

I. Relevant Background and Procedural History

The facts of this case are set forth in the Court’s memorandum opinion and order denying defendants’ motion to dismiss [*see* Doc. 15]. To briefly summarize, plaintiff commenced this action asserting strict liability, negligence and breach of warranty against defendants after learning that x-rays taken of his left hip revealed a failure of his hip implant [Doc. 4]. Plaintiff alleges that the hip implant was designed, manufactured, and marketed by defendant Stryker Corporation [*Id.*].

Defendants moved to dismiss plaintiff’s first amended complaint for failure to state a claim upon which relief can be granted [Doc. 8]. Defendants contended that the Medical Device Amendments of 1976 (the “MDA”) preempt plaintiff’s state law claims [Doc. 9]. The Court denied defendants’ motion to dismiss finding that plaintiff’s state law claims survive preemption under the analysis set forth in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), because they “parallel” federal requirements [*see* Doc. 15].

II. Defendants’ Motion for Reconsideration

A. Standard of Review

Rule 60(b) of the Federal Rules of Civil Procedure provides that a party may obtain relief from a final judgment, order, or proceeding for the following reasons:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);

- (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
- (4) the judgment is void;
- (5) the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
- (6) any other reason that justifies relief.

Fed. R. Civ. P. 60(b). Broadly construing defendants' motion, it appears that defendants seek relief pursuant to Rule 60(b)(2) and (b)(3).¹ The decision to grant relief under Rule 60(b)(2) as well as (b)(3) rests in the discretion of the district court. *Good v. Ohio Edison Co.*, 149 F.3d 413, 423 (6th Cir.1998).

With respect to Rule 60(b)(2), in order to prevail, "a movant must demonstrate (1) that it exercised due diligence in obtaining the information and (2) [that] the evidence is material and controlling and clearly would have produced a different result if presented before the original judgment. In other words, the evidence cannot be merely impeaching or

¹Although defendants state that their motion is based on newly discovered evidence that relates to a misrepresentation of facts in plaintiff's first amended complaint, defendants also cite Rule 60(b)(1) and appear to argue that the Court made a legal error [*see* Doc. 24 (submitting that the Court's order "is at odds with the myriad opinions preempting claims against the Trident hip system")]. A motion brought pursuant to Rule 60(b)(1) must be done so within the normal time for taking an appeal. *Pierce v. United Mine Workers of Am. Welfare and Ret. Funds of 1950 and 1974*, 770 F.2d 449, 451 (6th Cir. 1985) (citation omitted). Defendants, therefore, had thirty days from the date of the Court's order denying their motion to dismiss, June 3, 2010, to file any motions pursuant to Rule 60(b)(1). *See* Fed. R. App. P. 4(a). Defendants' motion to reconsider was filed on July 22, 2010, more than thirty days after the Court's order. Accordingly, any argument that the Court made a legal error is time-barred.

cumulative.” *Good*, 149 F.3d at 423 (citations and quotation marks omitted) (alteration in original).

Under Rule 60(b)(3), “the Sixth Circuit requires a demonstration by the moving party, supported by clear and convincing evidence, that one or more of the three kinds of misbehavior referred to in the rule occurred.”² *Jordan v. Paccar, Inc.*, 97 F.3d 1452 (Table), 1996 WL 528950, at *9 (6th Cir. 1996). The non-moving party then has the burden to “demonstrate by clear and convincing evidence that the misbehavior which occurred had no prejudicial effect on the outcome of the litigation.” *Id.*

B. Analysis

Defendants’ argue that after the Court’s June 3, 2010 order, they discovered that the acetabular shell component of the plaintiff’s hip implant was not manufactured in Ireland as alleged by plaintiff, but in New Jersey, and that shells manufactured in New Jersey were never part of a recall based on alleged violations of regulations [Doc. 25]. They submit that

² For the purpose of a Rule 60(b)(3) motion, the Sixth Circuit has held:

“Misrepresentation” can be interpreted as an affirmative misstatement. “Fraud” can be interpreted as reaching deliberate omissions when a response is required by law or when the non-moving party has volunteered information that would be misleading without the omitted material. And “other misconduct” can be interpreted to reach questionable behavior affecting the fairness of litigation other than statements or the failure to make statements.”

Jordan, 1996 WL 528950, at *6 (citations omitted). *See also Info-Hold, Inc. v. Sound Merch., Inc.*, 538 F.3d 448, 456 (6th Cir. 2009) (setting forth the following definition of fraud for purposes of Rule 60(b)(3): “Fraud is the knowing misrepresentation of a material fact, or concealment of the same when there is a duty to disclose, done to induce another to act to his or her detriment”) (citations omitted).

they learned such information “only after pressing plaintiff’s counsel for copies of the product identification stickers from plaintiff’s hip surgery records – records which plaintiff’s counsel must have had since at least January 2010 when the First Amended Complaint was filed” [*Id.*]. Defendants contend that this information is “newly discovered evidence [that] relates to a misrepresentation of facts in Plaintiff’s First Amended Complaint concerning a recall of the acetabular shell at issue, which the Court relied upon in denying defendants’ Motion to Dismiss” [Doc. 19].

Plaintiff argues that the “newly discovered evidence” does not “alter the fact that Plaintiff’s claims are still premised upon violations of FDA regulations” as the New Jersey facility was cited by the United States Food and Drug Administration (the “FDA”) “for the same kinds of violations [as the Ireland facility] which resulted in the manufacture of adulterated and nonconforming products” [Doc. 23]. He submits a warning letter issued by the FDA concerning violations at the New Jersey facility in support of this argument [*see* Docs. 23, 23-1]. Plaintiff therefore contends that his “claims are not materially altered” and that defendants’ motion for reconsideration should be denied.

As an initial matter, the Court questions whether defendants exercised due diligence in obtaining the information concerning the facility where the shell of plaintiff’s hip implant was manufactured. A review of the first amended complaint and the product stickers attached to the affidavit of William Cymbaluk, which was submitted by defendants, evidences that the information defendants sought was set forth in the first amended complaint

[see Doc. 4, p. 3 (stating the alleged lot number and identification number); Doc. 19-2, p. 8]. Thus, it is questionable whether such information is “newly discovered.”

The Court also questions whether plaintiff engaged in a misrepresentation, fraud, or other misconduct worthy of Rule 60(b)(3) relief. A party moving pursuant to Rule 60(b)(3) must submit “clear and convincing” evidence of the fraud, misrepresentation or other misconduct. Although defendants submit that plaintiff’s counsel has engaged in misconduct in other cases involving the same hip implant system as plaintiff’s, and that plaintiff’s counsel did not properly investigate the claims prior to filing this action, defendants also submit that plaintiff’s counsel voluntarily dismissed at least two cases after learning she had alleged untrue facts and, in this case, she has moved to amend the complaint to reflect the true facts. Thus, the Court is not willing to find that there is “clear and convincing” evidence of fraud, misrepresentation or other misconduct.³

Regardless, a comparison of the standards for Rule 60(b)(2) and (b)(3) reveal that a motion for reconsideration under either provision should be denied if the Court’s decision would not change in light of the new evidence or as a result of the fraud, misrepresentation or other misconduct. Such is the case here. The Court premised its decision to deny defendants’ motion to dismiss on the grounds that plaintiff alleged “that defendants failed to comply with FDA regulations in manufacturing the Trident System, [and that] Plaintiff advance[d] several theories of state common law liability to link those compliance failures

³ The Court also is unwilling to penalize plaintiff for the alleged conduct of plaintiff’s counsel occurring in courts outside of this Court for cases involving different plaintiffs.

to the ultimate failure of the device implanted in his hip” [Doc. 15]. Plaintiff has submitted that violations very similar to those at the Ireland facility occurred at the New Jersey facility, and defendants admit that whether a recall was instituted is irrelevant to the preemption argument [*see* Doc. 24]. Accordingly, the Court’s decision would not change as a result of the new information, and defendants’ motion for reconsideration is denied.

III. Plaintiff’s Motion to Amend

A. Standard of Review

Under the Federal Rules of Civil Procedure, a party amending a pleading after a responsive pleading has been served “may amend his pleading only by leave of court . . . and leave shall be freely given when justice so requires.” Fed. R. Civ. P. 15(a). The rationale for this liberal policy is to allow disputes to be resolved on the merits and not as a result of technical objections to the pleadings. *See Marks v. Shell Oil Co.*, 830 F.2d 68, 69 (6th Cir. 1987).

A motion to amend a complaint should be denied, however, “if the amendment is brought in bad faith, for dilatory purposes, results in undue delay or prejudice to the opposing party, or would be futile.” *Crawford v. Roane*, 53 F.3d 750, 753 (6th Cir. 1995) (citation omitted). Amendment of a complaint is futile when the proposed amendment would not permit the complaint to survive a motion to dismiss. *Miller v. Calhoun County*, 408 F.3d 803, 807 (6th Cir. 2005) (citing *Neighborhood Dev. Corp. v. Advisory Council on Historic Pres.*, 632 F.2d 21, 23 (6th Cir. 1980)). A complaint will survive a motion to dismiss if it “contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is

plausible on its face, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), and a claim is plausible on its face if “the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 556).

B. Analysis

Plaintiff requests that the Court grant leave to file a second amended complaint to reflect the proper facility where plaintiff’s “acetabular cup was manufactured” [Doc. 22]. He submits that such facts do not alter his claims “in any substantial way in light of the deficiencies found at the [p]lant where [p]laintiff’s acetabular cup was manufactured” [*Id.*] Plaintiff further submits that granting the motion for leave to amend would not unduly prejudice defendants, would not unduly delay this action, and would not be futile [*Id.*]

Defendants oppose the motion for leave to amend and suggest that “plaintiff cannot simply swap one FDA warning letter . . . for a different letter written to a different facility concerning different purported violations, and pretend that he has adequately pled a parallel claim” [Doc. 24]. Although defendants discuss the criteria for alleging a parallel claim, defendants do not discuss the proposed second amended complaint’s allegations and do not contend that it would not survive a motion to dismiss [*see id.*].

The Court has reviewed the original complaint as well as the proposed second amended complaint and is not convinced at this time that it would prejudice defendants, unduly delay this action or be futile in light of the Court’s previous order denying

defendants' motion to dismiss. Accordingly, plaintiff's motion for leave to amend the complaint is granted.

IV. Conclusion

For the reasons set forth above, the Court **DENIES** defendants' Motion for Reconsideration of June 3, 2010 Memorandum Opinion and Order Denying Defendants' Rule 12 Motion to Dismiss [Doc. 19] and **GRANTS** plaintiff's Motion for Leave to Amend Complaint [Doc. 22]. Plaintiff is directed to file the second amended complaint within ten (10) days of the entry of this Order.

IT IS SO ORDERED.

s/ Thomas A. Varlan
UNITED STATES DISTRICT JUDGE