

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

PROVIDENCE, SC

SUPERIOR COURT

(FILE – NOVEMBER 9, 2007)

PAMELA SHEARIER

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v.

C.A. No. PC/07-2639

DAVOL INC. and C.R. BARD, INC.

DECISION

GIBNEY, J. Davol Inc. and C.R. Bard, Inc. (“Defendants”) move to dismiss Pamela Shearier’s complaint pursuant to Super. Civ. P. 12(b)(6). Ms. Shearier (“Plaintiff”) objects to the motion.

**I
Facts and Travel**

On May 23, 2007, Ms. Shearier filed a complaint in this Court, alleging that she had been severely injured by a defective and dangerous condition of a Composix® Kugel Mesh Patch (“Kugel Patch”) designed, manufactured, and distributed by Defendants. On September 16, 2003, Ms. Shearier underwent an incisional hernia repair, during which a Kugel Patch was implanted in her abdomen. Within a few months of this procedure, Ms. Shearier began to experience debilitating abdominal pain, for which she sought medical treatment. Her physicians, unable to diagnose the cause of her suffering, attributed it to standard hernia repair or infection.

Ms. Shearier’s condition worsened progressively, and by January 2004, hospitalization and surgery were necessary. During the surgery, her physicians discovered that the ring which held the Kugel Patch mesh in an oval shape had fractured, and the broken ends were protruding into Ms. Shearier’s abdomen. The area surrounding the device had become severely infected, and the Kugel Patch was removed. As result, Ms. Shearier was treated for sepsis, and required to undergo a second surgery and additional hospitalization.

Ms. Shearier alleges that her injuries were the result of a dangerous defect associated with Defendants' product. She further alleges that Defendants conducted post-market design research on the Kugel Patch, which included a survey of physicians using the product in 2002. The survey resulted in unfavorable responses and complaints, and Plaintiff contends that Defendants either intentionally and actively concealed these results and complaints, or negligently failed to monitor these surveys. In 2004, Defendants uncovered a serious design defect in the memory recoil ring of the mesh Kugel Patch. Plaintiff alleges that Defendants withheld knowledge of this defect from individuals implanted with the Kugel Patch, their physicians, and the Federal Drug Administration (FDA). Defendants waited until 2005 to initiate a partial distribution hold, to recall certain sizes of the Kugel Patch, and to notify the FDA and the public of the severity of complications resulting from the product's defective design. In 2006 and 2007, the FDA continued to recall additional sizes and variations of the Kugel Patch. Defendants never notified Plaintiff of the defect, and she contends that she did not learn of it until after the FDA recalled the product in 2006. Ms. Shearier's complaint alleges negligence, strict product liability, negligent infliction of emotional distress, intentional infliction of emotional distress, breach of implied warranty, failure to warn, and fraud.

Defendants have filed the instant motion to dismiss, averring that Plaintiff's claims are untimely under G.L. 1956 § 9-1-14(b). Defendants contend that Plaintiff knew or should have known of her injuries resulting from the Kugel Patch shortly after her implant surgery in September 2003, or at the latest by her explant surgery in February 2004. Defendants argue that Plaintiff's physicians were able to determine by that point that her pain was not a typical post-operative complication, and it was at this point—when the cause of her injury was manifested—that the three-year time limit imposed by the statute of limitations began to run. Defendants

contend that Plaintiff has failed to make an affirmative pleading as to how her cause of action is protected under the discovery rule, and as she did not commence this action until May 2007, her claims are time-barred.

Plaintiff opposes the motion to dismiss on the grounds that she was not aware either that the Kugel Patch was dangerously defective, or that the defect caused her injury until after Defendants had informed the FDA and the public of the defective condition in 2005. She argues that it was impossible to connect her injury to the product's design defect before the Defendants' initial recall in 2005, and that the three-year statute of limitations was therefore tolled until this point. Plaintiff additionally contends that her allegations of fraud against the Defendants tolls the statute of limitation under G.L. 1956 § 9-1-20. Plaintiff avers that she has presented in her complaint factual allegations that the Defendants concealed the existence of the defect (and thus, Ms. Shearier's cause of action) at least until they initiated the first recall in 2005, and perhaps until the formal recall through the FDA in 2006. Therefore, Plaintiff argues that the three-year statute of limitations began to run in either 2005 or 2006 and, as a result, her 2007 complaint was timely.

II Standard of Review

In determining whether to grant a Rule 12(b)(6) motion, the Court "assumes the allegations contained in the complaint to be true and views the facts in the light most favorable to the plaintiffs." Giuliano v. Pastina, 793 A.2d 1035, 1036 (R.I. 2002) (citations omitted). The standard is lenient to the plaintiff, and "no complaint will be deemed insufficient unless it is clear beyond a reasonable doubt that the plaintiff will . . . not be entitled to relief under any set of facts which might be proved in support of his [or her] claim." Bragg v. Warwick Shoppers World, 102 R.I. 8, 12, 227 A.2d 582, 584 (R.I. 1967). It is well-settled that a complaint is not

insufficient unless the face of the complaint reveals “some insuperable bar to relief.” Goldstein v. Rhode Island Hosp. Trust Nat’l Bank, 110 R.I. 580, 586, 296 A.2d 112, 115 (R.I. 1972). If in viewing the four corners of the complaint, the trial justice finds that the dates included show the action to be untimely, the statute of limitations may present such a bar to relief. See Martin v. Howard, 784 A.2d 291, 299 (R.I. 2001). However, the “application of the statute of limitations is a matter of law for the trial justice to determine.” Ashey v. Kupchan, 618 A.2d 1268, 1270 (R.I. 1993).

III Analysis

Under § 9-1-14(b), causes of action brought for personal injury must be “commenced and sued within three (3) years next after the cause of action shall accrue, and not after.” The time of accrual under the rule has been interpreted in some product liability cases to be the time of injury. See e.g. Renaud v. Sigma-Aldrich Corp., 662 A.2d 711, 714 (R.I. 1995) (citations omitted). However, the Rhode Island Supreme Court has adopted the discovery rule, which states “the statute of limitations does not begin to run until the plaintiff ‘discovers, or with reasonable diligence should have discovered, the wrongful conduct’” Supreme Bakery, Inc. v. Bagley, 742 A.2d 1202, 1204 (R.I. 2000) (citations omitted); see also Wilkinson v. Harrington, 104 R.I. 224, 233, 243 A.2d 745, 753 (1968) (first applying the discovery rule in medical malpractice cases). The discovery rule has been applied to various types of personal injury actions, and designed to give the plaintiff the reasonable opportunity to “become cognizant of the injury and its cause before the statute of limitations begins to run.” Anthony v. Abbott Laboratories, 490 A.2d 43, 45 (R.I. 1985); see also O’Coin v. Woonsocket Inst. Trust

Co., 535 A.2d 1263, 1266 (R.I. 1988) (noting the types of actions, where the rule has been held to apply).

The discovery rule was applied specifically to product liability cases in the Rhode Island Supreme Court's decision, Anthony v. Abbott Laboratories, 490 A.2d 43, 46 (R.I. 1985). Although this Court is mindful that the decision in Anthony has been narrowly interpreted, the Court is persuaded that it applies here. See Benner v. J.H. Lynch & Sons, 641 A.2d 332, 337 (R.I. 1994). After Anthony, and the subsequent decisions which limit its holding, the discovery rule applies "in a drug product-liability action where the manifestation of an injury, the cause of that injury, and the person's knowledge of the wrongdoing by the manufacturer occur at different points in time." Benner, 641 A.2d at 337 (citing Anthony, 490 A.2d at 46).

In this motion to dismiss, this Court must accept as true Plaintiff's allegation that Defendants failed to disclose the design defect in the Kugel Patch until 2005, when Defendants initiated the first recall of the product and notified the FDA. See Giuliano, 793 A.2d at 1036. Accepting this fact as true, Plaintiff could not reasonably have known that the design defect in the Kugel Patch caused her injury until 2005, several years after the injury occurred. It would be illogical to assert that upon her injury in 2003, Plaintiff would assume that the Kugel Patch fractured as a result of a design defect—rather than any other of the myriad possible causes—and immediately commenced action against Defendants. Even Plaintiff's physicians were not aware of the precise cause of her injury when it occurred in 2003. Without Defendants' release of information about the defect, Plaintiff could not have been cognizant of the fact that this defect caused her injury. See Anthony, 490 A.2d at 45.

Even if this Court reads the discovery rule—as it is established in Anthony—to apply only to such cases where the plaintiff's injury, discovery of the cause of injury, and discovery of

the defendant's wrongdoing occur at three different points in time, the rule would still apply to Ms. Shearier's claim. She alleges that she discovered her injury in 2003, learned the cause of the injury during her explant surgery in 2004, and learned of the alleged wrongdoing on the part of the Defendants in 2005. Viewing Ms. Shearier's claims in a light most favorable to her, the Court finds that the statute of limitations should be tolled under the discovery rule, and thus, Plaintiff's claim is sufficient and timely. See Giuliano, 793 A.2d at 1036.

Under the standard of review, this Court must also accept as true the Plaintiff's allegation of fraudulent concealment. See id. Plaintiff has pled that Defendants knew or should have known of the Kugel Patch's design defect, that they delayed release of that information for several years, and that they misrepresented the product as safe for use. Taking Plaintiff's claim of fraud as true, the statute of limitations should be tolled under § 9-1-20. The statute states:

“If any person, liable to an action by another, shall fraudulently, by actual misrepresentation, conceal from him or her the existence of the cause of action, the cause of action shall be deemed to accrue against the person so liable at the time when the person entitled to sue thereon shall first discover its existence.” Section 9-1-20.

Plaintiffs have sufficiently alleged actual misrepresentation and concealment on the part of the Defendants. See Renaud v. Sigma-Aldrich Corp., 662 A.2d 711, 714 (R.I. 1995) (finding that “[i]n order to toll the running of the statute of limitations . . . there would have to be a showing that . . . the party asserting the statute-of-limitations defense attempted by fraud or misrepresentation to conceal the existence of the cause of action”) (citing Benner v. J.H. Lynch & Sons, Inc., 641 A.2d 332, 337-38 (R.I. 1994)). Here, Plaintiff has alleged fraud, and has indicated facts that, if proven, would support her claim. See Bragg, 102 R.I. at 12, 227 A.2d at 584. If taken as true, Plaintiff's allegations would result in a tolling of the statute of limitations under § 9-1-20. See Renaud, 662 A.2d at 714. Therefore, there is no insuperable bar to

Plaintiff's recovery, and thus, Defendants' motion to dismiss is denied. Goldstein, 110 R.I. at 586, 296 A.2d at 115.

IV Conclusion

The sole function of a motion to dismiss is to test the sufficiency of the complaint. McKenna v. Williams, 874 A.2d 217, 225 (R.I. 2005). If the Plaintiff is entitled to relief under any conceivable set of facts, the motion to dismiss must be denied. Id. Viewing the facts in a light most favorable to the Plaintiff, this Court finds that Ms. Shearier has alleged a set of facts which show that the statute of limitations does not present an insuperable bar to her recovery. Accordingly, Defendants' motion to dismiss under Rule 12(b)(6) is denied. Counsel shall prepare the appropriate order for entry.