UNITED STATE DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

IRENE JENKINS,	)	
	)	
Plaintiff,	)	
	)	No. 3:11-CV-342
	)	(CAMPBELL/SHIRLEY)
V.	)	
	)	
NOVARTIS PHARMACEUTICAL CORP.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

This case is before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and the referral of the District Judge.

Now before the Court is Plaintiff's Motion for Leave to Amend to Assert Additional Theory of Recovery [Doc. 60], in which the Plaintiff moves the Court for leave to amend her Complaint to: (1) "assert the additional theory of breach of implied warranty, which is subject to a four-year statute of limitations," (2) "assert that she received the drug Zometa, which is manufactured by Defendant, as well as Aredia, which is the drug Plaintiff's decedent has alleged she received," (3) "delete allegations of negligence *per se*, which Plaintiff has conceded," and (4) "correct an erroneous reference to Merck, rather than Novartis, in Paragraph 14 of the Complaint." [Doc. 60 at 1]. Defendant has responded in opposition arguing that Plaintiff's requested amendments are futile and that Plaintiff's delay in requesting leave to amend amounts to undue delay. [Doc. 64].

Rule 15 of the Federal Rules of Civil Procedure directs that, where an amendment is not made as a matter of course, "a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). "The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). However, in cases of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment," the court may exercise its discretion to deny the request to amend. Foman v. Davis, 371 U.S. 178, 182 (1962).

As an initial matter, the Court finds that the Plaintiffs' proposed deletion of negligence *per se* allegations and proposed substitution of the name "Novartis" for "Merck" are not actually challenged. These changes appear to be challenged to the extent they are part of the "bundle" of proposed changes, but the Defendant has devoted little, if any, oral or written arguments to opposing these changes. Thus, the Court finds that the requests to make these amendments is well-taken under Rule 15, and these requests to amend are **GRANTED**.

The Court, thus, turns its attention to the remaining two requests for amendment: the addition of a claim for breach of warranty of merchantability and the addition of Zometa usage to the Plaintiff's claims and factual allegations. Defendant argues that the Court should deny the Plaintiff's request to amend based upon: (1) undue delay in making the request and (2) futility. The Court will address each argument in turn.

A. UNDUE DELAY

Defendant argues that the Plaintiff has unduly delayed her request to amend, and the request may be denied on this basis alone. [Doc. 64]. Defendant notes that Plaintiff first filed a claim based upon the instant allegations on June 8, 2005, and filed the instant suit on August 9,

2006. Defendant maintains that the Plaintiff had an obligation to act diligently in asserting these claims, but she, instead, waited over five years, until December 2, 2011, to file a motion to amend her complaint. The Defendant submits that this delay is simply too long, and cites the Court to various cases from this Court and the Court of Appeals in support of its position. See Scheib v. Boderk, 3:07-CV-446, 2011 WL 208341 (E.D. Tenn. Jan. 21, 2011) (Phillips, J.) ("By any measure, three and a half years, without justification, amounts to undue delay."); Duggins v. Steak 'N Shake, Inc., 195 F.3d 828, 834 (6th Cir. 1999) (affirming district court's denial of leave to amend complaint without justification after close of discovery and dispositive motions had been filed); Morse v. McWhorter, 290 F.3d 795, 800 (6th Cir. 2002) ("At some point . . . delay will become 'undue,' placing an unwarranted burden on the court.").

Plaintiff replies that: the pleadings in this case have not been previously amended; there is no deadline for such amendments set; and this case is not yet set for trial. [Doc. 65]. Plaintiff maintains that the delay in bringing this motion was not undue, and it has not prejudiced the Defendant. Plaintiff distinguishes the instant case from Scheib v. Boderk, 3:07-CV-446, a case in which the plaintiff had amended its complaint four times, the deadline for discovery and dispositive motions had expired, and the amendment created a need for further discovery and possibly another continuance of the trial. Similarly, Plaintiff distinguishes Duggins v. Steak 'N Shake, Inc., 195 F.3d 828, as a case in which many deadlines had expired and there would be a reopening of discovery.

The Court has considered the undeniable delay in filing this Motion to Amend. Under certain circumstances, this lengthy delay would support denying the request to amend. The Court finds, however, that in this case the delay does not rise to a level that supports denying the motion based upon undue delay alone. This matter is not set for trial, nor has the period for

discovery closed. The Court recognizes that the Defendant *may* have to revisit some of its deposition discovery because of the motion to amend, but the proposed additions operate off much the same facts. The Court cannot find a "significant showing of prejudice" to the Defendant, Moore v. City of Paducah, 790 F.2d 557, 562 (6th Cir. 1986), and therefore, the undersigned will not deny the Motion to Amend based upon undue delay.

B. FUTILITY

Defendant argues that the proposed amendments to add a claim for breach of warranty of merchantability and to add Zometa usage to the Plaintiff's claims and factual allegations should be denied as futile based upon the statute of repose and statutes of limitation found in the Tennessee Code Annotated.

1. Statute of Repose, Tennessee Code Annotated § 29-28-103

Defendant argues, first, that the Plaintiff's proposed amendments are barred by Tennessee's statue of repose. [Doc. 64 at 2]. Tennessee Code Annotated § 29-28-103(a) provides:

> Any action against a manufacturer or seller of a product for injury to person or property caused by its defective or unreasonably dangerous condition must be brought within the period fixed by §§ 28-3-104, 28-3-105, 28-3-202 and 47-2-725, but notwithstanding any exceptions to these provisions, it must be brought within six (6) years of the date of injury, in any event, the action must be brought within ten (10) years from the date on which the product was first purchased for use or consumption, or within one (1) year after the expiration of the anticipated life of the product, whichever is the shorter, except in the case of injury to minors whose action must be brought within a period of one (1) year after attaining the age of majority, whichever occurs sooner.

In this case, Plaintiff does not dispute that the statute of repose would govern the timeliness of the proposed amendments. [Doc. 65 at 2]. Instead, she argues that the Defendant bears the burden of demonstrating that the statute of repose bars the amendments, and she maintains that the statute of repose does not preclude the amendments.

a. Breach of Implied Warranty of Merchantability

Plaintiff seeks to add Count III, for breach of warranty of merchantability based upon the Defendant placing Aredia and Zometa, which Plaintiff maintains were not of merchantable quality, in the stream of commerce. [Doc. 60-1 at 4-5]. The statute of repose codified in § 29-28-103(a) applies to breach of warranty claims. See Electric Power Bd. of Chattanooga v. Westinghouse Elec. Corp., 716 F. Supp. 1069, 1073 (E.D. Tenn. 1988)

Plaintiff concedes that she first received Aredia in February 1997, more than fourteen years before filing the Motion to Amend, and she began receiving Zometa in November 2001, more than ten years before filing the Motion to Amend. [Doc. 146 at 1]. Plaintiff's earliest date of injury was August 24, 2000, over ten years before the Motion to Amend was filed. The Court finds that, as of the date of the filing of the Motion to Amend, the claim for breach of implied warranty of merchantability was barred by both the six-years-from-injury provision of § 29-28-103(a) and the ten-years-from-purchase provision of § 29-28-103(a). The Court must, however, determine whether the proposed amendments relate back to the date on which the Complaint was originally filed.

Plaintiff alleges that the breach of warranty claim relates back to its pleading filed June 8, 2005. [Doc. 65 at 6-7]. In support of this position, Plaintiff cites the Court to Tennessee Code Annotated § 28-1-104. [Id. at 7]. Tennessee Code Annotated § 28-1-104 states:

> The time for the limitation of an action by either a surety or accommodation endorser against their principal on negotiable paper, or for any matter growing out of the suretyship, does not commence to run until judgment is rendered against the surety or endorser, or the surety or endorser until the surety or endorser has paid the money.

The Plaintiff does not explain how § 28-1-104 could govern any relation back to the initial Complaint, and the Court cannot discern the basis on which this section would govern the relation back.

Plaintiff also cites Rule 15 of the Federal Rules of Civil Procedure, which directs that an "amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out--or attempted to be set out--in the original pleading . . . ." Fed. R. Civ. P. 15(c)(1)(B). Defendant does not dispute that Rule 15(c)(1) would govern this issue. See Doc. 64 at 5. Defendant argues that even if Plaintiff's claims did relate back, the claims are still barred by the statute of repose. [Doc. 64 at 5, n. 3].

The Court finds that the proposed breach of warranty claim relates back to either June 8, 2005, or August 9, 2006, because "it asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out--or attempted to be set out--in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). Plaintiff claims that the proposed breach of warranty should relate back to June 8, 2005, the original filing date in Thorn v. Novartis, No. 3:04-CV-586 (E.D. Tenn.), a completely separate suit. [See Doc. 65 at 6-7; Doc. 147-6; and Doc. 16 in 3:04-CV-586]. The Court, however, need not decide between these dates for purposes of the statute of repose, because the Court finds that even using the later date, the Plaintiff's claims are not barred by the statute of repose.

Plaintiff first received Aredia in February 1997, less than ten years before August 9, 2006, and Plaintiff first received Zometa in November 2001, which again is less than ten years before August 9, 2006. Thus, the Court finds the ten-years-from-purchase provision of § 29-28-103(a) does not preclude the addition of the claim for breach of the implied warranty of merchantability.

Plaintiff's earliest date of injury was August 24, 2000, which is less than six years before the original Complaint in this case was filed on August 9, 2006. Thus, the Court finds that the six-years-from-injury provision of § 29-28-103(a) does not preclude the addition of the claim for breach of the implied warranty of merchantability.

In its latest filing, the Defendant also argues that the expiration date may preclude the addition of the claim for breach of the implied warranty of merchantability. The Defendant concedes however, that this particular statute of repose issue is not fully developed and it would "require substantial discovery and factual investigation to develop this repose defense." At this time, the Court finds that it lacks sufficient knowledge about the expiration dates of the medicine Plaintiff received to rule that the claims are precluded by the one-year-after-expiration provision of the statute of repose. The Defendant may move for dismissal based on this argument once it is more fully developed.

b. Zometa Usage

Plaintiff also moves the Court to grant her leave "assert that she received the drug Zometa, which is manufactured by Defendant, as well as Aredia, which is the drug Plaintiff's decedent has alleged she received." [Doc. 60 at 1]. The Court finds that, for the reasons more fully stated above, the addition of allegations relating to Zometa, regardless of whether they

relate back to June 8, 2005, or to August 9, 2006, the proposed addition of claims relating to Zometa is not barred by § 29-28-103(a).

2. Statute of Limitation, Tennessee Code Annotated § 28-3-104

Neither party disputes under the Tennessee Products Liability Act, § 29-28-101, *et seq.*, a products-liability action includes actions for breach of express or implied warranties. See Tenn. Code Ann. § 29-28-102(6). A one-year statute of limitations applies to products liability claims. See Tenn. Code Ann. § 28-3-104; Montgomery v. Harrah's Entertainment, 2009 WL 4591075, *2 (W.D. Tenn. 2009). In a products-liability case, the cause of action accrues "on the date of the personal injury, not the date of the negligence or the sale of the product." Tenn. Code. Ann § 28-3-104(b).

In supplemental briefing, filed April 1, 2013, the Plaintiff conceded that as early as August 24, 2000, "exposed bone is noted" in an area from which teeth had been extracted. [Doc. 146 at ¶ 1]. Plaintiff adds, "There is no evidence that Ms. Jenkins or her doctors suspected the exposed bone was related to her use of Aredia." [Id.]. Plaintiff further concedes that on April 2, 2004, Dr. Carlson sent a letter to Dr. Wooten advising him that Ms. Jenkins had Aredia-induced osteonecrosis of the mandible and maxilla. [Id.]. The Plaintiff has argued that this letter does not constitute knowledge for statute of limitations purposes.

The Plaintiff has argued in her filings that the implied warranty claim should be addressed under the U.C.C. framework found in Tennessee Code Annotated § 47-2-314, which states the elements of a claim for breach of the implied warranty of merchantability. Plaintiff argues that the introductory portion of § 29-28-103 governs the issue, when it states that "[a]ny action against a manufacturer or seller of a product for injury to person or property caused by its

defective or unreasonably dangerous condition must be brought within the period fixed by §§ 28-3-104, 28-3-105, 28-3-202 and **47-2-725**." (emphasis added). Tennessee Code Annotated § 47-2-725 states: "An action for breach of any contract for sale must be commenced within four (4) years after the cause of action has accrued."

The Supreme Court of Tennessee previously held that the statute of limitations contained in this U.C.C. provision "should control in all actions wherein a breach of warranty of a contract of sale is alleged, irrespective of whether the damages sought are for personal injuries or injuries to property." Layman v. Keller Ladders, Inc., 455 S.W.2d 594, 596 (Tenn. 1970). However, more recent case law has recognized that, where plaintiff's claims, "clearly sound in tort . . . the statute of limitations for products liability claims applies." See Vaugh v. DP Packaging, Inc., 17 F. App'x 286, 291 (6th Cir.2001) (noting the finding of magistrate judge that claims of personal injuries resulting from use of pepper spray were grounded in products liability, not breach of implied warranty); see also Pera v. Kroger Co., 674 S.W.2d 715, 719 (Tenn. 1984) ("It is well settled in this state that the gravamen of an action, rather than its designation as an action for tort or contract, determines the applicable statute of limitations.").

The Court has examined the Proposed Amended Complaint, along with other filings in this case. The Court finds that the personal injuries allegedly resulting from the use of Zometa and Aredia are grounded in products liability for personal injury, not liability based upon breach of the implied warranty of merchantability. District Judge Todd Campbell, who presided over the multi-district litigation stage of this litigation in the Middle District of Tennessee, described this suit and its 1760 companion cases in the Multi-District Litigation as "pharmaceutical products liability suits alleging that [Defendant's] products Aredia and Zometa caused injury." [Doc. 43 at 1]. Plaintiff has not disagreed with this description, and in the Proposed Amended

Complaint, Plaintiff herself describes the suit as "a product liability action specified by Tennessee common law." [Doc. 60-1 at ¶ 8]. Plaintiff simply labels Count III of the Proposed Amended Complaint to be "Breach of Implied Warranty of Merchantability." [Id. at 4]. She does not cite any portion of the Tennessee Code Annotated or reference a specific portion of the U.C.C., as adopted in Tennessee, under which she intends to proceed.

Having examined the record, pleadings, and filings, the Court finds that this case is a products liability action based upon personal injuries, despite the label assigned to Count III, and accordingly, the one-year statute of limitations contained in § 28-3-104 applies to the proposed amendment. The undersigned finds that the latest date of injury is April 2, 2004, the date on which Dr. Carlson sent a letter to Dr. Wooton advising that Ms. Jenkins had Aredia-induced osteonecrosis of the mandible and maxilla. [Doc. 146 at 2; Doc. 146-5 at 4].

The Court again finds that the implied warranty of merchantability and Zometa allegations relate back to a date of filing because they assert "a claim or defense that arose out of the conduct, transaction, or occurrence set out--or attempted to be set out--in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). Once again, the Court is not required to choose between the filing date of August 9, 2006, or the filing date of June 8, 2005. The filing on August 9, 2006, occurred after the statute of limitations had expired, and as a result, Plaintiff is barred from pursuing this claim. Even if the Court found that the proposed amendments related back to the filing of Second Amended Class Action Complaint, which added Plaintiff to Thorn v. Novartis, Case No. 3:04-CV-586, on June 8, 2005, the Plaintiff's amendments would still be barred by the one-year statute of limitations.[1] The Court is not prepared to find that the Plaintiff's

[1] The Court would note that the Plaintiff, in briefing the instant motion, endorsed this date, stating: "Because Ms. Jenkin's proffered breach of warranty claim arises out of the conduct, transaction, and occurrences set out in Ms. Jenkins's original complaint, Ms. Jenkin's proffered breach of warranty claim relates back to that pleading, which

amendments, proposed in December 2011, should relate back to the filing of Thorn v. Novartis, Case No. 3:04-CV-586, on December 10, 2004, despite the fact that the Plaintiff was *not* a party to Thorn when it filed and the case was never certified as a class action.

Alternatively, if the Court were to toll the statute of limitations for the ten months that Thorn v. Novartis was pending as a proposed class action pursuant to a class action tolling doctrine, see Tigg v. Pirelli Tire Corp, 232 S.W.3d 28 (Tenn. 2007) (discussing but not adopting this doctrine), and tolled approximately ten months representing the period during which the class certification request was pending in Thorn v. Novartis, No. 3:04-CV-586, the Plaintiff's claim would still be barred. Subtracting ten months from twenty-eight months that elapsed between April 2, 2004, and August 9, 2006, does not reduce the time elapsed to less than twelve months, and thus, does not save the claim.

Based upon the foregoing, the undersigned finds the addition of Count III would be futile. Accordingly, to the extent Plaintiff seeks to amend assert the additional theory of breach of implied warranty contained in Count III, this request is **DENIED** based upon futility. Further, and for the same reasons, the Court finds that the Plaintiff's request to add Zometa is not well-taken, because this claim is barred by the statute of limitations contained in Tennessee Code Annotated § 28-3-104, and the request to add Zometa is **DENIED**.

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for statute of limitations purposes, is **June 8, 2005**." [Doc. 65 at 6-7].

C. CONCLUSION

Based upon the foregoing, the Plaintiff's Motion to Amend **[Doc. 60]** is **GRANTED IN PART** and **DENIED IN PART**. Plaintiff may file an Amended Complaint deleting allegations of negligence *per se* and correcting the erroneous reference to Merck, rather than Novartis, on or before **April 30, 2013**. Given the relatively minor changes to be made, the Defendant shall file any responsive pleading or motion on or before **May 15, 2013**.

IT IS SO ORDERED.

ENTER:

s/ C. Clifford Shirley, Jr.
United States Magistrate Judge