Hershberger et al v. Ethicon Endo-Surgery, Inc. et al Doc. 350

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

SANDRA HERSHBERGER, et al.

Plaintiffs,

v. CIVIL ACTION NO. 2:10-cv-00837

ETHICON ENDO-SURGERY, INC., et al.

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the Court are three motions in limine by Defendants Ethicon Endo-Surgery, Inc., and Johnson & Johnson, Inc. ("Defendants" or "Ethicon"). Defendants move to exclude other events and occurrences involving Ethicon staplers [Docket 181], evidence relating to Medwatch reporting forms [Docket 183], and evidence of its late discovery disclosures [Docket 179].

The full factual background of this case is set out in the Court's February 15, 2012, Memorandum Opinion and Order addressing Defendant Ethicon's motions in limine to exclude various expert witnesses and need not be repeated here. (Docket 334.)

I. MOTION IN LIMINE TO EXCLUDE OTHER EVENTS EVIDENCE

In this motion, Defendants seek to exclude from trial the introduction of investigative reports related to Ethicon stapler performance, as well as allegations of other incidents concerning stapler performance and litigation related to Ethicon staplers. (Docket 182 at 1-2.) The basis for exclusion is threefold—Defendants argue that the evidence is: (1) irrelevant under Rules 401 and 402 of the Federal Rules of Evidence and the substantial similarity test; (2) far outweighed by undue prejudice under Rule 403; and (3) inadmissible hearsay. Plaintiff responded to the motion by arguing that

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forty-five internal incident files produced by Defendants in discovery are relevant evidence in this case and should be admitted at trial. (Docket 206 at 5-9.) Neither party addressed any evidence related to other litigation concerning Ethicon staplers,[1] and accordingly, the Court confronts only the forty-five incidents summarized by the parties.

Attached to her memorandum in response, Plaintiff has proffered a summary of the forty-five incidents and offered to produce to the Court the investigative files in full. (Docket 206 at 9, Docket 206-13.) The files were maintained and produced by Defendants during (or shortly after the close of) discovery, and they appear to constitute Ethicon's adverse event files, required to be kept by a medical device manufacturer pursuant to 21 C.F.R. pt. 803. They are, therefore, compiled by Defendants. An exemplar of twenty-one investigative files exists under seal in the record from a hearing before Magistrate Judge Stanley, Docket 263, and production of additional files is therefore unnecessary. Defendants produced a chart of their own in reply to Plaintiff's chart, which sets forth the "inherent differences" between the allegations in this case and the forty-five incident files. The incident files themselves appear to be approximately ten pages in length and contain some blend of the following documents: (1) cover pages with date, product, and location information, a brief event description, contact information for all parties involved, and notes of each entry in the investigative file; (2) Product Issue Verification Reports, containing much of the same information; (3) Product Issue Analysis Reports, which are prepared by an Ethicon engineer upon receipt of the allegedly faulty stapler after the incident and detail the results of various functionality testing and related observations; and (4) MedWatch forms, which are incident reports required to be submitted to the

[1] Both parties cited *Chism v. Ethicon Endo-Surgery, Inc.*, 2009 WL 3066679 (E.D. Ark. 2009), as persuasive precedent in their respective briefing, but neither argued for the introduction of any evidence from that case.

FDA under federal law.[2] All information contained in the various reports is necessarily derived second- or third-hand from medical personnel reporting an incident directly to Ethicon or through regional sales representatives. Thus, much of the information resembles the following "Event Description" from a Product Issue Analysis Report: "It was reported by the sales rep. that the device cut and did not staple (no staples came out of the device). The sales rep was not provided how the case was complete. There was no reported patient's consequence. The device will be returned for analysis." (Docket 263-1 at 4.)

A. Legal Standards

It is fairly well-established that evidence of similar incidents may be relevant as direct proof of negligence, a design defect, notice of a defect, or causation. *See, e.g.*, *Jiminez v. DaimlerChrysler Corp.*, 269 F.3d 439, 456 (4th Cir. 2001); *United Oil Co., Inc. v. Parts Assocs., Inc.*, 227 F.R.D. 404 (D. Md. 2005); *Buckman v. Bombardier Corp.*, 893 F. Supp. 547, 552 (E.D.N.C. 1995). Prior to admitting evidence of other incidents, however, the proponent of the evidence must present a factual foundation for the Court to determine that the other incidents were "substantially similar" to the allegations at issue. *See Brooks v. Chrysler Corp.*, 786 F.2d 1191, 1195 (D.C. Cir. 1986) ("Evidence

[2] The MedWatch forms in the incident files appear to be exclusively Form 3500A, which is the FDA form used by medical device manufacturers and distributors to report mandatory adverse events. Form 3500, in contrast, pertains to voluntary reporting by healthcare professionals, consumers, and patients. From the Court's review, the other incident files contain only MedWatch Form 3500As, prepared by an Ethicon representative, and no Form 3500s. *See generally* 21 C.F.R. § 803.20 ("There are two versions of the MedWatch form for individual reports of adverse events. If you are a health professional or consumer, you may use the FDA Form 3500 to submit voluntary reports regarding FDA–regulated products. If you are a user facility, importer, or manufacturer, you must use the FDA Form 3500A to submit mandatory reports about FDA–regulated products."). Every MedWatch Form 3500A has the following sentence printed in the lower left corner: "Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event."

of prior instances is admissible on the issues of the existence of a design defect and a defendant's knowledge of that defect only if a plaintiff shows that the incidents occurred under circumstances substantially similar to those at issue in the case at bar."); *see also Buckman*, 893 F. Supp. at 552. Substantial similarity generally requires the proponent of other incidents evidence to establish: (1) the products are similar; (2) the alleged defect is similar; (3) causation related to the defect in the other incidents; and (4) exclusion of all reasonable secondary explanations for the cause of the other incidents. *Buckman*, 893 F. Supp. at 552 (citing *Hale v. Fireston Tire & Rubber Co.*, 756 F.2d 1322, 1332 (8th Cir. 1985)).

Even when substantial similarity of circumstances exists, the Court must determine whether the evidence is admissible for the specific purpose for which it is offered. In addition, the Court has broad discretion to exclude similar incidents evidence under Rule 403 due to its highly prejudicial nature and tendency to confuse the jury. *E.g.*, *Brooks*, 786 F.2d at 1195; *McKinnon v. Skil Corp.*, 638 F.2d 270, 277 (1st Cir. 1981); *Buckman*, 893 F. Supp. at 552.

B. Relevance under Federal Rules of Evidence 401 & 402

As an initial matter, the allegations in Ethicon's adverse event files and summarized in the parties' respective charts appear to fail the substantial similarity test. Based upon the parties' proffered summaries, as well as the complete files for approximately half of the incidents, the Court finds the forty-five complaints involve similar devices and allegations of similar defects. The reports also reflect that various medical professionals attribute the incidents to a defect involving failure to deploy staples or a perceived absence of staples. Notwithstanding these similarities, nowhere in the incident files is there any indication that reasonable secondary explanations for the other incidents were eliminated. The most obvious reasonable secondary explanation, which to the

Court's knowledge was not ruled out in any of the forty-five other incidents, is surgical team error. Put simply, the forty-five other incidents are not clearly the result of a faulty Ethicon stapler, and thus, they are not substantially similar so as to permit their admission as direct evidence of negligence or a defect.

However, the threshold for admissibility is significantly lower if the other incidents are used to prove Ethicon's notice or knowledge of a product issue. *See Benedi v. McNeil–P.P.C., Inc.*, 66 F.3d 1378, 1386 (4th Cir. 1995). ("When prior incidents are admitted to prove notice, the required similarity of the prior incidents to the case at hand is more relaxed than when prior incidents are admitted to prove negligence. The incidents need only be sufficiently similar to make the defendant aware of the dangerous situation.") (citations omitted). Under this more relaxed standard, the other incidents are relevant to demonstrate that Ethicon was on notice that a portion of their customer base had expressed quality concerns.

As Plaintiff did not divulge for what purposes she intends to introduce similar incidents evidence, the Court is left to speculate as to its various uses in this case. The complaint sets for Plaintiff's causes of action as: (1) negligent design and manufacture; (2) strict liability for defective design and manufacture; (3) breach of implied warranty; and (4) punitive damages. (Docket 1-1.)

(1) Negligence Claim

As to the negligence claim, it may be argued that evidence of other similar incidents is relevant to show that it was reasonably foreseeable to Ethicon that its circular staplers may cause injury. The similar incidents evidence would, in this case, presumably show that Ethicon had notice or knowledge of other staplers that reportedly malfunctioned, and Ethicon was therefore better positioned to foresee the injury that is the subject of this litigation. The Court perceives such use

to be permissible under Rules 401 and 402, as the other incidents are relevant considerations in determining whether Ethicon acted as a reasonably prudent manufacturer would in similar circumstances.

However, using similar incidents evidence as direct proof of negligence in this case—that is, arguing that Ethicon was negligent in marketing defective staplers in the past and it therefore was negligent in this case—is strictly prohibited in light of the Court's above ruling regarding the (dis)similarity of the incidents.

(2) Product Defect Claim

As to the product defect claim, evidence of similar incidents is wholly inadmissible pursuant to the Court's similarity finding. In a strict liability cause of action, Ethicon's knowledge or notice of a potential defect in its product is irrelevant. The only perceivable uses of the other incidents are as direct evidence of a defect or to establish causation. Such use is impermissible because the other incidents are not sufficiently similar; reasonable secondary explanations were never eliminated.

(*3) Breach of Warranty Claim*

The Court perceives no relevant use of the other incident evidence to Plaintiff's breach of warranty claim. Presenting other incidents evidence to demonstrate that Ethicon's stapler was not fit for its intended or foreseeable uses is impermissible under the Court's similarity ruling.

(4) Punitive Damages

The most obvious use of the other incidents evidence is to establish notice of product complaints in the context of a punitive damages claim. Such evidence is directly relevant to the jury's determination of whether Ethicon acted in a wanton, willful, or reckless manner. The relaxed

similarity standard permits the other incidents to be used as evidence of knowledge or notice to Ethicon, which is appropriate to argue to the jury in seeking punitive damages.

C. Admissibility under Federal Rule of Evidence 403

From the Court's review, then, the other incidents are only somewhat similar and therefore relevant for just two purposes: (1) to argue notice and knowledge in the context of reasonable foreseeability as to the negligence claim; and (2) to argue notice and knowledge as they relate to punitive damages. All other uses of the other incidents evidence are irrelevant under the Court's substantial similarity analysis and the above discussion.

However, the Court's admissibility inquiry is not yet complete. The remaining uses of the other incidents evidence must also be analyzed under the dictates of Rule 403. Under Rule 403, otherwise admissible evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice or jury confusion. As discussed above, Ethicon's knowledge or notice of other reported incidents is directly relevant to Plaintiff's punitive damages claim. It is not essential to her negligence claim.

As to the negligence claim, then, the Court **FINDS** that introduction of other similar incidents is likely to waste time and confuse the jury. The applicability of other incidents to the negligence claim is somewhat obscure, and there is significant danger that the jury will consider the other incidents as direct evidence of negligence. Further, the probative value of the other events is minor—these records amount to uncorroborated and incomplete customer complaints constituting approximately 0.003% of Ethicon's sales during the relevant time period.[3] In consideration of the

[3] This figure is derived from the parties' respective assertions that forty-five similar incidents exist out of at least 1.5 million Ethicon staplers of similar functionality sold during the same time period.

foregoing, the Court **FINDS** other incidents are inadmissible under Rule 403 as to the negligence claim.

As the punitive damages claim however, the risk of confusion is diminished—Ethicon's knowledge and notice of other product complaints is directly relevant to punitive damages. Accordingly, the Court **FINDS** that Rule 403 does not operate to exclude other incidents evidence as to punitive damages.

D. Hearsay under Federal Rules of Evidence 801-803; Disposition of the [183] Motion in Limine

With regard to the parties' hearsay arguments, the Court notes simply that permitting the contents of the reports into evidence to demonstrate Ethicon's knowledge and notice of other complaints is likely a non-hearsay purpose.[4] Whether the forty-five complaints are true or reliable would be of little importance in the context of the punitive damages claim; rather, the focus would be on Ethicon's receipt of the allegations and its subsequent actions. Nevertheless, each record is different, and the Court will therefore reserve until trial more specific rulings regarding hearsay objections to the use of other incidents in the context of Plaintiff's punitive damages claim. For this reason, Defendants' Motion in Limine to Preclude Evidence Relating to MedWatch Forms [Docket 183] is **DENIED**.

E. Disposition of the [181] Motion in Limine

In light of the foregoing analysis, Defendants' Motion in Limine to Preclude Reference to Other Events and Occurrences Involving Ethicon Staplers [Docket 181] is **GRANTED IN PART**

[4] In addition, to the extent Plaintiff may wish to cross-examine a defense witness regarding the general subject matter of the other incidents, i.e. the existence of reports of faulty staplers, such use may well be permissible.

and **DENIED IN PART**. The motion in **GRANTED** insofar as it seeks to preclude Plaintiff from introducing other incidents as evidence of a product defect or negligence without establishing substantial similarity to the Court. The ruling above makes clear that, based on the documents before the Court (and Plaintiff's failure to articulate, at this point, her purpose for seeking admission of the other incidents evidence), substantial similarity is lacking due to the non-elimination of reasonable secondary explanations. The motion is **DENIED** insofar as it seeks to preclude Plaintiff from introducing the other incidents to establish a mental state sufficient for the jury to award punitive damages.

II. MOTION IN LIMINE TO EXCLUDE LATE DISCOVERY DISCLOSURES

Defendant Ethicon also moves "to preclude Plaintiffs from offering evidence, arguing, or referring in any way to any alleged late discovery disclosures by Ethicon . . . ." (Docket 179.)

Defendant argues in its notably brief supporting memorandum of law (Docket 180) that, assuming it committed misconduct in the course of discovery, it is inappropriate for a Court to permit as a sanction for that misconduct the introduction of evidence that is otherwise inadmissible under the Federal Rules of Evidence. (Docket 180.) Defendant claims that the similar incident evidence that was the subject of the parties' extended discovery disputes is not admissible under the Federal Rules of Evidence because it fails to pass the relevancy thresholds of Rules 401-404 of the Federal Rules of Evidence. Defendant reasons that the injection of irrelevant evidence at trial can "only serve to prejudice Ethicon in the eyes of the jury." (*Id.*) Defendant appears to be saying that, even if it did improperly delay in disclosing evidence in the course of discovery, the decision of what type of sanction should be guided by the Rules of Civil Procedure, Rule 37 in particular. The Court agrees that admitting otherwise inadmissible evidence, as a sanction or otherwise, is improper.

For the reasons that will appear in the Court's forthcoming Memorandum Opinion addressing Plaintiff's motion for sanctions, the Court **GRANTS** Defendant's motion in limine [Docket 179] to preclude introduction of evidence of Defendant's late disclosure of similar incident evidence in the course of discovery.

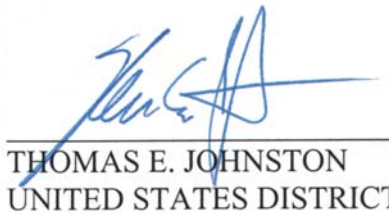
III. CONCLUSION

For the foregoing reasons, Defendants' motion to exclude other events and occurrences involving Ethicon staplers [Docket 181] is **GRANTED IN PART** and **DENIED IN PART**; the motion to exclude evidence relating to MedWatch reporting forms [Docket 183] is **DENIED**, though the issue will likely be revisited at trial; and the motion to exclude evidence of its late discovery disclosures [Docket 179] is **GRANTED**.

IT IS SO ORDERED.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 30, 2012



THOMAS E. JOHNSTON
UNITED STATES DISTRICT JUDGE