* 555 U.S. at 559–60. That "warning" was necessarily inadequate, because it did not exist. Thus, the main question from *Wyeth*—whether a nonexistent warning should be included on a label at all—is different from the one presented here: the adequacy

[2] Maze points to another study, conducted in 2015 by Yana Vinogradova. But not only does this study address venous thromboembolism (a different vascular condition) rather than stroke, the study is not included or referred to in her amended complaint or any attached exhibit. Considering materials beyond the complaint is sometimes permissible, but only "so long as they are referred to in the complaint." *Rondigo, L.L.C. v. Twp. of Richmond*, 641 F.3d 673, 681 (6th Cir. 2011). Because this study was not, whatever it might say about strokes does not apply here.

[3] *Wyeth* is further distinguishable by its procedural posture, as defendant rightly points out. That case was an appeal after a jury verdict. 555 U.S. at 558. The Court thus did not confront or even mention the question presented here: whether the plaintiff's pleadings were adequate to state a non-preempted claim. Moreover, the Court noted that "[t]he record is limited concerning what newly acquired information Wyeth had or should have had about the risks of IV-push administration of Phenergan because Wyeth did not argue before the trial court that such information was required for a CBE labeling change." *Id.* at 569. From that statement it appears that Wyeth forfeited the very defense raised by Bayer here: that newly acquired information about the risk of stroke is required to avoid preemption and lacking from the amended complaint.

of the FDA-approved, repeated stroke warning that the Yaz label has included all along. The former is heads-or-tails, the latter involves matter-of-degree questioning with respect to something that was clearly known and considered by the FDA in 2012. Without some indication that the science available now is somehow different, the Court will not second guess the adequacy of Yaz's warning label with state tort law.

Based on the allegations in Maze's complaint, federal law (specifically the CBE procedure) would not have allowed Bayer to modify the Yaz label, which had already been approved by the FDA, in the way that plaintiffs suggest is necessary to make its stroke warning adequate. And because Bayer could not unilaterally change the label, it could not have complied with that construction of Tennessee law without violating federal law in the form of the FDA regulations cited above. Thus, even if plaintiffs have any claim under Tennessee law—a matter the Court does not reach—it is preempted. Maze's complaint therefore must be dismissed.

IV. Conclusion

For the reasons explained above, Bayer's motion to dismiss will be **GRANTED**, and the complaint will be dismissed. A separate order will be entered as a judgment.

ENTER:

s/ Thomas A. Varlan
CHIEF UNITED STATES DISTRICT JUDGE