

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DAWNETTE BREDBERG)
AND MICHAEL BREDBERG)

Plaintiffs,)

v.)

Boston Scientific Corporation)
(D/B/A Mansfield Scientific, Inc.))

And Microvasive, Inc.,)

Defendants.)

C.A. No.: N20C-10-031 PEL

Submitted: January 4, 2021

Decided: June 2, 2021

ON DEFENDANT’S MOTION TO DISMISS – MOTION GRANTED

OPINION AND ORDER

*Robert J. Leoni, Esquire, Shelby & Leoni, 221 Main Street Wilmington, DE 19804,
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Jones, J.

Plaintiffs Dawnette and Michael Bredberg (the “Bredbergs”) have brought the instant products liability action against Defendant Boston Scientific Corporation (“Boston Scientific”). According to the Complaint filed in this action, Dawnette Bredberg suffered injuries after receiving surgery to implant a pelvic mesh device manufactured by Boston Scientific called the Obtryx to treat stress urinary incontinence in April of 2005. The Complaint in this action asserts direct claims for Negligence (Count I), Breach of Warranty (Count II), and Failure to Warn (Count III) as well as a derivative claim for Loss of Consortium (Count IV).

Defendant has filed a Motion to Dismiss the action, arguing that the Bredbergs’ claims are time-barred by the statute of limitations and that they are deficiently plead. For the reasons articulated below, the Defendant’s Motion is **GRANTED** as plaintiffs’ action is time-barred.

BACKGROUND

The background of this case is taken from the factual allegations set forth in Plaintiffs’ Complaint in this action and the exhibits thereto. These allegations are presumed to be true at the Motion to Dismiss stage of this litigation.

Defendant Boston Scientific is a Delaware Corporation engaged in the business of designing, manufacturing, marketing, packaging, labeling, and selling medical devices.¹ One of Defendant’s products is called the Obtryx, which is a pelvic mesh device targeted at women who suffer from pain, discomfort, and stress urinary

¹ Compl. ¶¶ 2-3

incontinence as a result of the weakening or damage caused to the walls of the vagina.² According to the Complaint, The Obtryx “contain[s] a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, emerging scientific evidence suggests that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population who have undergone surgery to implant it. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.”³

Plaintiffs Dawnette and Michael Bredberg are married and reside in Tabor, Iowa.⁴ On or about April 20, 2005, Dawnette underwent surgery in Iowa which implanted her with an Obtryx device that was designed, manufactured, packaged, labeled, and sold by Defendant.⁵ Dawnette was implanted with the Obtryx with the intention of treating her for stress urinary incontinence, which is among the uses for which Defendant marketed and sold the Obtryx.⁶ The Complaint claims that as a result of the Obtryx implantation, Dawnette has “suffered serious bodily injuries, including, but not limited to erosion, and other injuries” and that “as a result of having the [Obtryx] implanted into her, Dawnette Bredberg has experienced significant mental and physical pain and suffering and has sustained permanent

² Compl. ¶ 4.

³ Compl. ¶ 5.

⁴ Compl. ¶ 1.

⁵ Compl. ¶ 45; Pl.’s Response Br. To Def.’s Mot. To Dismiss (hereinafter “Response”) at 1.

⁶ Compl. ¶ 46.

injury.”⁷ Dawnette underwent revision surgery on December 25, 2005, in order to remove pelvic mesh from the Obtryx which had eroded inside of her body.⁸ Dawnette underwent an additional revision surgery to remove pelvic mesh from her body on October 3, 2018.⁹ The Complaint asserts that “[d]espite the multiple revision surgeries, Mrs. Bredberg suffered from and continues to suffer from: pain, dyspareunia, and vaginal scarring due to complications from Defendant’s defective mesh product.”¹⁰

Plaintiffs filed the Complaint in this action on October 2, 2020. Boston Scientific filed a Motion to Dismiss on November 23, 2020. The matter has been fully briefed and is ripe for decision.

STANDARD OF REVIEW

Defendant has moved to dismiss this action pursuant to Superior Court Rules of Civil Procedure 12(b)(6), 8(a), and 9(b).¹¹

Under Superior Court Rule 12(b)(6), the Court may dismiss an action for failure to state a claim upon which relief can be granted. In order to state a claim upon which relief can be granted, a plaintiff need only make a “short and plain statement of the claim showing that the pleader is entitled to relief.”¹² However, “conclusory allegations that lack a factual basis will not survive a motion to dismiss”

⁷ Compl. ¶ 48, 50.

⁸ Response at 1.

⁹ *Id.*

¹⁰ *Id.*

¹¹ Both the Plaintiffs and Defendant agree that Delaware procedural law and Iowa substantive law apply to this action.

¹² Supr. Ct. R. 12(b)(6).

under this standard.¹³ On a Motion to Dismiss under Rule 12(b)(6), the Court will accept all well-pled allegations of the Complaint as true and will draw all reasonable inferences that logically flow from those allegations in favor of the plaintiff as the non-moving party.¹⁴ A Court can dismiss for failure to state a claim under Rule 12(b)(6) if “it appears with reasonable certainty that the plaintiff could not prove any set of facts that would entitle her to relief.”¹⁵

STATUTE OF LIMITATIONS

Defendant asserts that this action should be dismissed in its entirety due to expiration of the statute of limitations. The parties’ briefing does not indicate whether they agree that the law of the forum state (Delaware) or the law of the state where the alleged torts took place (Iowa, where Dawnette Bredberg had her initial Obtryx surgery and presumably her revision surgeries) applies to Plaintiff’s claims.¹⁶ It is not necessary to decide which state’s law applies to the substantive claims, however, because Plaintiff’s claims on all counts are time-barred by the statute of limitations under both Delaware and Iowa law. Delaware and Iowa both apply a two-year limitations period for personal injury claims alleging product liability.¹⁷

¹³ *Shah v. Am. Sols., Inc.*, N11C-07-196, 2012 WL 1413593, at *2 (Del. Super, Mar. 8, 2012).

¹⁴ *Tanisha Maretta Williams v. Newark Country Club*, 2016 WL 6781221 at 1 (Del. Super., November 2, 2016); *William L. Spence Jr., v. Allison J. Funk, et al.*, 396 A.2d 967, 968 (Del. 1978); *Richard Clinton, et al. v. Enterprise Rent-a-Car Co., et al.*, 977 A.2d 892, 895 (Del. 2009).

¹⁵ *Rammuno v. Cawley*, 705 A 2d 1029, 1034 (Del 1998).

¹⁶ The Plaintiffs’ Response indicates that Dawnette Bredberg’s initial surgery took place at a hospital located in Council Bluffs, Iowa. The Response and other briefing do not expressly state where Dawnette underwent the two revision surgeries described in the Response. The Court will assume that the revision surgeries took place in Iowa, where her initial surgery took place and where the Bredbergs currently reside.

¹⁷ 10 *Del. C.* § 8119; Iowa Code Ann § 614.1(2A). Iowa also has a statute of repose which limits a plaintiff’s right to bring personal injury actions based on a product defect. Under the Iowa statute of repose, a product defect action must be brought within 15 years from the date the product was purchased or installed for use. Iowa Code Ann §

A. PERSONAL INJURY CLAIMS

This Court has previously observed that “Parties rarely dispute which statute of limitations applies or what the statute says.”¹⁸ Instead, statute of limitations disputes almost always revolve around the date on which a plaintiff’s cause of action accrued because it is this date that determines when the statute of limitations begins to run.¹⁹ This case is no exception. Defendant argues that Dawnette Bredberg’s personal injury claims accrued in either December of 2005 following her first revision surgery or October 2008 following a public notice of defects associated with pelvic mesh devices issues by the Food & Drug Administration. In either case, the statute of limitations for Plaintiffs’ personal injury claims would have expired long before Plaintiffs filed the instant lawsuit on October 2, 2020. Plaintiff, by contrast, argues that Dawnette’s claims accrued when she underwent her second revision surgery on October 3, 2018.²⁰ This would mean that the Complaint in this action was timely-filed on October 2, 2020 – one day before the expiration of the limitations period. Defendant’s position is correct, and the statute of limitations expired before this lawsuit was filed.

614.1 (2A). The mesh implant device was installed in this case on April 20, 2005. Under Iowa’s Statute of Repose, the complaint had to be filed by April 20, 2020 – over 5 months before the complaint was filed in this case.

¹⁸ *Burrell v. Astrazeneca LP*, 2010 WL 3706584, at *4 (Del. Supr. 2010).

¹⁹ *Id.*; see also *U.S. Cellular Inv. Co. of Allentown v. Bell Atl. Mobile Sys., Inc.*, 677 A.2d 497, 503 (Del.1996) (“In addressing when an action is time-barred, a necessary first step in the analysis is determining the time when the action accrued.”) (citing *Ewing v. Beck*, 520 A.2d 653, 662-64 (Del.1987)).

²⁰ Response Br. At 15-16

Under Delaware law, a cause of action for personal injuries expires two years from “the date upon which it is claimed that such alleged injuries were sustained.”²¹ There is an exception to this general rule also known as the “inherently unknowable injury” doctrine. Under this doctrine, when an inherently unknowable injury has been sustained by a person who is blamelessly ignorant of the act or omission and injury complained of, and the harmful effect thereof develops gradually over a period of time, the injury is deemed to be “sustained. . .when the harmful effect first manifests itself and becomes physically ascertainable.”²² In other words, tolling of the statute of limitations ends where plaintiff discovers, or in the exercise of reasonable diligence should have discovered, that there is a connection between her injury and the alleged defective product.²³ “The notice standard [for a plaintiff under this doctrine] is not actual notice [of their claim.] It is inquiry notice.”²⁴ A plaintiff is deemed to have inquiry notice of her claim where a reasonable investigation of publicly available sources would have led the plaintiff to discover that they had a potential claim against the defendant.²⁵ After this point, the statute of limitations is no longer tolled.

²¹ 10 Del. C. § 8119.

²² *Burrell v. Astrazeneca LP*, 2010 WL 3706584, at *5 (Del. Supr. 2010)(citing *Layton v. Allen*, 246 A.2d 794, 798 (Del. 1968)).

²³ *Brown v E.I. duPont de Nemours & Co.*, 820 A2d 362,366 (Del Supr., 2003); see also *Burrell* at *5 (citing *Ryan v. Gifford*, 918 A.2d 341, 359 (Del. Ch. 2007). See also *Becker v. Hamada, Inc.*, 455 A.2d 353, 356 (Del.1982) (quoting *Omaha Paper Stock Co. v. Martin K. Eby Constr. Co.*, 193 Neb. 848, 230 N.W.2d 87, 89-90 (Neb.1975) (“Even in malpractice and fraud cases where a discovery rule is applied it is not the actual discovery of the reason for the injury which is the criteria.... [D]iscovery means discovery of facts constituting the basis of the cause of action or the existence of facts sufficient to put a person of ordinary intelligence and prudence on inquiry which, if pursued, would lead to the discovery.”))

²⁴ *Burrell*, at *6.

²⁵ *Id.*

In the instant case, Plaintiff had a second mesh revision surgery in October of 2005. In 2008 the FDA issued a notice that there was a connection between the type of symptoms Plaintiff suffered and pelvic mesh implants. These two facts lead this Court to conclude that by 2008, Plaintiff's claims had accrued, and the statute of limitations had started to run. This means that the statute of limitations expired two years later in 2010 at the latest. The Complaint in this action was not filed until 2020, and by this time the products liability claims were time-barred.

B. DOCTRINE OF FRAUDULENT CONCEALMENT

Plaintiffs next claim that the doctrine of fraudulent concealment (the “doctrine”) applies to this case and estops Boston Scientific from asserting any statute of limitations defense.²⁶ A party wishing to invoke the doctrine must prove each of the following four elements: “(1) the defendant made a false representation or concealed material facts; (2) the plaintiff lack[ed] knowledge of the true facts; (3) the defendant intended the plaintiff to act upon such [false] representations; and (4) the plaintiff did in fact rely upon such [false] representations.”²⁷ A plaintiff asserting the doctrine must also show that the defendant “engaged in some affirmative act to conceal the cause of action” unless the defendant bears a confidential or fiduciary relationship to the plaintiff.²⁸ This act of affirmative concealment “must be independent of and

²⁶ *Skadburg v. Gately*, 911 N.W.2d 786 (Iowa 2018) (holding that the doctrine of fraudulent concealment estops a defendant from asserting a statute of limitations defense, but does not affect the tolling of a limitations period for the action.)

²⁷ *Christy v. Miulli*, 692 N.W.2d 694, 702 (Iowa 2005).

²⁸ *Skadburg*, at 798.

subsequent to the original wrongdoing establishing liability.”²⁹ Additionally, “the circumstances justifying an estoppel end when the plaintiff becomes aware of the fraud, or by the use of ordinary care and diligence should have discovered it.”³⁰ Plaintiffs’ reliance on this doctrine is misplaced and the doctrine in inapplicable to this case.³¹

As discussed above, Plaintiff had inquiry notice of the connection between her symptoms necessitating the first revision surgery and the mesh inserted into her body by 2008 at the latest. As such Plaintiff cannot meet the requirements of the fraudulent concealment doctrine because she should have discovered the alleged fraud by due diligence long before 2020.

Plaintiffs’ reliance on the fraudulent concealment doctrine also fails for a second reason. A plaintiff asserting the doctrine must also show that the defendant “engaged in some affirmative act to conceal the cause of action” unless the defendant bears a confidential or fiduciary relationship to the plaintiff.³² Boston Scientific did

²⁹ *Id.*

³⁰ *Id.* (internal citations and quotations omitted.)

³¹ As an initial matter, it was procedurally appropriate for Plaintiffs to invoke the doctrine for the first time in this litigation in their Opposition Brief. Defendant has argued that Plaintiff’s use of the doctrine is procedurally barred because Plaintiffs raised it “for the first time in their Opposition [Brief in response to the Defendant’s Motion to Dismiss.]” Defendant appears to be suggesting that Plaintiff had to invoke the doctrine in the Complaint. Defendant cites the Iowa case *Estate of Anderson* for the proposition that “a party seeking shelter under the doctrine of fraudulent concealment *must plead and prove*” the doctrine’s elements. Def.’s Reply Br. At 4 (citing *Est. of Anderson ex rel. Herren v. Iowa Dermatology Clinic, PLC*, 819 N.W.2d 408, 415 (Iowa 2012)) (emphasis added). Defendant misconstrues the use of the term “plead” in this case. The term “plead” does not mean that a plaintiff in a civil case must anticipate that a defendant will seek to dismiss their case due to expiration of the statute of limitations, and preemptively address that argument by explicitly invoking the doctrine of fraudulent concealment in the initial complaint. Such a requirement would make little sense, since the doctrine is a counterargument which will be invoked *in response to* a claim that the statute of limitations has expired in a motion to dismiss. Instead, the term “plead” in this context simply means that the facts upon which the doctrine is invoked must be included in the pleadings. While Plaintiff has failed to do so in this case, it was nevertheless procedurally appropriate for the Plaintiffs to invoke the doctrine of fraudulent concealment for the first time in their Response Brief.

³² *Skadburg*, at 798.

not bear a fiduciary relationship to either of the Plaintiffs. While Plaintiffs correctly point out that under Iowa law, “the close relationship of trust and confidence between patient and physician gives rise to duties of disclosure which may obviate the need for a patient to prove an affirmative act of concealment,”³³ they overlook a critical distinction in this case: this is an action against the manufacturer of the medical device, not the physician who implanted it. Boston Scientific was not Dawnette’s physician, and any claims of a special patient-physician relationship between her and Boston Scientific are misplaced.³⁴

As such, the statute of limitations under both Delaware and Iowa law expired before the Plaintiffs filed the instant litigation in October of 2020. Plaintiff’s claims on Counts I, III, and IV are therefore barred by the statute of limitations, and the Defendant’s Motion to Dismiss is **GRANTED** with respect to these claims.

C. Breach of Warranty Claims

Boston Scientific has also moved to dismiss Plaintiff’s claim for breach of warranty on the basis that the statute of limitations had expired by the time Plaintiffs filed their Complaint. Delaware applies a four-year statute of limitations to breach of warranty claims.³⁵ Iowa applies a five-year statute of limitations to breach of warranty claims.³⁶ Breach of warranty claims accrue upon tender of delivery,

³³ *Koppes v. Pearson*, 384 N.W.2d 381, 386 (Iowa 1986).

³⁴ Additionally, it is a mischaracterization to claim that any special standards that apply to a physician’s duties of disclosure are “fiduciary duties.”

³⁵ 10 *Del. C.* § 2-725

³⁶ Iowa Code Ann. § 614.1(4)

regardless of the aggrieved party's lack of knowledge of the breach.³⁷ Here, the Plaintiffs' breach of warranty claims accrued on the date of Dawnette's pelvic mesh implantation surgery on April 20, 2005. The statute of limitations for the breach of warranty claims expired either four or five years later in April 2009 or 2010 depending on whether the Delaware or Iowa statute of limitations applies.³⁸ This was over a decade before Plaintiffs filed the Complaint in this action. In this case, Plaintiff's warranty claims are barred under either Delaware or Iowa law and it makes no difference which state's statute of limitations applies. The statute of limitations for a breach of warranty claim under either Delaware or Iowa law expired before the Plaintiffs initiated this lawsuit. Accordingly, Boston Scientific's Motion is **GRANTED** with respect to Plaintiff's claim for breach of warranty, and Plaintiff's Count III for Breach of Warranty is **DISMISSED**.

D. Loss of Consortium Claim

Michael Bredberg has also asserted a derivative claim for loss of consortium in this action based upon his wife Dawnette's direct claims. Since the direct claims in this action have been dismissed for the reasons stated above, Michael's derivative claim cannot survive Defendant's Motion to Dismiss. The Motion is **GRANTED**

³⁷ See *Lima Delta Company v. Gulfstream Aerospace Corporation*, 2019 WL 624589 (Del. Super. 2019); see also *Hagan v. Boston Scientific Corp.*, at *8 (Del. Super. 2021); *Barnett v. Boston Scientific Corp.*, at *7 (Del. Super. 2021). Iowa Code § 554.2725; *Skadburg v Gately*, 911 N.W.2d 786 (Iowa Supr., 2018). The result is the same under Iowa law. See *Franzen v. Deere and Co.*, 334 N.W.2d 730, 733 (Iowa 1983) (breach of warranty claims subject to a two-year statute of limitations under Iowa law.)

³⁸ If this Court were forced to choose which of the two state's statute applies under Delaware's Borrowing Statute, 10 *Del C.* § 8121, this Court would apply the Delaware statute of limitations as that is the shorter of the two statute of limitations as between Delaware and Iowa. *Burrell*, 2010 WL 3706584 (Del Super. 2010).

with respect to Plaintiffs' Count IV for loss of consortium, and Plaintiffs' Count IV is **DISMISSED** from this action.

CONCLUSION

In summary, the Defendant's Motion to Dismiss is GRANTED for both Dawnette's personal injury and breach of warranty claims described in Counts I-III of the Complaint. Since the derivative loss of consortium claims in this case are derivative of Dawnette's direct claims, Defendant's Motion is also GRANTED with respect to Plaintiff's Count IV for Loss of Consortium and that claim is DISMISSED.

Accordingly, the Defendant's Motion to Dismiss is GRANTED in full and all claims in this case are DISMISSED.

IT IS SO ORDERED.

/s/ Francis J. Jones
Francis J. Jones, Judge

cc: File&ServeXpress