Elmore et al v. Smith & Nephew, Inc. Doc. 25

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

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| CHERYL ELMORE and KEN ELMORE, | ) | |
| | ) | |
| Plaintiffs, | ) | No. 12 C 8347 |
| v. | ) | |
| | ) | Judge Robert W. Gettleman |
| SMITH & NEPHEW, INC., a Delaware corporation, | ) | |
| | ) | |
| | ) | |
| Defendant. | ) | |

**MEMORANDUM OPINION AND ORDER**

Plaintiffs Cheryl ("Cheryl") and Ken Elmore filed a three-count complaint against defendant Smith & Nephew, Inc., manufacturer of the Birmingham Hip Resurfacing ("BHR") System, alleging strict products liability, negligence, and loss of consortium. Plaintiffs based these state common-law claims on violations of 21 C.F.R. § 820 et seq., which describes the "current good manufacturing practices" (CGMPs) of the U.S. Food and Drug Administration ("FDA"), specific quality control requirements for medical devices. Defendant argues that that plaintiffs' complaint should be dismissed because plaintiffs' claims are expressly and impliedly preempted and, alternatively, because plaintiffs' complaint is insufficient under Fed. R. Civ. P. 8. For the reasons stated below, the court denies defendant's motion.

**FACTS**

In October 2008, doctors implanted a BHR System in plaintiff Cheryl's right hip. The device was manufactured by Smith & Nephew and consisted of two components, a femoral head and an acetabular cup. The FDA had granted premarket approval ("PMA") for the device approximately two years earlier.

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Shortly after surgery, the femoral head component began to loosen. To rectify this problem, Cheryl's doctor performed revision surgery on Cheryl's right hip. The doctor replaced the size 48 acetabular cup with a size 50 acetabular dysplasia cup, leaving the original femoral head component in place.

Approximately one year after the revision surgery, Cheryl began to experience the feeling of looseness and popping within her right hip. These sensations became increasingly painful. Roughly two years after the initial surgery, doctors detected high levels of chromium and cobalt in Cheryl's blood and noted the collection of fluid around Cheryl's right hip joint. Cheryl's doctor performed a second revision surgery in December 2010, removing both components of the original BHR system. This time, a total hip replacement was performed using new Smith & Nephew hardware.

Since the 2010 revision surgery, Cheryl has suffered ongoing fracturing in her right hip socket. She is unable to stand for more than one hour a day, uses a cane and wheelchair to move around, and treats ongoing pain with narcotics. In October 2012, plaintiffs brought their three-count plaint against Smith & Nephew.

## DISCUSSION

### Preemption

Plaintiffs base their Illinois common-law claims on violations of 21 C.F.R. § 820 et seq. The CGMP requirements of these regulations "are intended to ensure that finished [medical] devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act" ("the Act"). 21 C.F.R. § 820.1. Under the Medical Device Amendments (MDA) to the Act, Class III devices, which include hip resurfacing systems, require PMA before they are

made available to consumers. 21 U.S.C. § 360(e). PMA is a rigorous process. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). Even after PMA is granted, the FDA still requires that medical device manufacturers comply with CGMPs. See generally 21 C.F.R. § 820 et seq. Plaintiffs' strict products liability, negligence, and loss of consortium claims are based on numerous violations of CGMPs, including defendant's failure to comply with design controls under 21 C.F.R. § 820.30, failure to inspect and verify products under 21 C.F.R. § 820.80, and failure to take appropriate corrective and preventative actions under 21 C.F.R. § 820.100.

Defendant argues that plaintiffs' claims are barred under the Act's express preemption clause, which provides that no state may establish any requirement that is, (1) "different from or in addition to" any requirement under the Act, and (2) related to the device's safety or effectiveness, or any other device requirement within in the Act. 21 U.S.C. § 360k. Once a medical device has cleared the FDA's stringent PMA process, defendant contends, a plaintiff cannot attack the design of the device under tort law. Defendant points to CGMPs in plaintiff's complaint that it argues are required prior to PMA. Basing state-law negligence claims on these provisions is an attack on the PMA process itself, defendant argues.

Defendant's argument is rejected for two reasons. First, a medical device manufacturer's required adherence to CGMPs does not end once PMA is granted. See Bausch v. Stryker Corp., 630 F.3d 546, 556 (7th Cir. 2010) (upholding state-law negligence claims based on allegation that the defendant failed to comply with a CGMP concerning manufacturer control of devices that failed to conform to PMA specifications); see also Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 441 (6th Cir. 2010) (upholding state-law negligence claims when manufacturer failed to completely remove all manufacturing material from the device, as required by a specific

CGMP, even though manufacturer had complied with device cleaning process defined for PMA). Plaintiffs correctly point out that even after a medical device has received pre-market approval, "manufacturers of medical devices [still] must comply with various regulations on labeling and advertising, manufacturing, postmarketing surveillance, device tracking, and adverse event reporting." Judith A. Johnson, Cong. Research Serv., R42130, FDA Regulation of Medical Devices 13 (2012).

Second, plaintiff's state-law claims are sufficiently parallel to the federal requirements. Both the United States Supreme Court and the Seventh Circuit have addressed the scope of the preemption clause. In Lohr, the Court held that FDA regulations did not preempt common-law negligence and strict liability claims because the duties on which those claims were based paralleled federal requirements. Lohr, 518 U.S. at 495. The device at issue in Lohr, a pacemaker, was not subject to PMA because it was "substantially equivalent" to other devices already on the market, and thus approved under a less rigorous process known as 510(k). Id. at 480; see also 21 U.S.C. § 360(b)(1)(B). Although the Court held that the general standards imposed by the 510(k) process were not "requirements" that triggered § 360k preemption, the Court nevertheless made clear that § 360k does not preempt common law duties that are parallel to federal regulations. Lohr, 518 U.S. at 495. "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirement narrower, not broader, than the federal requirement." Id. The

Seventh Circuit has recognized that Lohr "also applies to products that have gone through [PMA]." Bausch, 630 F.3d at 546.

The Supreme Court addressed the issue again in Riegel, reaffirming its interpretation of the scope of the preemption clause. See Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008). In Riegel, the state tort law at issue imposed requirements in addition to those contained in the federal regulations that risked disrupting the larger federal regulatory scheme. See id. at 325. The district court recognized "that parallel claims would not be preempted," but the plaintiff never contended her claims actually paralleled federal law. Id. Accordingly, the Court "decline[d] to address that argument in the first instance" and held plaintiffs' claims preempted because they were not parallel to federal requirements. Id.

Most recently, the Seventh Circuit has held that 360k does not preempt common-law negligence and strict liability claims related to a defective hip replacement system. Bausch, 630 F.3d at 549. Medical device manufactures that receive PMA are protected from civil liability to the extent that they comply with federal law, but this protection does not foreclose claims based on violations of federal law. See id. ("The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.").

Plaintiffs' negligence and strict liability claims are not expressly preempted because they do not impose requirements that are "different from or in addition to" the federal requirements on which they are based. Like the strict liability and negligence claims in Bausch, plaintiffs' claims run parallel to underlying federal regulations. Under Illinois law, violation of a statute designed to protect human life is prima facie evidence of negligence. See, e.g., Kalata v.

Anheuser-Busch Cos., Inc., 581 N.E.2d 656, 661 (Ill. 1991); see also Bausch, 630 F.3d at 553 (collecting cases). In addition, Illinois "imposes strict liability on sellers of unreasonably dangerous products where the dangerous condition existed when it left the manufacturer's control." Apperson v. E.I. du Pont de Nemours & Co., 41 F.3d 1103, 1106 (7th Cir. 1994). Design or manufacturing defects may cause a product to become "unreasonably dangerous." Id. Because plaintiffs' common-law claims are based on alleged violations of federal law, they impose no requirement "different from, or in addition to" the requirements of the federal regulations, and are not expressly preempted.

Defendant also argues that plaintiffs' claims are impliedly preempted and that plaintiffs may not bring a private cause of action against a manufacturer based on violations of regulations that are (1) requirements for PMA, or (2) postmarket surveillance measures that only the FDA may enforce.

State law claims may be impliedly preempted when they conflict with federal law and stand in the way of congressional objectives. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001). In Buckman, the plaintiffs alleged that the defendant, a manufacturer of orthopedic bone screws, had made fraudulent representations to the FDA to obtain PMA. Id., 531 U.S. at 343. The court held that plaintiffs' conflicting state-law fraud claims were impliedly preempted because they would skew the "delicate balance of statutory objectives" addressed by the federal regulations. Id. at 348.

Tort claims related to health and safety are distinct from claims alleging fraud on a federal agency. See Buckman, 531 U.S. at 347; see also Bausch, 630 F.3d at 556–57. As the Court in Buckman noted, fraud claims against federal agencies are typically governed by federal

law because the entire relationship between a federal agency and the entities it regulates "originates from, is governed by, and terminates according to federal law." Buckman, 531 U.S. at 347. Unlike fraud claims, however, tort claims related to health and safety naturally fall within the states' historic police powers. See id. at 348. Unless there is clear congressional intent to the contrary, courts begin with the presumption that federal law will not supersede traditional police powers held by the states. Lohr, 518 U.S. at 485.

A private litigant may still base state common-law claims on conduct that violates the Act, so long as that conduct would result in liability independent of the Act. See Bausch, 630 F.3d at 557–58 (finding negligence and strict liability claims based on manufacturing defects were not impliedly preempted where plaintiffs were already owed a well-known duty under state law—"the duty of a manufacturer to use due care in manufacturing a medical device"). Id. at 558. Nevertheless, Defendant contends that plaintiffs' state-law claims are not parallel to the federal requirements because they are not "substantially identical." Yet state tort claims need not match federal requirements word for word. See Bausch, 630 F.3d at 557. In Bausch, plaintiff's claim that a medical device was "adulterated" was not preempted simply because no specific state tort duty required the manufacture of "unadulterated" devices. Id. The Seventh Circuit held that "evidence showing a violation of federal law . . . goes a long way toward showing that the manufacturer breached a duty under state law toward the patient." Bausch, 630 F.3d at 557.

Plaintiffs' claims are not impliedly preempted because they are based on common-law duties of care that exist independently of the FDA regulations. As in Bausch, plaintiffs' common-law claims do not conflict with the primary objective of the FDA's regulatory

scheme—ensuring the safety and effectiveness of medical devices. Rather, plaintiffs' negligence and strict liability claims are based on the breach of well-recognized duties already owed under state law. Under Bausch, such claims are permissible provided that the plaintiff can show he or she "was harmed by a violation of applicable federal law." Bausch, 630 F.3d at 558. Although plaintiffs' claims are premised on alleged violations of federal regulations, they are also capable of existing independent of those regulations. For these reasons, under the Seventh Circuit's holding in Bausch, plaintiffs' negligence and strict liability claims are neither expressly nor impliedly preempted. Because plaintiffs' loss of consortium claim is contingent on the underlying negligence and strict liability claims, it also is not preempted.

**Sufficiency of plaintiffs' complaint**

Defendant argues that plaintiffs' complaint is inadequate under Fed. R. Civ. P. 8 because it lacks the factual grounding necessary to make the claims plausible. Rule 8 requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8. Rule 8(a)(2). The purpose of Rule 8 is twofold: (1) to give defendants fair notice of the nature of the claim; and (2) to state a claim that is plausible on its face. Bausch, 630 F.3d at 560. Notice pleading remains the standard under Rule 8, and heightened fact pleading is not required to state a claim. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). For a complaint to be plausible on its face, it must raise a reasonable expectation that discovery will reveal evidence to support the plaintiff's allegations. Id. at 556; see also Brooks v. Ross, 578 F.3d 574, 581 (7th Cir. 2009). Nevertheless, some factual support must be provided to ground the claims. See Brooks 578 F.3d at 581. A complaint that contains only bare legal

conclusions will not "unlock the doors of discovery." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

To state a claim for negligence in Illinois that is based on a violation of a statute designed to protect human life, a plaintiff must show that, (1) the violation proximately caused his or her injury, and (2) the statute was designed to protect a class of persons from injury to which the plaintiff belongs. Kalata, 581 N.E.2d at 661. To state a claim for product liability, a plaintiff must show that the product was unreasonably dangerous at time it left the defendant's control. Apperson, 41 F.3d at 1106. Negligence and strict liability claims for defective products need not specify a precise defect, and discovery may be needed to pinpoint the specific defect at issue. Bausch, 630 F.3d at 560. In the case of Class III medical devices, potentially valuable information related to PMA is kept confidential as a matter of federal law. Id. While a complaint must still satisfy Rule 8, a plaintiff's pleading burden corresponds to the amount of information available. Id. at 561.

Defendant points to the complaint in Bausch as one that demonstrates a sufficient factual basis. In the Bausch complaint, the plaintiff alleged that: (1) the manufacturer had recalled a batch of the hip replacement systems at issue; (2) the FDA had informed the manufacturer of numerous quality control violations upon its inspection of defendant's manufacturing facility; and (3) the FDA had issued the manufacturer a warning letter. Bausch, 630 F.3d at 558–59. Defendant correctly notes that these facts related specifically to the hip replacement system—not the plaintiff's medical condition. In the instant case, plaintiffs argue that the high levels of chromium and cobalt found in Cheryl Elmore's blood indicate that the BHR was in an "unreasonably dangerous" condition at the time it left defendant's control. In addition, plaintiffs

point to the high fluid levels detected around Cheryl's hip joint, and her eventual need for revision surgery and complete removal of the BHR System. Defendants counter that the occurrence of medical complications after a major surgery does not provide the factual grounding necessary to make a claim plausible on its face under Twombly and Iqbal.

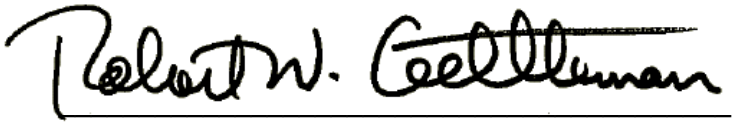
As pled, plaintiffs' complaint is plausible on its face. Two revision surgeries, coupled with increased chromium and cobalt levels in Cheryl's blood, provide sufficient factual grounding on which to base negligence and strict liability claims. The complaint does more than assert bare legal conclusions. It makes a reasonable inference of liability, at the very least, plausible on the face of the complaint. While recalls and warning letters, such as those presented Bausch, would strengthen plaintiffs' complaint, they are not necessary to survive a motion to dismiss. As the Seventh Circuit has noted, plaintiffs alleging defective manufacture are at a disadvantage in terms of discovery. Bausch, 640 F.3d 546. By including the report prepared after the second revision surgery, plaintiffs have at least attempted to include device-specific information, in addition to facts related to Cheryl's injuries. Plaintiffs' pleading burden is commensurate with the amount of information they can access prior to discovery. Id. at 561. Here, plaintiffs have assembled the minimal factual grounding necessary to meet the plausibility standard required under Twombly and Iqbal. Consequently, the complaint complies with Fed. R. Civ. P. 8.

## CONCLUSION

For the foregoing reasons, defendant's motion to dismiss is denied. Defendant is directed to answer the complaint on or before May 10, 2013. The parties are directed to file a joint status

report using the court's form on or before May 17, 2013. This matter is set for a report on status May 23, 2013, at 9:00 a.m. The April 23, 2013, status hearing is cancelled.

**ENTER: April 19, 2013**



**Robert W. Gettleman**
**United States District Judge**