

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
VICTORIA DIVISION**

CALVIN TIMBERLAKE, et al,

Plaintiffs,

v.

SYNTHES SPINE, INC., et al,

Defendants.

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CIVIL ACTION NO. V-08-4

OPINION AND ORDER

Before the Court are Plaintiffs Calvin Timberlake, Anastasia Scott, and Matthew Scott’s (“Plaintiffs”) Motion for Leave to Dismiss Defendants Viscogliosi Brothers, LLC, Marc R. Viscogliosi, John J. Viscogliosi, and Anthony G. Viscogliosi’s (“Viscogliosi Defendants”) and to File Plaintiffs’ Fifth Amended Complaint (Dkt. No. 153); Viscogliosi Defendants’ Motion to Sever Scott Plaintiffs’ Claims and Motion to Dismiss the Scott Plaintiffs Pursuant to Federal Rules of Civil Procedure 12(B)(2) and 12(B)(3) (Dkt. No. 126); and Defendants Synthes Spine Company, L.P. and Spine Solutions, Inc.’s (“Spine Defendants”) Motion to Dismiss, or in the Alternative, Motion to Sever Scott Plaintiffs’ Claims (Dkt. No. 127).

I. Background

Plaintiffs brought this action after Calvin Timberlake and Anastasia Scott each underwent surgery implanting the artificial intervertebral disc, ProDisc. Plaintiffs allege that both devices failed, requiring Mr. Timberlake and Ms. Scott to undergo a second surgery and causing them permanent injury.

According to Plaintiffs’ Fourth Amended Original Complaint (Dkt. No. 124), prior to the ProDisc’s approval by the FDA and while it was still undergoing clinical trials, Mr. Timberlake began researching alternative treatment options for his degenerative disc disease because

traditional treatments were not resolving his condition. Around the same time, Ms. Scott also began researching artificial disc replacement after being told by her physician that she would require an implantation to treat her degenerative disc disease. Both Plaintiffs read multiple reports of the successes of the ProDisc trials and discussed the possibility of having the ProDisc implanted with their doctors, and both relied on the reports in their ultimate decision to have the ProDisc implanted. However, Plaintiffs later discovered that the reports they read about the ProDisc were incomplete and misleading. Plaintiffs maintain they would not have had the ProDisc implanted had they been aware of the deceptive manner in which the ProDisc obtained FDA approval.

Plaintiffs claim the Viscogliosi Defendants originally formed Spine Solutions, Inc. (“Spine Solutions”) in order to obtain FDA approval for and eventually market the ProDisc. In furtherance of this endeavor, the Viscogliosi Defendants and Spine Solutions solicited physicians to conduct the clinical investigations of the ProDisc who were also willing to invest in Spine Solutions. According to Plaintiffs, the Viscogliosi Defendants and Spine Solutions believed that having investor-physicians conduct the clinical trials would result in their ability to more readily obtain other investors and would ensure that the physicians were “in their pocket” so that the outcome of the clinical trials would be favorable. Eventually, Synthes Spine Company, L.P. (“Synthes”) purchased Spine Solutions. Synthes completed the clinical trials and ultimately applied for and received pre-market approval from the FDA for use of the ProDisc. However, the Viscogliosi Defendants and Synthes provided incomplete and misleading information concerning the clinical trials to the FDA and failed to disclose to the FDA—and later the Plaintiffs and the general public—that doctors and clinics that were participating in the clinical trials would benefit financially if the FDA approved the device and from the sale of the ProDisc.

II. Plaintiffs' Motion for Leave to Amend (Dkt. No. 153)

In their Fourth Amended Original Complaint, Plaintiffs allege causes of action against the Viscogliosi Defendants and Spine Defendants for fraud/misrepresentation, violation of the FDA approval process, negligence, strict liability in tort (products), breach of warranty, and conspiracy. Plaintiffs now wish to dismiss the Viscogliosi Defendants and pursue these claims only against the Spine Defendants, and therefore seek leave of Court to file their Fifth Amended Original Complaint. The Viscogliosi Defendants are unopposed to Plaintiffs' motion. The Spine Defendants do not oppose dismissing the Viscogliosi Defendants; however, they do oppose Plaintiffs' request for leave to amend.

According to the Spine Defendants, Plaintiffs' Fifth Amended Original Complaint adds new legal theories of recovery and changes liability for the alleged improper investment activities from the Viscogliosi Defendants to the Spine Defendants. The Spine Defendants contend this shift in liability significantly expands the scope of Plaintiffs' claims against them and ““would work a massive change in the nature and direction of this case.”” (Dkt. No. 156, ¶ 24 (quoting *Mayeux v. Louisiana Health Serv. & Indemnity Co.*, 376 F.3d 420, 427 (5th Cir. 2005))).) As such, the Spine Defendants claim they would need to conduct additional fact investigation, serve additional written discovery on the individual Viscogliosi Defendants, re-designate their expert witnesses, and possibly identify new expert witnesses, all of which would cause undue prejudice and delay in this case.

A. Legal Standard

The Federal Rules of Civil Procedure set forth a liberal policy in favor of permitting amendment of pleadings, and district courts are not to deny such amendments absent “a substantial reason” to do so. *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 (5th Cir. 1981); *Potter v. Bexar County Hosp. Dist.*, 195 Fed. App'x. 205, 208—09 (5th Cir. 2006)

(unpublished); *see also Caudle Aviation, Inc. v. Hartford Fire Ins. Co.*, Civ. A. No. 06-4653, 2007 WL 60993, at *1 (E.D. La. Jan. 5, 2007) (applying the relevant standards in the context of a motion to amend pleadings to assert counterclaims and third-party claims). Indeed, the Fifth Circuit has long recognized that the Federal Rules “evinced[] a bias in favor of granting leave to amend.” *Dussouy*, 660 F.2d at 597. Accordingly, while leave to amend “is by no means automatic,” *Wimm v. Jack Eckerd Corp.*, 3 F.3d 137, 139 (5th Cir. 1993) (quotation omitted), courts “should freely give leave when justice so requires.” FED. R. CIV. P. 15(a). When determining whether to grant a motion for leave to amend, courts in this circuit may consider several factors, including undue delay, bad faith or dilatory motive, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, and futility of the amendment. *Jones v. Robinson Prop. Group, L.P.*, 427 F.3d 987, 994 (5th Cir. 2005); *Avatar Exploration, Inc. v. Chevron, U.S.A., Inc.*, 933 F.2d 314, 321 (5th Cir. 1991). The definition of futility adopted by the Fifth Circuit includes circumstances in which a proposed amendment to assert a claim would fail to state a claim upon which relief could be granted under Rule 12(b)(6). *Stripling v. Jordan Prod. Co., LLC*, 234 F.3d 863, 872—73 (5th Cir. 2000).

B. Analysis

After considering the motion, response, reply, sur-reply,¹ and applicable law, the Court finds that the Spine Defendants have failed to provide a “substantial reason” to justify denying Plaintiffs’ request for leave to amend, and the factors set forth by the Fifth Circuit favor amendment. *See Jones* 427 F.3d at 994; *Avatar Exploration*, 933 F.2d at 321. Allowing amendment serves the interests of judicial efficiency because Plaintiffs dismiss a number of defendants and clarify the allegations as to the remaining defendants in this case. Moreover, it does not appear that Plaintiffs filed this motion in bad faith, or that amendment would be futile.

1. The Spine Defendants’ motion for leave to file a sur-reply to Plaintiffs’ motion for leave to amend (Dkt. No. 159) is GRANTED.

Most importantly, the Court finds that Plaintiff’s Fifth Amended Original Complaint poses no undue prejudice to the Spine Defendants and would not cause undue delay because it pleads the exact same causes of action against the Spine Defendants as Plaintiffs’ Fourth Amended Original Complaint. Plaintiffs’ current complaint alleges that the Viscogliosi Defendants formed Spine Solutions and the entities conspired to conduct unlawful activities together. Plaintiff’s proposed amended complaint merely clarifies that Spine Solutions was acting through its principals—the Viscogliosi Defendants—but still alleges the same legal theories of recovery against the Spine Defendants.²

Moreover, the Court finds no merit to the Spine Defendants’ claim that “[a]s the investment activity allegations were never alleged against Synthes and Spine Solutions, there was no need for [them] to conduct any discovery related to these allegations.” (Dkt. No. 4, ¶ 7.) Plaintiffs’ Fourth Amended Original Complaint contains numerous allegations that the Spine Defendants improperly solicited doctor-investors to conduct the clinical trials and then failed to disclose this information to the FDA. (*See* Dkt. No. 124, ¶ 42 (Spine Solutions hired a team of employees and consultants to solicit investors); ¶ 48 (Spine Solutions instructed employees and consultants to seek physicians who would invest in the companies and participate in FDA clinical trials); ¶ 49 (Spine Solutions stated that having doctor-investors “in our pocket” would ensure the clinical trials had favorable results and intentionally set up a conflict for its personal financial interest); ¶ 57 (Synthes was aware of improper investment activity prior to ProDisc’s FDA approval); ¶ 58 (Synthes entered into settlement agreement with State of New Jersey agreeing to end practice of soliciting physicians to participate in clinical trials); ¶¶ 65—67

2. Plaintiffs do add two new factual allegations against Spine Solutions in their amended complaint—(1) that Spine Solutions began a campaign to fraudulently persuade the FDA that the ProDisc was substantially similar to another device called the Charite, and (2) that Spine Solutions engaged in and was prosecuted for embezzling investor funds. However, neither allegation forms the basis for a new legal theory of recovery, but instead provides further background with respect to the fraud and misrepresentation claims already alleged against the Spine Defendants.

(alleging fraud/misrepresentation claims against Spine Solutions for its improper recruitment of clinical investigators as investors in the ProDisc and failure to disclose the same to the FDA.)

While the Court finds that the Spine Defendants were on notice with respect to Plaintiffs' claims against them regarding improper investment activities, in order to prevent any alleged prejudice, the Spine Defendants may seek an extension of time in which to conduct additional discovery related to Plaintiffs' amended pleading. This should not cause undue delay, as the Court recently granted Plaintiff's request to designate one additional expert witness and provided that the Spine Defendants may seek an extension of time to file *Daubert* motions in this case. (Dkt. No. 157.)

The Court **GRANTS** Plaintiffs' Motion for Leave to Dismiss Viscogliosi Defendants and to File Plaintiffs' Fifth Amended Complaint (Dkt. No. 153).

III. Viscogliosi Defendants' Motion to Sever and Dismiss (Dkt. No. 126)

The Viscogliosi Defendants have been dismissed as parties to this case. The Court **DENIES** their Motion to Sever Scott Plaintiffs' Claims and Motion to Dismiss the Scott Plaintiffs Pursuant to Federal Rules of Civil Procedure 12(B)(2) and 12(B)(3) (Dkt. No. 126) as moot.

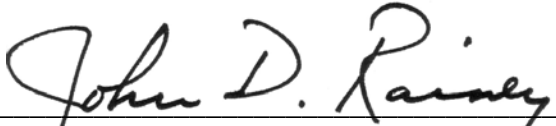
IV. Spine Defendants' Motion to Dismiss or Sever (Dkt. No. 127)

An amended complaint supersedes a prior complaint and renders it of no legal effect unless the amended complaint specifically refers to or adopts the earlier pleading. *See King v. Dogan*, 31 F.3d 344, 346 (5th Cir. 1994) (citing *Boelens v. Redman Homes, Inc.*, 759 F.2d 504, 508 (5th Cir. 1985)). Plaintiff's Fifth Amended Original Complaint replays all of the claims underlying the Spine Defendants' motion to dismiss but makes no reference to nor adopts any portion of Plaintiffs' Fourth Amended Original Complaint (Dkt. No. 124). Because the currently pending motion to dismiss addresses only the claims in Plaintiffs' Fourth Amended Original

Complaint, the Court **DENIES** the Spine Defendants' Motion to Dismiss, or in the Alternative, Motion to Sever Scott Plaintiffs' Claims (Dkt. No. 127) as moot.

It is so **ORDERED**.

SIGNED this 25th day of February, 2010.



JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE