IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

MARGARET J. BAUSCH,)	
Plaintiff,)	
v.)	No. 08 C 4248
STRYKER CORPORATION, et al.,)	
Defendants.)	

MEMORANDUM OPINION

SAMUEL DER-YEGHIAYAN, District Judge

This matter is before the court on Plaintiff Margaret J. Bausch's (Bausch) motion for reconsideration and for leave to file an amended complaint. For the reasons stated below, we deny Bausch's motion in its entirety.

BACKGROUND

Bausch alleges that she underwent a right total hip replacement surgery during which a surgeon implanted a Trident Brand Ceramic on Ceramic Hip Replacement System (Trident). According to Bausch, the Trident was designed, manufactured, and sold by Defendants. Bausch alleges that the Trident used in her surgery was defective rendering it unreasonably dangerous. Specifically, Bausch alleges that the Trident contained a component known as the Trident Hemispherical Acetabular

Shell, which was recalled by Defendants in January 2008. Bausch further alleges that Defendants had notice of defects in the Trident prior to her surgery and that the United States Food and Drug Administration (FDA) had issued a letter to Defendants advising them that certain manufacturing methods relating to the Trident were not in conformity with industry, regulatory standards, and Defendants' own specifications. Bausch claims that the defect in her Trident caused her to have an unstable right hip, pain, suffering, disability, loss of normal life, the need for revision surgery, delayed care for her other hip, and medical and other expenses.

Bausch brought the instant action and includes in her complaint strict liability in tort claims (Count I) and negligence claims (Count II). We granted Defendant Howmedica Osteonics Corporation's and Defendant Stryker Ireland, Ltd.'s motions to dismiss and we dismissed the action against all Defendants. Subsequent to the court's dismissal of all claims in this case, the Clerk of Court promptly entered judgment in the instant action. Bausch now brings the instant motion to reconsider and for leave to file an amended complaint.

LEGAL STANDARD

Federal Rule of Civil Procedure 59(e) (Rule 59(e)) permits parties to file, within ten business days of the entry of a judgment, a motion to alter or amend the judgment. Fed. R. Civ. P. 59(e); Fed. R. Civ. P. 6. Rule 59(e) motions do not give a party the opportunity to rehash old arguments or to present new arguments or evidence "that could and should have been presented to the district court prior to the

judgment." *Moro v. Shell Oil Co.*, 91 F.3d 872, 876 (7th Cir. 1996)(citing *LB Credit Corp. v. Resolution Trust Corp.*, 49 F.3d 1263, 1267 (7th Cir. 1995)). Rather, for a Rule 59(e) motion, the movant "must clearly establish either a manifest error of law or fact or must present newly discovered evidence" in order to be successful. *LB Credit Corp.*, 49 F.3d at 1267 (quoting *Federal Deposit Ins. Corp. v. Meyer*, 781 F.2d 1260, 1268 (7th Cir. 1986)). The decision of whether to grant or deny a motion brought pursuant to Rule 59(e) "is entrusted to the sound judgment of the district court. . . ." *In re Prince*, 85 F.3d 314, 324 (7th Cir. 1996).

Pursuant to Federal Rule of Civil Procedure 60(b) (Rule 60(b)), a party may seek relief from a final judgment if the party can establish "(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 . . ., misrepresentation, or misconduct by an opposing party; (4) the judgment is void; (5) the judgment has been satisfied, released or discharged . . .; or (6) any other reason that justifies relief." Fed. R. Civ. P. 60(b). Relief under Rule 60(b) is an "extraordinary remedy" granted only in "exceptional circumstances." *Harrington v. City of Chicago*, 433 F.3d 542, 546 (7th Cir. 2006)(quoting *Karraker v. Rent-A-Center, Inc.*, 411 F.3d 831, 837 (7th Cir. 2005)).

Pursuant to Federal Rule of Civil Procedure 15(a) (Rule 15(a)), "[a] party may amend its pleading once as a matter of course: (A) before being served with a responsive pleading; or (B) within 20 days after serving the pleading if a responsive pleading is not allowed and the action is not yet on the trial calendar." Fed. R. Civ.

P. 15(a)(1). If a party cannot amend the complaint as a matter of course, that party "may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). Pursuant to Rule 15(a), a court should "freely give leave when justice so requires." *Id.* A court may deny leave to amend a complaint based on "undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, and futility of the amendment." *Airborn Beepers & Video, Inc. v. AT & T Mobility LLC*, 499 F.3d 663, 666 (7th Cir. 2007).

DISCUSSION

Although Bausch styles the instant motion as a motion for reconsideration and for leave to file an amended complaint, Bausch has failed to advance any argument that this court erred in its underlying ruling on the merits of the motions to dismiss. Rather, Bausch argues that the court should have given her an opportunity to file an amended complaint and Bausch argues that she now can bring new claims under Illinois law that are not preempted by federal law. As to Bausch's motion for reconsideration, Bausch has not pointed to any manifest error of law or fact and has not presented any newly discovered evidence that would justify relief under Rule 59(e). *LB Credit Corp.*, 49 F.3d at 1267. Bausch has likewise failed to point to any grounds that would justify relief under Rule 60(b). *Harrington*, 433 F.3d at 546. Notwithstanding, Bausch argues that the court should vacate the ruling dismissing

the action and allow her to amend her complaint.

Bausch contends that the court should have allowed her to amend the complaint in the event that the court granted the motions to dismiss her complaint. Bausch points out that she included one sentence in her answer to the motions to dismiss in which she stated: "[i]f for any reason the Court disagrees [with her arguments] and believes all or any part of plaintiff's complaint should be dismissed, she respectfully requests the dismissal be without prejudice and with the opportunity to amend." (Ans. Mot. Dis. 9). However, Bausch never filed any formal motion requesting leave to amend her complaint and her request, included in the body of a brief opposing Defendants' motions to dismiss, was improper. Bausch's one sentence improper request did not even include any details of her proposed amendment, nor did she attach a proposed amended complaint in conjunction with her request. See Hecker v. Deere & Co., 556 F.3d 575, 591 (7th Cir. 2009)(citing Viacom, Inc. v. Harbridge Merchant Servs., 20 F.3d 771, 785 (7th Cir. 1994) for the proposition that a plaintiff must either attach a proposed complaint or "specifically inform[] the court how it would cure deficiencies in the earlier complaint"). If Bausch, after reviewing the motions to dismiss, believed that her complaint was defective, she had the ability to amend her complaint as a matter of course in order to cure the deficiency. Bausch did not do so. Thus, Bausch has failed to show that she filed a proper motion to amend her complaint prior to the court's ruling on the motions to dismiss and prior to the entry of judgment. We also note that there is no basis for relief under Federal Rule of Civil Procedure 60(a) since there were no

"clerical mistakes" or "mistakes arising from oversight or omission" in the judgment. Fed. R. Civ. P. 60(a).

In the instant motion for leave to amend the complaint, brought after judgment had been entered in this case, Bausch has not shown that she should be entitled to amend her complaint. After the court granted Defendants' motions to dismiss, the Clerk of Court promptly entered judgment, as is required by Federal Rule of Civil Procedure 58(b)(1). Fed. R. Civ. P. 58(b)(1)(stating that "unless the court orders otherwise, the clerk must, without awaiting the court's direction, promptly prepare, sign and enter judgment when . . . the court denies all relief"). Bausch is precluded from amending her complaint absent some grounds for reinstating the instant action. See Sigsworth v. City of Aurora, Ill., 487 F.3d 506, 511 (7th Cir. 2007)(citing Paganis v. Blonstein, 3 F.3d 1067, 1073 n.8 (7th Cir. 1993) for the proposition that "unless a final judgment is set aside or vacated, a plaintiff may not amend her complaint"); see also Hecker, 556 F.3d at 590-91 (indicating that "a plaintiff can amend a complaint only after the court grants the Rule 59(e) motion").

Bausch has also not shown why she could not have properly moved to amend her complaint sooner and Bausch's undue delay in bringing a proper motion to amend is further grounds for denying the instant motion. *Airborn Beepers & Video*, *Inc.*, 499 F.3d at 666 (indicating that "undue delay" is a basis for denying a motion to amend). As Defendants point out, Bausch premises her proposed new claims on Illinois case law that has existed for years prior to the instant action. Yet, rather than

properly amending her complaint to pursue her now-asserted theory of relief, which could have been done as a matter of course prior to Defendants' answers to her complaint, Bausch did not properly move to amend her complaint until after the motions to dismiss were filed by two Defendants, after those motions were fully briefed by two different Defendants, after the court ruled on those motions, and after the Clerk of Court entered judgement in the instant action. See Pugh v. Tribune Co., 521 F.3d 686, 698 (7th Cir. 2008)(stating that "[c]ourts have rejected the argument that . . . [plaintiffs are] entitled to wait and see what the district court sa[ys] before making any changes to the complaint-because it would impose unnecessary costs and inefficiencies on both the courts and the party opponents" and that "'plaintiffs do not get leisurely repeated bites at the apple, forcing a district judge to decide whether each successive complaint was adequate")(quoting in part ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 57 (1st Cir. 2008)). To allow plaintiffs to have "repeated bites," when plaintiffs merely include a sentence in the opposition brief conditionally requesting to amend their complaint in the event the court rules against them, after the parties have expended resources, would result in an endless cycle of litigation and would be a travesty of justice. Therefore, Bausch's motion to amend the complaint is untimely.

Finally, even if Bausch was not precluded from amending the complaint by the entry of judgment and even if Bausch's motion to amend was properly and timely-brought, we also find that Bausch's proposed amended complaint does not correct

the deficiencies in Bausch's first complaint and the attempt to cure would be futile. Airborn Beepers & Video, Inc., 499 F.3d at 666 (indicating that "futility of the amendment" is grounds for declining to allow an amended complaint). Bausch's proposed amended complaint continues to assert negligence and strict liability claims under Illinois common law. However, Bausch recasts her claims as claims premised on Defendants' alleged conduct in non-compliance with federal regulations. Bausch argues that her newly-asserted claims in the proposed amended complaint "do not concern the nature of the product." (Mot. Recon. 7-8). Bausch further argues that Illinois jurisprudence provides a framework that allows her to assert such negligence and strict liability claims in a manner that is not preempted by federal law.

As the court explained more fully in its ruling on the merits of the motions to dismiss, the language in the preemption clause of the Medical Devices Amendment of 1976, 21 U.S.C. § 360k, to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (MDA) preempts tort claims targeting Class III medical devices, to the extent that such claims are "different from, or in addition to" the requirements imposed by the regulatory "regime" established by the MDA for such devices. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1006 (2008). The Supreme Court in *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008) stated that only a narrow universe of claims that are directly "parallel" to federal regulations of Class III medical devices could survive an MDA preemption challenge. *Id.* at 1011. The Supreme Court has never set forth an explicit definition of a claim that is "parallel" to federal regulations other

than to cite, as an example of such a claim, state statutory "damages remed[ies] for claims premised on a violation of FDA regulations." *Id*.

Despite the changes to her claims, Bausch is still left holding a square peg for the round hole that is the parallel claims exception under *Riegel*. Bausch relies heavily on the fact that various courts in Illinois have previously suggested that a plaintiff may be able to prove a *prima facie* case for negligence or strict liability by showing that a defendant violated a statute. See (Mot. Recon. 4-6); Abbasi ex. rel. Abbasi v. Paraskevoulakos, 718 N.E.2d 181, 186 (Ill. 1999); Anderson v. Hyster Co., 385 N.E. 2d 690, 692-93 (Ill. 1979). Bausch has tailored her allegations in her proposed amended complaint to reflect that all of Defendants' alleged tortious conduct that injured her was also in violation of the federal regulations. However, there is more to a common law tort claim than establishing a *prima facie* case. See Kalata v. Anheuser-Busch Cos., Inc., 581 N.E. 2d 656, 661 (Ill. 1991)(holding that although "[a] violation of a statute or ordinance designed to protect human life or property is *prima facie* evidence of negligence . . . [t]he violation does not constitute negligence per se . . . and therefore the defendant may prevail by showing that he acted reasonably under the circumstances"). Thus, it is clear under Illinois law that, even under Bausch's new theory of relief, common law tort principles inevitably invade any such cause of action and could certainly subject the makers of Class III medical devices to requirements that are "different from, or in addition to" federal regulations. Such claims do not fall under the exception to preemption described in

Riegel and are also preempted by the MDA. *Riegel*, 128 S.Ct. at 1007.

We stress that we have not held, as Bausch suggests, that there is no possible

claim that would be considered "parallel" to federal regulations, other than the

example cited by the Supreme Court in Riegel. Id. at 1011. Such a finding would be

outside the scope of the court's review in the instant case, which is to decide whether

the proposed claims would ask a jury at trial to hold Defendants to a standard that

differs from or adds to the standards imposed by the MDA regulatory regime. Since

such is the case here, we find that Bausch's proposed amended complaint is futile.

Based on the foregoing, we find that Bausch has failed to show a sufficient basis to

grant the motion to reconsider, and we also find that, even if the judgment is vacated

to allow Bausch to amend her complaint, the proposed amended complaint would be

futile. Therefore, we deny the instant motion for reconsideration and for leave to file

an amended complaint.

CONCLUSION

Based on the foregoing analysis, we deny the motion for reconsideration and

leave to file an amended complaint.

Samuel Der-Yeghiayan

United States District Court Judge

Dated: August 31, 2009

10