UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
at LEXINGTON

CIVIL ACTION NO. 5:08-476-KKC

RACHEL GRIGSBY and
GARY GRIGSBY, PLAINTIFFS,

v. **OPINION AND ORDER**

I-FLOW CORPORATION,
ASTRAZENECA LP,
ASTRAZENECA PHARMACEUTICALS LP, and
ZENECA HOLDINGS, INC., DEFENDANTS.

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This matter is before the Court on several motions including a Motion to Dismiss or in the Alternative for More Definite Statement filed by the Defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Zeneca Holdings, Inc. (together, "AstraZeneca") (DE 24); Motion for Leave to File Second Amended Complaint filed by the Plaintiffs (DE 27); AstraZeneca's Motion to Strike certain exhibits (DE 28); AstraZeneca's Motion to Withdraw its Motion to Dismiss and Motion to Strike (DE 34); AstraZeneca's Motion for Costs and Fees (DE 35); and the Plaintiffs' Motion for Costs, Fees and Sanctions Pursuant to FRCP 11(c) (DE 37).

I. BACKGROUND.

A. The Complaint.

The Plaintiffs assert in their Complaint that Plaintiff Rachel Grigsby underwent surgery to her right shoulder in Lexington, Kentucky on or about February 3, 2006 and that a medical device called the "ON-Q Pain-Buster Post-Op Pain Relief System" was implanted into her shoulder joint. (DE 9, Complaint ¶ 11). They assert that the medical device injected continuous doses of pain relief

medication, including bupivacaine, directly into the shoulder joint for up to 48 hours following surgery. (DE 9, Complaint ¶ 12). The Plaintiffs assert that the device was "designed, manufactured, marketed, and distributed" by Defendant I-Flow Corporation. (DE 9, Complaint ¶ 11).

The Plaintiffs assert that the device is designed and intended to be used with "commonly used anesthetics such as marcaine manufactured and distributed by the Defendants Abbott, Hospira, Atrazeneca Pharmaceuticals, Astrazeneca LP and Zeneca Holdings." (DE 9, Complaint ¶ 13). The Plaintiffs assert that the continuous injection of such medications over time directly into the shoulder joint, however, can cause serious and permanent damage to the cartilage of the shoulder joint, causing a condition called chondrolysis, which is the complete or nearly complete loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition. (DE 9, Complaint ¶ 13). The Plaintiff asserts that Plaintiff Rachel Grigsby suffered a loss of cartilage and a narrowing of the joint space and/or chondrolysis. (DE 9, Complaint ¶ 13).

The Plaintiffs assert strict liability, negligence, and breach of warranty claims against Defendant I-Flow. The Plaintiffs also asserted strict liability, negligence, and breach of warranty claims against Abbot, Hospira, and Astrzeneca, stating the following:

> The marcaine and/or bupivacaine analgesic pain medication manufactured and placed into the stream of commerce by the Defendants Abbot, Hospira, Astrazeneca Pharmaceuticals, Astrazeneca LP and Zeneca Holdings, was unreasonably and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the medication. . . ."

(DE 9, Complaint ¶ 29).

They further assert that the "marcaine medication manufactured by the Defendants Abbott, Hospira, Astrazeneca Pharmaceuticals, Astrazeneca LP and Zeneca Holdings, caused Plaintiff to suffer the permanent loss of cartilage in her shoulder. . . ." (DE 9, Complaint ¶ 30).

The Plaintiffs assert that "[b]y intentionally promoting and knowingly selling marcaine for continuous use in the intra-articular space of the shoulder following surgery, the Defendants Abbott, Hospira, Astrazeneca Pharmaceuticals, Astrazeneca LP and Zeneca Holdings, impliedly warranted to Plaintiff that marcaine was merchantable, that it was proven safe and effective for use. . . ." (DE 9, Amended Complaint ¶ 36).

The parties have stipulated to the dismissal, without prejudice, of all claims asserted against Hospira/Abbot Labs. (DE 38). Thus, the only remaining defendants are I-Flow Corporation and AstraZeneca.

B. Astrazeneca's Motion to Dismiss (DE 24).

AstraZeneca moved to dismiss the Complaint for failure to state a claim upon which relief can be granted. (DE 24, Motion at 1). AstraZeneca argued that the Plaintiffs "fail[ed] to identify the type of 'pain medication' allegedly used by Mrs. Grigsby that caused her injuries or which Defendant manufactured it" and that "Plaintiffs do not allege that Mrs. Grigsby used a pain medication manufactured by AstraZeneca." (DE 24, Memo., at1).

AstraZeneca also moved to dismiss on the basis that the Plaintiffs allege in their Complaint that Mrs. Grigsby used a pain medication called "marcaine" but that Astrazeneca does not market or distribute marcaine. (DE 24, Memo., at 8-9).

In the alternative to dismissal of the Complaint, the Plaintiffs argued that the Court should order the Plaintiffs to file an amended complaint "identifying the specific pain medication that allegedly caused Mrs. Grigsby's injuries and who manufactured it." (DE 24, Mot., at 2).

C. The Plaintiffs' Motion to File Second Amended Complaint (DE 27).

The Plaintiffs responded to the motion to dismiss and also moved to file a Second Amended

Complaint. (DE 27). In their response, the Plaintiffs explain Mrs. Grigsby's medical records indicate that the pain pump she used was filled with 100 millileters of .5% plain "marcaine." (DE 27, Mem., at 2). They explain that "marcaine" is the trade name for the bipuvacaine manufactured by former Defendant Hospira but is also the commonly used name for bupivacaine in the healthcare industry. (DE 27, Mem., at 2 n.1). The Plaintiffs state that bupivacaine and marcaine are just different names for the same drug: Bupivacaine Hydrochloride. (DE 27, Mem. at 8).

The Plaintiffs explain that, at the time of Mrs. Grigsby's surgery, AstraZeneca manufatured .5% bupivacaine under the trade name "Sensorcaine" and that former Defendants Abbott Labs and Hospira manufactured .5% bupivacaine under the trade name "Marcaine," but that it was the normal practice in the medical community to refer to the medication interchangeably as "marcaine" or "bupivacaine." (DE 27, Mem. at 3). The Plaintiffs assert that Mrs. Grigsby's surgery was conducted at the Kentucky Surgery Center (DE 27, Mem. at 2) and that, at the time of Mrs. Grigsby's surgery, nearly the entire inventory of .5% plain bupivacaine at the Kentucky Surgery Center was Sensorcaine manufactured by AstraZeneca. (DE 27, Mem. at 3).

As support, the Plaintiffs attach certain documents provided by the vendor who sold bupivacaine to the Kentucky Surgery Center for 2005 and 2006. (DE 27, Ex. B). The Plaintiffs assert that there may have been a small amount of .5% bupivacaine manufactured by former Defendants Abbot/Hospira in the inventory of the Kentucky Surgery Center on the date of Mrs. Grigsby's surgery (DE 27, Mem. at 3), but that, for certain specified reasons, it is unlikely that the pain pump used by Mrs. Grigsby was filled with bupivacaine manufactured by Abbott/Hospira. (DE 27, Mem. at 4).

The Plaintiffs argue that their complaint clearly identifies the two manufacturers that made

the .5% bupivacaine that was in the inventory of the Kentucky Surgery Center at the time of Mrs. Grigsby's surgery – AstraZeneca and Abbot/Hospira. (DE 27, Mem. at 6).

The Plaintiffs request that this Court deny the Motion to Dismiss and grant them leave to file a second amended complaint into which they can incorporate more specific information they have obtained since the filing of the Complaint. (DE 27, Mem. at 10).

D. AstraZeneca's Motion to Strike Exhibits to Plaintiffs' Response (DE 28).

AstraZeneca followed with a Motion to Strike the exhibits attached to the Plaintiffs' response to the Motion to Dismiss, arguing that they should not be considered on a Motion to Dismiss and were "unauthenticated, inadmissible hearsay documents. . . ." (DE 28). In their response to the Motion to Dismiss, the Plaintiffs had cited the exhibits as evidence that AstraZeneca manufactured the medicine used by Mrs. Grigsby.

AstraZeneca also filed a Reply brief to its Motion to Dismiss in which it continued to argue that, even if the Court should consider the exhibits attached to the Plaintiffs' response to the Motion to Dismiss, the Court must dismiss the Complaint because "these records do not substantiate that Ms. Grigsby was administered Sensorcaine after her surgery on February 3, 2006." (DE 29, Reply at 3). AstraZeneca further asserts that it has not sold "the unbranded generic name bupivacaine HCI, in the United States." (DE 29, Reply at 3). Thus, argued AstraZeneca, the Plaintiffs "have no basis for asserting that Ms. Grigsby was exposed to an AstraZeneca local anesthetic." (DE 29, Reply at 3).

The Plaintiffs then filed a supplemental response (DE 32) to AstraZeneca's Motion to Dismiss, attaching evidence that they assert establishes conclusively that AstraZeneca manufactured the medicine used by Mrs. Grigsby. The Plaintiffs further assert that the evidence is authenticated through an attached affidavit by Glenda Beasley, a Registered Nurse and Clinical Director at the

Kentucky Surgery Center.

E. AstraZeneca's Motion to Withdraw its Motion to Dismiss and Motion to Strike. (DE 34).

AstraZeneca followed with a Motion to Withdraw in which it asks the Court to withdraw its Motion to Dismiss and Motion to Strike. (DE 34). AstraZeneca also states that it does not oppose the Plaintiff's Motion for Leave to File Second Amended Complaint.

F. AstraZeneca's Motion for Attorney's Fees.

Contained within AstraZeneca's Motion to Withdraw is also a motion by AstraZeneca for the attorney's fees and costs it incurred in filing the motions that it was now seeking to withdraw, i.e., its Motions to Dismiss and to Strike. (DE 34). AztraZeneca asserts that the Plaintiffs should have conducted an investigation prior to filing their lawsuit that would have allowed them to make specific factual allegations against AstraZeneca that they are now able to make. AstraZeneca asserts that, had the Plaintiffs conducted a "reasonable pre-suit investigation" then AstraZeneca would not have moved to dismiss the Complaint or to strike the exhibits attached to the Plaintiff's response to the Motion to Dismiss.

G. The Plaintiffs' Motion for Costs, Fees and Sanctions under Rule 11.

The Plaintiffs followed with their own Motion for Costs, Fees and Sanctions under Federal Rule of Civil Procedure 11. (DE 37). In support of their motion for fees, the Plaintiffs argue that AstraZeneca falsely stated numerous times in its Motion to Dismiss that the Plaintiffs did not conduct a reasonable investigation prior to filing their Complaint. The Plaintiffs assert they conducted as thorough investigation as possible before filing suit and that, as a result of their extensive investigation, they were able to narrow down the scope of potential defendants to two:

Hospira/Abbot and AstraZeneca.

The Plaintiffs also assert that, at the time that AstraZeneca filed its Motion to Dismiss, information was readily available to it that would establish that one of its vendors sold AstraZeneca's product Sensorcaine to the Kentucky Surgery Center in February 2006. (DE 36, Mem. at 11).

The Plaintiffs assert that the Court must impose sanctions on AstraZeneca because either it knew when it filed its Motion to Dismiss that it made the Sensorcaine used by Mrs. Grigsby or it could have readily ascertained that fact through its vendor for central Kentucky.

AstraZeneca responds that it need not have investigated whether the Plaintiff used one of its products before filing the Motion to Dismiss because "it is well established that a defendant in a product liability suit. . . is not required to affirmatively investigate, after service of a lawsuit, whether the plaintiff used one of its products." (DE 42). AstraZeneca further argues that it could not have ascertained from its vendor whether it sold the product used by Mrs. Grigsby because it no longer has a vendor in central Kentucky and because the Plaintiff's Complaint did not state "where the surgery at issue occurred or what product was allegedly implicated." Finally, AstraZeneca argues that it would be too complicated for it to determine whether Mrs. Grigsby used one of its products because "the distribution process is much more complicated than Plaintiffs claim, with pharmaceutical companies contracting with Group Purchasing Organizations and large distributors, who in turn sell to smaller distributors and hospitals."

AstraZeneca also argues that the Plaintiffs' Rule 11 motion must be denied because the Plaintiffs did not notify AstraZeneca that they intended to move for sanctions 21 days before filing the Rule 11 motion as required under Rule 11(c)(2).

II. ANALYSIS.

Perhaps the easiest way to sort through these various motions is to begin with AstraZeneca's motion to withdraw two of them. The Court will grant AstraZeneca's Motion to Withdraw its Motion to Dismiss and Motion to Strike and those two motions will be withdrawn.

In its Motion to Dismiss, AstraZeneca also asked the Court to grant the alternative relief of ordering the Plaintiffs to file a Second Amended Complaint "identifying the specific pain medication that allegedly caused Mrs. Grigsby's injuries and who manufactured it." (DE 24, Mot. at 1-2). AstraZeneca has not specifically moved to withdraw its Motion for More Definite Statement. However, because AstraZeneca has now moved to withdraw its Motion to Dismiss the Complaint, the Court assumes that AstraZeneca now finds the allegations in the Complaint sufficient and also withdraws its Motion for More Definite Statement.

To the extent that AstraZeneca has not withdrawn the Motion for a more Definite Statement, it will be denied. In their Complaint the Plaintiffs allege that the "Pain-Buster is designed and intended to be used with commonly used anesthetics such as marcaine manufactured and distributed by [AstraZeneca] (DE 9, Amended Complaint ¶ 13); that "the Plaintiff had a Pain-Buster inserted post-operatively, and received dangerous doses of continuously injected medication in her shoulder joint;"(DE 9, Amended Complaint ¶ 13); that the "marcaine and/or bupivacaine analgesic pain medication manufactured and placed into the stream of commerce by [AstraZeneca] was unreasonably and dangerously defective" (DE 9, Amended Complaint ¶ 29); that "the marcaine medication manufactured by [AstraZeneca] caused Plaintiff to suffer the permanent loss of cartilage in her shoulder. . ." (DE 9, Amended Complaint ¶ 30).

The Complaint thus sufficiently alleges "the specific pain medication that allegedly caused

Mrs. Grigsby's injuries" – marcaine and/or bupivacaine – and "who manufactured it" – AstraZeneca.

Further, the Plaintiffs have indicated an intent to file a Second Amended Complaint with more specific allegations in it and AstraZeneca has indicated that it has no objection to the filing of a second amended complaint. Accordingly, it is not necessary for this Court to order the Plaintiffs to file a Second Amended Complaint that provides a more definite statement "identifying the specific pain medication that allegedly caused Mrs. Grigsby's injuries and who manufactured it" as AstraZeneca requests.

As to the Plaintiffs' Motion for Leave to File Second Amended Complaint, AstraZeneca now states it has no objection to that motion. However, the Plaintiffs did not tender a proposed amended complaint. Thus, neither this Court nor AstraZeneca has had an opportunity to review the proposed amendments. Accordingly, the Motion to Amend will be denied with leave for the Plaintiffs to refile the motion with a tendered amended complaint.

That leaves two unresolved motions: AstraZeneca's Motion for Costs and Fees (DE 35) and the Plaintiffs' Motion for Costs, Fees, and Sanctions Pursuant to FRCP 11(c) (DE 37).

In its motion, AstraZeneca argues that the Plaintiffs should pay the costs and fees it incurred in filing the Motion to Dismiss and Motion to Strike – both of which it has now withdrawn. In its Motion, AstraZeneca does not explain what law entitles it to attorney's fees and costs. This Court can certainly award attorney's fees and costs as sanctions for a violation of Rule 11. Fed. R. Civ. P. 11(c). And AstraZeneca's motion could be read to rely on Rule 11. AstraZeneca cites only three cases in support of its motion, all of which decided motions for sanctions under Rule 11. *See Albright v. Upjohn Co.*, 788 F.2d 1217 (6th Cir. 1986); *Whittington v. Ohio River Co.*, 115 F.R.D.

201 (E.D. Ky. 1987) and *Mann v. G&G Manufacturing, Inc.*, 900 F.2d 953 (6th Cir. 1990).

Moreover, AstraZeneca argues that it is entitled to attorney's fees because the Plaintiffs failed to conduct "the required pre-suit factual investigation" prior to filing the lawsuit. (DE 35, Mem. at 1; *See also* DE 35, Mem. at 2 "prior to filing the lawsuit, Plaintiffs did not conduct any factual inquiry or investigation. . . ."). This certainly sounds like AstraZeneca is charging that the Plaintiffs failed to comply with Rule 11's obligation "to conduct a reasonable inquiry into the law and facts before signing papers filed with the court. . . " *Rentz v. Dynasty Apparel Industries, Inc.*, 556 F.3d 389, 401 (6th Cir. 2009); *See also* Fed. R. Civ. P. 11(b).

But, AstraZeneca never mentions Rule 11 in its motion for attorney's fees and, in fact, it expressly disclaims that the motion is made under Rule 11, stating that "nowhere in AstraZeneca's Motion for Costs and Fees did they mention, refer to or seek relief based on any violation of FRCP 11." (DE 40, Reply at 2 n.1). Further, AstraZeneca's motion does not comply with the procedural requirements of Rule 11. A motion for sanctions under Rule 11 must be made separately from any other motion and must be served on the non-moving party 21 days before filing with the Court. Fed. R. Civ. P. 11(c)(2).

Thus, if AztraZeneca does rely upon Rule 11 in its motion for attorney's fees and costs, the motion must be denied because AstraZeneca has not complied with the rule's procedural requirements. To the extent that AstraZeneca relies upon some authority other than Rule 11 in support of its motion for attorney's fees and costs, the Court will deny the motion because AstraZeneca has not explained what that authority is.

As to the Plantiffs' Motion for Costs, Fees and Sanctions Pursuant to FRCP 11(c), this motion will also be denied. AstraZeneca asserts that the Plaintiffs also failed to comply with the

procedural requirements of Rule 11(c)(2) and the Plaintiffs do not dispute that in their Reply Memorandum.

III. CONCLUSION.

For all these reasons, the Court hereby ORDERS as follows:

1) AstraZeneca's Motion to Withdraw (DE 34) its Motion to Dismiss and Motion to Strike is GRANTED;

2) AstraZeneca's Motion to Dismiss (DE 24) and Motion to Strike (DE 28) are WITHDRAWN;

3) AstraZeneca's Motion for more Definite Statement (DE 24) is DENIED;

4) The Plaintiffs' Motion for Leave to File Second Amended Complaint (DE 27) is DENIED with leave for the Plaintiffs to refile it with a tendered Amended Complaint;

5) AstraZeneca's Motion for Costs and Fees (DE 35) is DENIED; and

6) the Plaintiffs' Motion for Costs, Fees and Sanctions Pursuant to FCRP 11(c) is DENIED.

Dated this 22nd day of July, 2009.

Signed By:
Karen K. Caldwell
United States District Judge