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SCANNED ON 10/22/2004

SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: Sherry Klein Heitler Justice

PART 30

0104337/2001

INDEX NO. 104337/01

ROSNER, WILLIAM
vs
MIRA

MOTION DATE

MOTION SEQ. NO. (004)

SEQ 4 00

MOTION CAL. NO.

AMEND SUPPLEMENT PLEADINGS

Is motion to/for

	PAPERS NUMBERED
Notice of Motion/ Order to Show Cause — Affidavits — Exhibits ...	
Answering Affidavits — Exhibits	
Replying Affidavits	

Cross-Motion: ☐ Yes ☐ No

Upon the foregoing papers, it is ordered that this motion

is decided in accordance with the memorandum decision dated 10-18-04

FILED

OCT 22 2004

COUNTY CLERK'S OFFICE

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE

Dated: 10-18-04

SHERRY KLEIN HEITLER J.S.C.

Check one: ☐ FINAL DISPOSITION ☑ NON-FINAL DISPOSITION

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: IAS PART 30

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WILLIAM ROSNER and KAREN ROSNER,

Index No. 104337/01

Plaintiffs,

DECISION & ORDER

-against-

MIRA, INC., EYE RESEARCH INSTITUTE OF RETINA FOUNDATION and THE SCHEPENS EYE RESEARCH INSTITUTE,

Defendants.

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SHERRY KLEIN HEITLER, J.:

Motion sequence numbers 004 and 005 are consolidated herein for disposition. In motion sequence number 004, plaintiffs William Rosner and Karen Rosner (Rosner) move, pursuant to CPLR § 3025, for leave to amend their complaint to seek punitive damages for injuries arising from the use of the "Miragel" implant, an ophthalmic polymer designed to correct torn retinae, that is used as a scleral buckling device. Defendant Mira, Inc. (Mira) cross-moves for leave to amend its answer to include the affirmative defense of statute of limitations.

In motion sequence number 005, defendant The Schepens Eye Research Institute (SERI) moves, pursuant to CPLR § 3212 for summary judgment dismissing Rosner's complaint in its entirety on the grounds that it is time-barred as to SERI.

Mira manufactured the Miragel implant from the spring of 1985 through October 1994. The Miragel was designed and tested by SERI. In 1990, Mira was marketing the Miragel implant as one for which "[f]ifteen years of rigorous laboratory research and well-designed clinical trials have shown Miragel to be safe, effective and well tolerated by the eye." Notice of Motion,

Exhibit D.

In the summer of 1992, Rosner had three surgeries on his left eye. In one procedure, to repair a left-eye retinal detachment at Albany Memorial Hospital, Rosner, who already had a silicone implant in the eye, was fitted with a Miragel implant. In August and October of that year, Rosner complained of pain and double vision, but the conditions eased and Rosner had many years with no complications in the eye.

On December 7, 1998, Rosner saw a retinologist, Stanley Chang, M.D. (Chang), because he felt a foreign body under his left eye lid and intermittent pain in his left eye. Chang recommended that he continue to observe Rosner, and if the discomfort continued that the implant might have to be removed.

In May of 1999, Rosner saw neurologist Dr. Carl Braun, M.D. (Braun) in connection with an incident during which he developed a slow diminution of vision in his left eye. At that appointment, Rosner informed Braun that Chang thought there might be a relative constriction of blood vessels in the left eye. After the examination, Braun concluded that there was probably no amaurosis fujax (transient monocular blindness), but that there was a remote possibility that a migraine-type affliction was the cause of the incident.

In December of 1999, despite Chang's continued recommendation to do nothing, Rosner decided to have the Miragel implant removed. When Chang attempted to remove the Miragel in January of 2000 it shattered in Rosner's eye.

After the procedure, Rosner was still experiencing pain. Chang performed tests, including an MRI, to identify the cause of the continued pain. Chang discovered that a remnant of the Miragel that had shattered remained in the eye of Rosner. Nonetheless, Chang was still

unable to identify, with certainty, the cause of Rosner's pain. Consequently, in a second procedure, he removed the Miragel remnant, and also removed the other implant to check for potential infection. A retinal detachment ensued, and Rosner now suffers permanent loss of vision, and permanent pain, in his left eye.

SERI's Motion for Summary Judgment – Motion Sequence Number 005

SERI moves for summary judgment based on the affirmative defense that the complaint was not filed within the applicable statute of limitations, and is, thus, time-barred.

This cause of action for personal injury, due to the implantation of a medical device in Rosner's body, is governed by CPLR § 214-c, which states that:

> the three year [limitations period applicable to implantation of devices within the body] shall be computed from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier.

SERI argues that the limitations period accrued, at the latest, when Rosner first complained of eye pain, at an appointment with Chang, in December of 1998. SERI maintains that Chang observed the swelling of the Miragel implant at that appointment, that the swelling is the pertinent malfunction, and that Rosner was, therefore, on notice that the implant had malfunctioned. Therefore, SERI contends that the statute of limitations started running in December of 1998, and Rosner's claim against SERI is time-barred because it was not filed until September of 2002, more than three years later.

Rosner argues that: (i) the primary condition upon which his claim is based is not the swelling of the Miragel (which is merely a symptom), but the loss of vision that occurred as a result of the July 2000 operation; and (ii) the fragmentation of the Miragel made removal of the

other implant necessary, which, in turn, caused the ensuing loss of vision. Thus, according to Rosner, the limitations period began running in 2000, when the second operation took place, and the filing of the claim against SERI in September of 2002 was timely. In addition, Rosner asserts that in any event, there were two separate injuries (the pain from the swelling, and the shattering of the Miragel), and, thus, New York's "two-injury rule" applies, and Rosner may recover.

Summary judgment is governed by CPLR 3212, under which SERI must show that "there is no defense to the cause of action or that the cause of action or defense has no merit." Here, SERI, as movant, must make a prima facie showing of entitlement to judgment as a matter of law, tendering sufficient evidence to demonstrate the absence of any material issue of fact. Winegrad v New York Univ. Med. Ctr., 64 NY2d 851, 853 (1985); Zuckerman v City of NY, 49 NY2d 557, 562 (1980); Sillman v Twentieth Century-Fox Film Corp., 3 NY2d 395, 404 (1957).

The court finds that issues of fact preclude summary judgment. There are issues of fact as to: (i) whether the pain Rosner was experiencing in 1998 was identifiable to the Miragel; and (ii) whether the swelling of the Miragel in 1998 constituted, or should have constituted, notice that the device was defective or malfunctioning. The court also finds, that, in any event, the two-injury rule applies, and Rosner may, at least, maintain a cause of action for the injuries arising from the shattering of the Miragel.

Chang examined Rosner in 1998, at which time Chang was not able to identify the cause of the pain in Rosner's eye and advised him to endure it. In 1999, Rosner had an episode of temporary vision loss and pain in the eye. As a result of this episode, Rosner saw a neurologist, Braun, who ran various tests. Braun concluded that there was a remote possibility that a migraine-type affliction was the cause of the incident. LaMarche Affidavit, Exhibit H, at 2.

Thus, in early 1999, neither Braun, nor Chang, could relate the pain directly to the putative malfunction in the Miragel. This gives rise to a reasonable inference that the pain did not give Rosner notice that the implant was defective. See Myers v Fir Cab Corp., 64 NY2d 806 (1985) (on a motion for summary judgment defendant is entitled to the benefit of every favorable inference that may be drawn from the competing contentions of the parties).

Also, Chang, whose statements enjoy the benefit of every favorable inference (id.), did not discover the cause of the pain in Rosner's left eye even after having performed the first operation on Rosner. Chang Affirmation, ¶ 5. Thus, in a second operation, Chang also removed the silicone implant from Rosner's eye, suspecting that the pain was being caused by an infection unrelated to the Miragel. The fact that Chang, even after removing parts of the Miragel, still did not know the source of the pain also gives rise to an inference that Rosner was not on notice that the Miragel implant may have caused his injury.

The function of the court is one of issue finding, not issue determination. Sillman v Twentieth Century-Fox Film Corp., 3 NY2d at 404; Wiener v Ga-Ro Die Cutting, 104 AD2d 331, 333, affd 65 NY2d 732 (1985). Thus, the court cannot determine that the pain that Rosner felt, did, or should have, put him on notice that in an eye with two implants, specifically the Miragel, and not the other implant, caused, or should have been known to cause, his pain. See e.g. Braune v Abbott Labs., 895 F Supp 530, 556 (ED NY 1995) ("... the date that a plaintiff constructively discovered his or her 'injury' is a mixed question of fact and law to be determined by the jury"). This is especially so when Chang, the treating physician, even after removing the Miragel, could not make such a determination before a second operation. Chang Affirmation, ¶ 5 ("[w]e thought that the Miragel fragment was causing the pain, but we couldn't be certain.... It

was only after there proved to be no infection connected with the silicone buckle that one was able to relate, with reasonable certainty, the pain and inflammation ... to the after-effects of the fragmented Miragel buckle"); Braune v Abbott Labs., supra, 895 F Supp at 550 ("... the American rule of discovery for statute of limitations purposes requires knowledge – or its handmaiden, reasonable diligence in obtaining such knowledge – both of the 'injury' and its unnatural cause").

Finally, New York courts recognize that a single causal factor may produce two diseases that are separate and distinct, and each such disease may give rise to its own cause of action. "Under the [two-injury] rule, diseases that share a common cause may nonetheless be held separate and distinct where their biological manifestations are different and where the presence of one is not necessarily a predicate for the other's development." Geressy v Digital Equip. Corp., 980 F Supp 640, 651 (ED NY 1997), affd in part sub nom Madden v Digital Equip. Corp., 152 F3d 919 (2nd Cir 1998) (citation and internal quotation marks omitted); see also Fusaro v Porter-Hayden Co., 145 Misc 2d 911, 916 (Sup Ct, NY County 1989), affd 170 AD2d 239 (1st Dept 1991); Sweeney v General Print. Inc., 210 AD2d 865, 866 (1994).

Here, Rosner experienced two biological manifestations from the alleged malfunction of the Miragel. The first was allegedly the pain that he experienced in his left eye. The second, separate manifestation, occurred upon the shattering of the Miragel. Although the two-injury rule is inapplicable where continued contact with a causal agent leads to a worsening of the original condition rather than a separate and unrelated injury, the court cannot determine, as a matter of law, whether Rosner's second injury was a result "merely [of] the aggravation, or exacerbation, of that injury by continued contact with the same offending product." Geressy v

Digital Equip. Corp., supra, 980 F Supp at 651 (citation omitted); compare Braune v Abbott Labs., supra, 895 F Supp at 555 ("[w]here the statute of limitations has run on one exposure-related medical problem, a later exposure-related medical problem that is 'separate and distinct' is still actionable under New York's two-injury rule").

It is well settled that if there is any doubt as to the existence of material issues of fact, summary judgment should be denied. Rotuba Extruders, Inc. v Ceppos, 46 NY2d 223, 231 (1978). Thus, the motion of SERI for summary judgment dismissing the action as time-barred is denied.

Motion and Cross Motion for Leave to Amend – Motion Sequence Number 004

Rosner's Motion for Leave to Amend

After substantial discovery, Rosner seeks leave to amend the complaint to include a claim for punitive damages due to: (i) Mira's alleged failure to follow guidelines for the approval of Miragel by the Food and Drug Administration (FDA); (ii) Mira's failure to test Miragel properly; (iii) false representations in the advertising of Miragel; and (iv) Mira's failure to issue a caution to users that the Miragel implants were subject to hydrolysis and becoming friable.

Leave to amend a pleading shall be freely granted absent prejudice or surprise resulting from the delay. CPLR 3025(b); Thomas Crimmins Contr. Co. v City of NY, 74 NY2d 166 (1989). Accordingly, it has been held that "a motion to amend an ad damnum clause, whether made before or after trial should generally be granted." Heller v Louis Provenzano, Inc., 303 AD2d 20, 22 (1st Dept 2003) (citation and internal quotation marks omitted).

Here, Mira has pointed to no prejudice that would result from the amendment. Nonetheless, if the proposed claim patently lacks merit, amendment of a pleading to assert that

claim would serve no purpose but to complicate, needlessly, discovery and trial. Thomas Crimmins Contr. Co. v City of NY, supra, 74 NY2d at 170. Thus, in order "to conserve judicial resources, an examination of the proposed amendment is warranted, and leave to amend should be denied when the proposed pleading is palpably insufficient as a matter of law." Ancrum v St. Barnabas Hosp., 301 AD2d 474, 475 (1st Dept 2003) (citations omitted); see also Sharapata v Town of Islip, 82 AD2d 350, 362 (1st Dept 1981), affd 56 NY2d 332 (1982) (the sufficiency or meritoriousness of a proposed pleading is a threshold issue).

"Unlike a claim for negligence, to establish a claim for punitive damages, plaintiff must demonstrate that the wrong to [him] rose to the level of such wanton dishonesty as to imply a criminal indifference to civil obligations." Heller v Louis Provenzano, Inc., 303 AD2d at 23 (citations and internal quotation marks omitted). Further, "in order to be awarded they must further the public policy which justifies them[;] ... the justification for an award of punitive damages is to punish the wrongdoer, both monetarily, and by making him a public example." Sharapata v Town of Islip, supra, 82 AD2d at 363.

To demonstrate that Mira had a level of wanton dishonesty that implies a criminal indifference to civil obligations, Rosner asserts that Mira: (i) in order to get approval from the FDA to manufacture and market Miragel, either submitted a false 510(k) application, or did not satisfy the FDA requirements for product testing; (ii) failed to keep track of investigational studies, so that it was unable to identify which implants failed and which ones did not; (iii) adopted no tests, protocols, or procedures to adequately demonstrate the long-term safety and efficacy of the implants; (iv) allowed an inaccurate description of Miragel to be placed in sales materials; (v) misrepresented to the FDA and the medical community that early reports of the

degradation of the implants did not apply to the Mira product; and (iv) failed to caution the public about the dangers of the implant.

The FDA has instituted extensive statutory pre-market approval mechanisms for medical products generally. An exception exists, however, for the manufacture and sale of products which are found, through what is termed a 510(k) application, to be "substantially equivalent" to devices already on the market. See e.g. Sowell v Bausch & Lomb, Inc., 230 AD2d 77, 80 (1st Dept 1997).

The misrepresentations that Rosner alleges Mira made in its 510(k) application to the FDA are not apparent from the documentary record. Regardless, if the Miragel was not substantially equivalent to its predecessor product, as required under the Federal Food, Drug, and Cosmetic Act (Act), it is in the province of federal courts that Mira may be held responsible. State fraud-on-the-FDA claims are preempted by federal law. See Buckman Co. v Plaintiff's Legal Comm., 531 US 341, 342 (2001).

Nonetheless, Rosner's complaint also alleges that Mira failed to warn the public about the dangers of the Miragel. Rosner has submitted evidence that in 1990, Mira was marketing the Miragel implant as one for which "[f]ifteen years of rigorous laboratory research and well-designed clinical trials have shown Miragel to be safe, effective and well tolerated by the eye." Notice of Motion, Exhibit D. Meanwhile, a month before this advertising was released, Mira's consultant, Dr. Tolentino, had recommended the surgical removal of Miragel implants from patients because they tended to become friable. Schepens Deposition, Shandell Affirmation, Exhibit C, at 51-52. Mira warned no one, including Rosner, about the danger.

New York recognizes the availability of punitive damages in product liability cases based

on a failure to warn the public. Home Ins. Co. v American Home Prods. Corp., 75 NY2d 196, 204 (1990); see also Rocanova v Equitable Life Assur. Soc. of US, 83 NY2d 603, 613 (1994). Here, Mira has not even disavowed that there was a failure to warn that the Miragel tended to undergo hydrolysis and become friable.

One of the purposes of punitive damages is to deter "those who deliberately and cooly engage in a far-flung fraudulent scheme, systematically conducted for profit." Walker v Sheldon, supra, 10 NY2d at 406. Although there are no all-inclusive rules or principles as to what is an appropriate case for the recovery of punitive damages (id.), in New York, the failure to warn is subject to such damages. Here, the allegations, if proven to be true, would constitute such "wanton dishonesty as to imply a criminal indifference to civil obligations." Heller v Louis Provenzano, Inc., 303 AD2d at 23.

Given that Mira has asserted no prejudice or surprise that would arise from granting Rosner's motion to amend (see Edenwald Contracting Co., Inc. v City of NY, 60 NY2d 957, 959 [1983]), and given that a motion to amend an ad damnum clause should generally be granted (Heller v Louis Provenzano, Inc., supra, 303 AD2d at 22), under the circumstances, the motion to amend the complaint to seek punitive damages is granted.

In partial opposition to the motion to amend, SERI requests modification of the language contained in Rosner's proposed relief clause. The clause currently requests judgment against the defendants, "... as well as punitive and exemplary damages against defendants as shall be called for by the proof and awarded by the Court and/or jury ...." Further Amended Complaint, Shandell Affirmation, Exhibit A, at 11.

SERI argues that the clause should be modified to read: "... as well as punitive and

exemplary damages against defendant MIRA Inc. as shall be called for by the proof ...." because Rosner "never sought to allege reckless, wanton or willful conduct against SERI." La Marche Affirmation, ¶ 4.

In New York, it is not only the form of the action or the particular tort committed that determines the availability of punitive damages. In addition, the moral culpability of the defendant, and motives in acting, may indicate whether punitive damages are available. Young v Robertshaw Controls Co., 123 Misc 2d 580, 588 (Sup Ct, NY County 1983), affd as modified 104 AD2d 84 (3rd Dept 1984); see also Roginsky v Richardson-Merrell, Inc., 378 F2d 832, 842-843 (2nd Cir 1967).

Here, Rosner has alleged no improper conduct or moral culpability on the part of SERI that might be subject to punitive damages. Thus, Rosner is hereby directed to limit the amendment seeking punitive damages to name Mira only.

Mira's Cross Motion for Leave to Amend

Mira cross-moves for leave to amend its answer to include an affirmative defense of statute of limitations. As stated herein, supra, if the proposed claim patently lacks merit (Sharapata v Town of Islip, 82 AD2d at 362), in order to conserve judicial resources, an examination of the proposed amendment is warranted (Ancrum v St. Barnabas Hosp., supra, 301 AD2d at 475).

Here, Mira seeks to amend because Rosner received the Miragel implant in July of 1992, and in August and October of that year, after three operations on the eye, he complained of pain and double vision. This observation is a patently insufficient basis upon which to grant the motion for leave to amend. Mira has alleged no relationship between the pain that Rosner

experienced in 1992 and the malfunctioning of the Miragel. Moreover, Rosner had many years of comfort after the pain. Further, it is not inconceivable that pain and double vision would occur in an eye that had undergone three operations in a matter of months.

In addition, Mira has waived the defense of statute of limitations by failure to plead the defense in a pre-answer motion, answer, or motion to dismiss. CPLR 3018[b]; 3211[e]; Tilbury Fabrics, Inc. v Stillwater, Inc., 81 AD2d 532, 533 (1st Dept 1981) ("[a] period of limitation is an affirmative defense which must be timely asserted, otherwise it is waived").

Moreover, Rosner asserts that prejudice would arise from granting Mira's motion to amend (see CPLR 3025[b]; Thomas Crimmins Contr. Co. v City of NY, supra, 74 NY2d at 166) because substantial discovery has been completed (Seda v New York City Hous. Auth., 181 AD2d 469, 470 [1st Dept 1992]).

Thus, although leave to amend should be freely granted (Edenwald Contr. Co., Inc. v City of NY, supra, 60 NY2d at 959), as the claim that is the subject of the amendment has no merit (Ancrum v St. Barnabas Hosp., supra, 301 AD2d at 475), and creates prejudice or surprise to Rosner (CPLR 3025[b]; Thomas Crimmins Contr. Co. v City of NY, supra, 74 NY2d at 166), Mira's motion for leave to amend the complaint to include the affirmative defense of statute of limitations is denied.

Accordingly, it is hereby

ORDERED that the motion of plaintiffs William Rosner and Karen Rosner for leave to amend their complaint is partially granted to the extent that the ad damnum clause of the complaint may be amended to name defendant Mira, Inc. only, in the form proposed by, and annexed to the moving papers of, defendant The Schepens Eye Research Institute; and it is

further

ORDERED that the complaint, amended in a manner consistent with this opinion, shall be deemed served upon service of a copy of the amended complaint and this order with notice of entry thereof; and it is further

ORDERED that the defendant Mira, Inc. shall serve an answer to the amended complaint within 20 days from the date of said service; and it is further

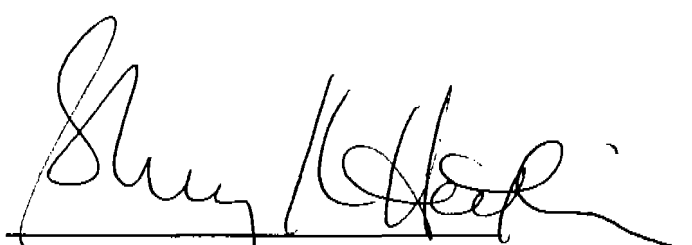
ORDERED that the motion of defendant Mira, Inc. for leave to amend its answer to include an affirmative defense of statute of limitations is denied; and it is further

ORDERED that the motion of defendant The Schepens Eye Research Institute for summary judgment dismissing the complaint in its entirety is denied; and it is further

ORDERED that counsel for the parties shall appear for a conference at 10:00 a.m. on November 1, 2004 at Room 438, 60 Centre Street, New York, New York 10007.

This shall constitute the decision and order of the court.

DATED: October 18, 2004



SHERRY KLEIN HEITLER
J.S.C.