

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JO ANN HARPOLD,)	
JEFF HARPOLD,)	
)	
Plaintiffs,)	
vs.)	NO. 1:06-cv-01666-DFH-DML
)	
ETHICON ENDO-SURGERY, INC.,)	
)	
Defendant.)	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JO ANN HARPOLD and JEFF HARPOLD,)
)
 Plaintiffs,)
)
 v.) CASE NO. 1:06-cv-1666-DFH-DML
)
 ETHICON ENDO-SURGERY, INC.,)
)
 Defendant.)

ENTRY ON MOTION FOR SUMMARY JUDGMENT

Plaintiff Jo Ann Harpold suffered complications when a PPH-03 Hemorrhoidal Circular Stapler manufactured by defendant Ethicon Endo-Surgery, Inc., failed to operate properly during a 2005 hemorrhoidectomy performed by Dr. Lemoyne Pringle. Mrs. Harpold and her husband Jeff Harpold brought this product liability suit against Ethicon in the Hendricks Superior Court. The defendant removed the case to this court. The complaint alleges claims under the Indiana Product Liability Act, Ind. Code § 34-20-1-1 *et seq.*, and seeks damages for medical expenses, pain and suffering, lost income and earning capacity, and Jeff Harpold's loss of services and consortium. Defendant Ethicon has moved for summary judgment. Jurisdiction arises under 28 U.S.C. § 1332. As explained below, the defendant's motion for summary judgment is denied.¹

¹The plaintiffs have requested an evidentiary hearing to demonstrate the use of the PPH-03. Dkt. No. 51. The defendant objects. Because the evidence in the (continued...)

I. *Summary Judgment Standard*

The purpose of summary judgment is to “pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Summary judgment is appropriate when there are no genuine issues of material fact, leaving the moving party entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). To prevail, the moving party must show that there is no genuine issue of material fact. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Where the non-moving parties bear the burden of proof on an issue at trial and the motion challenges that issue, the non-moving parties must come forward with evidence of specific facts showing that there is a genuine issue for trial. See Fed. R. Civ. P. 56(e)(2); see also *Silk v. City of Chicago*, 194 F.3d 788, 798 (7th Cir. 1999).

A factual issue is material only if resolving the factual issue might change the suit’s outcome under the governing law. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual issue is genuine only if there is sufficient evidence for a reasonable jury to return a verdict in favor of the non-moving party on the evidence presented. See *id.* In deciding a motion for summary judgment, a court may not assess the credibility of witnesses, choose between competing inferences, or balance the relative weight of conflicting evidence; the court must

¹(...continued)
record is sufficient to deny the motion for summary judgment, plaintiffs’ requested demonstration is not necessary. The request for an evidentiary hearing is denied.

view all the evidence in the record in the light reasonably most favorable to the non-moving parties and resolve all factual disputes in their favor. See Fed. R. Civ. P. 56(c); *Anderson*, 477 U.S. at 249-50.

II. *Undisputed Facts*

The following facts are undisputed for purposes of this motion for summary judgment. Jo Ann Harpold sought treatment from Dr. Lemoyne Pringle for internal hemorrhoids. After attempting conservative non-surgical treatment, Mrs. Harpold opted to have a surgical hemorrhoidectomy. Pringle Dep. 17, 21. Dr. Pringle decided to use the Proximate PPH-03 Hemorrhoidal Circular Stapler in the procedure. Defendant Ethicon Endo-Surgery, Inc. manufactured the PPH-03.

The PPH-03 is a single-use device that removes and anastomoses tissue in the colon or rectum after removal of hemorrhoidal tissue. Def. Ex. A at 5-6. Its operation is fairly complicated, but for purposes of the summary judgment motion, the following description will suffice. The PPH-03 is a long, probe-shaped device. It contains an “anvil” that is connected to a staple housing by an anvil shaft. Def. Ex. A at 2-4. The distance between the anvil and the staple housing can be adjusted by turning a knob located at the end of the device’s handle. Def. Ex. A at 2-5. After the doctor inserts the PPH-03 into the patient, the device manual instructs the doctor to close the distance between the anvil and staple housing by turning the knob. Def. Ex. A at 5. When the anvil and staple housing

are separated by an appropriate distance, an indicator on the handle is supposed to show a gauge in a green range. Def. Ex. A at 5. The manual contains the following warning: “Caution: DO NOT fire the instrument if the orange indicator is not advanced as far as possible within the green range of the gap setting scale.” Def. Ex. A at 5. When the indicator is in the green range, the anvil is between 0.75 and 1.50 millimeters from the staple housing. Hill Dep. 64. Once the indicator is in the green range, the doctor is supposed to remove a trigger safety and squeeze the trigger firmly. Def. Ex. A at 5. The manual instructs that, after squeezing firmly, the doctor “will feel reduced trigger pressure and hear a ‘crunch’ as the instrument completes the firing cycle.” *Id.* The doctor then releases the trigger and follows a procedure to remove the stapler.

When the doctor pulls the trigger, the PPH-03 fires staples that do not close initially. Hill Dep. 20-21. A circular knife in the stapler then engages and “excises the prolapsed mucosa and submucosa” Def. Ex. A at 5; Hill Dep. 20-21. The knife is supposed to make contact with the anvil and to cut through a breakaway washer that rests on the anvil head. Hill Dep. 21. As the doctor continues to squeeze the trigger, the staples are supposed to close. *Id.* at 21-22.

Dr. Pringle performed Mrs. Harpold’s hemorrhoidectomy on October 17, 2005. Pringle Dep. 25. Before using the device on Mrs. Harpold, Dr. Pringle had participated in a PPH-03 training session, observed several PPH-03 procedures, and used the device in surgeries two or three times. *Id.* at 28, 58-60. An Ethicon

representative was present in the operating room during Mrs. Harpold's procedure. *Id.* at 41. At the appropriate point in the surgery, Dr. Pringle inserted the device and adjusted the knob to bring the anvil closer to the staple housing. *Id.* at 35, 38. Dr. Pringle testified that he recalls the indicator was in the green range before he fired the stapler. *Id.* at 39. He then removed the safety and squeezed the trigger to fire the stapler. *Id.* at 40. Dr. Pringle testified that the trigger pressure was "constant throughout the firing." *Id.* He noticed nothing unusual about the pressure he felt or the sound he heard as he fired the stapler. *Id.* at 40-41. He said the sound was "very typical of what I've heard before." *Id.* at 45. Dr. Pringle removed the device from Mrs. Harpold, and he observed that she had "profuse bleeding." *Id.* at 43. A circular section of tissue had been excised, but the staples did not close the edges of the tissue. *Id.* at 45. After Dr. Pringle discovered the source of the bleeding, he inserted stitches to replicate the desired effect of the staples. *Id.* Dr. Pringle saw two or three unformed staples in Mrs. Harpold's anal canal. *Id.* at 54-55. The next day, Mrs. Harpold reported complications, and Dr. Pringle discovered that she had a perforation in her colon wall. *Id.* at 50-53. Dr. Pringle had to perform a colostomy on Mrs. Harpold on October 19, 2005. *Id.* at 55. He testified in his deposition that the PPH-03's failure to apply staples properly was a likely cause of Mrs. Harpold's colon perforation. *Id.* at 77-82.

After the October 17 surgery, the Ethicon representative present during the surgery took the PPH-03 from Dr. Pringle. Pringle Dep. 84-85. Ethicon inspected

and tested the device, and it produced an analysis report detailing its findings. Def. Ex. D.² The analysis was performed by Jorge Flores, an equipment engineer at Ethicon's Juarez, Mexico manufacturing plant. Def. Ex. D; Flores Dep. 7. He discovered that the breakaway washer, which is supposed to be cut cleanly by the circular blade, was indented but not cut. Def. Ex. D; Hill Dep. 33. The report concluded that the device was in good working condition. Def. Ex. D. Flores installed a new breakaway washer and performed a test fire of the stapler. The device worked properly. The breakaway washer was cut cleanly, and the staples formed fully in the test media. Def. Ex. D.

At his deposition, Flores made further observations about the PPH-03 used in Mrs. Harpold's surgery. He confirmed that its safety could be disengaged when the indicator was not in the green range. Flores Dep. 63. He also confirmed that its trigger could be depressed fully when the indicator was not in the green range. Flores Dep. 64.

²The court issued an order directing the parties to show cause why Exhibit D should remain under seal. Dkt. No. 41. The defendant responded to the show cause order and included a motion to seal Exhibit D. Dkt. No. 42. The plaintiffs do not object to Exhibit D remaining under seal. Dkt. No. 44. The court denies the motion and orders that Exhibit D be unsealed. Exhibit D does not contain information that qualifies as a "trade secret." The document is essentially a checklist of possible PPH-03 malfunctions with a conclusion. The exhibit is central to the defendant's case, and it would unduly hamper the trial to keep this critical exhibit under seal. The court stays the order to unseal Exhibit D for seven days after the filing of this entry to permit the defendant to seek emergency review by the Court of Appeals if it wishes to do so.

The plaintiffs also inspected the PPH-03 used in Mrs. Harpold's surgery. They hired Wolf Technical Services to report on the device. Wolf employee William Dickinson, an engineer, inspected the device and other evidence and prepared a report. Pl. Supp. Ex. 1. After briefing on the motion for summary judgment seemed complete, plaintiffs filed a motion to supplement their designation of evidence in response to the motion for summary judgment by adding Dickinson's report. Dkt. No. 64. Local Rule 56.1 requires parties to designate evidence in opposition to a motion for summary judgment no later than thirty days after service of the motion. S.D. Ind. Local R. 56.1(b). The rule permits the court to excuse failure to comply strictly with the rule "in the interests of justice or for good cause." S.D. Ind. Local R. 56.1(i). The court grants the plaintiffs' motion and will consider Dickinson's report. The report addresses a material issue: whether the safe firing range indicator on the device functions properly. It also supports the plaintiffs' theory that Dr. Pringle fired the stapler while the anvil was too far from the staple housing. The plaintiffs have also shown good cause for their failure to submit the report with their response brief. There have been discovery difficulties in this case, and the plaintiffs were unable to depose the source of the main defense exhibit, Mr. Flores, until July 23, 2008. The plaintiffs needed Mr. Flores' deposition to have sufficient information to obtain Mr. Dickinson's report. The plaintiffs obtained and disclosed the report within the time allowed by the case management plan. Nevertheless, a motion to extend further the time to respond to the defense motion under Rule 56(f) would have been the preferred course, thereby avoiding the extra briefing caused by the delay.

Dickinson reached several conclusions. He concluded that the device's safety could be disengaged when the anvil was 2.79 millimeters from the staple housing. Pl. Supp. Ex. 1 at 6. He concluded that the indicator was in the green range when the anvil was 2.11 millimeters from the staple housing. Pl. Supp. Ex. 1 at 6. He also concluded that the anvil could not move closer than 0.99 millimeters from the staple housing. Pl. Supp. Ex. 1 at 6. Finally, he concluded that the safety could be disengaged while the indicator was outside of the green range. Pl. Supp. Ex. 1 at 7-8.

III. *Discussion*

The defendant contends that the Harpolds cannot show that the PPH-03 used in Mrs. Harpold's surgery was defective and that any defect caused her injuries. The Indiana Product Liability Act (IPLA) governs "all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. This section was amended in 1995 and recodified in 1998 to apply to all product liability claims. See *Butler v. City of Peru*, 733 N.E.2d 912, 918 n.2 (Ind. 2000), citing Pub. L. No. 278-1995, § 1, 1995 Ind. Acts 4051, and Pub. L. No. 1-1998, § 15, 1998 Ind. Acts 125.

The IPLA provides that “a person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user’s or consumer’s property is subject to liability for physical harm caused by that product to the user” if certain conditions not relevant to this motion are met. Ind. Code § 34-20-2-1. To survive summary judgment, plaintiffs must point to evidence sufficient to permit a reasonable jury to conclude that the PPH-03 used on Mrs. Harpold was defective and that the defect caused harm to her. The defendant does not argue that any defect in the PPH-03 arose after its delivery. It argues only that the plaintiffs have no evidence that the PPH-03 used on Mrs. Harpold had a defect that caused her injuries.

Both plaintiffs and defendant have suggested theories to explain why the staples did not form fully in Mrs. Harpold’s surgery. The plaintiffs have pointed to sufficient evidence to permit a reasonable jury to conclude that their theory is accurate and that a defect in the PPH-03 caused Mrs. Harpold’s injuries.

A. *Defendant's Theory*

The defendant argues that the incomplete formation of the staples was caused by doctor error. It claims that the evidence shows conclusively that Dr. Pringle did not squeeze the trigger fully, causing the staples not to fire fully and preventing the cut tissue from being properly reconnected. Def. Br. 8. The defendant focuses on the PPH-03's breakaway washer, which was indented but not cut cleanly. Brian Hill, the project director responsible for the PPH-03's design and development, testified in his deposition that the indentation on the washer is consistent with the circular knife cutting through the patient's tissue but not being fired completely. Hill Dep. 33-34. In such a scenario, Hill said, the staples would not form fully. *Id.* at 34.

The defendant believes that this scenario is supported by Dr. Pringle's testimony that the pressure on the handle was constant throughout the firing. The PPH-03's manual states that the user should feel a decrease in pressure when the trigger is fully squeezed. Hill confirmed that the user should feel a decrease in pressure when the blade cuts through the breakaway washer. Hill Dep. 23. The defendant argues that Dr. Pringle must not have squeezed the trigger properly because he did not feel a decrease in pressure and the breakaway washer was not cut. The theory is also supported by Dr. Pringle's testimony that the indicator was in the green range before he fired the device and the defendant's examination of

the device, which concluded that it fired properly when operated according to the manual's instructions.

B. *Plaintiffs' Theory*

The plaintiffs reject the defendant's theory and point to two defects in the PPH-03 used on Mrs. Harpold that explain the failure of the staples to form properly. First, they argue that the indicator incorrectly showed that the anvil was the proper distance from the staple housing. Second, they argue that the safety can be disengaged and the trigger can be fired when the indicator is not in the green range, contrary to the PPH-03's design. The plaintiffs' theory is that, regardless of whether the indicator was in the green range, Dr. Pringle fired the stapler when the anvil was too far from the staple housing, which caused the staples not to close.

The Dickinson report supports the plaintiffs' theory. The report states that the device's safety could be disengaged when the anvil was 2.79 millimeters from the staple housing, which is greater than the manual's stated maximum firing distance of 1.5 millimeters. The report also states that the device's indicator was in the green range when the anvil was 2.11 millimeters from the staple housing, which is more than the manual's stated maximum firing distance. Both Flores and Dickinson testified that if the device is fired when the anvil is too far from the

staple housing, the staples will not form fully. Flores Dep. 35; Pl. Supp. Ex. 1 at 7.

C. *Summary Judgment is Inappropriate*

Either Dr. Pringle failed to squeeze the PPH-03's trigger fully or the anvil was too far from the staple housing, causing the staples to form improperly. The latter theory is the plaintiffs' theory. Evidence provides enough support for this theory to require that summary judgment be denied.

Dr. Pringle testified that the device's indicator was in the green range before he squeezed the trigger. He also said that he squeezed the trigger properly and that the sensation he received was consistent with his previous uses of the PPH-03. The Ethicon representative present at the surgery testified that the trigger appeared fully compressed. Withers Dep. 26. However, it is also obvious that the device did not fire properly and the staples did not form properly. The supplemental expert report produced by the plaintiffs provides a facially plausible explanation that supports their theory. The Dickinson report says that the PPH-03 used on Mrs. Harpold has a defective indicator. The report also says that the indicator shows that it is in the green range when in fact the anvil is too far from the staple housing to form staples properly. If the anvil is too far from the housing, the staples may not form correctly no matter how hard a user squeezes the trigger. If the indicator did not operate properly, the problem could have

arisen even if Dr. Pringle complied with the manual's direction not to squeeze the trigger until the indicator was in the green range.

The defective indicator could have caused the incomplete staple firing. This, in turn, could have caused Mrs. Harpold's injuries. Dr. Pringle said that the staples did not close the area of tissue that they were supposed to close. He saw severe bleeding in the same area. He also explained in his deposition that the failure of the staples to fire and close properly was a likely cause of the colon perforation.

A reasonable jury could hear this evidence and find in favor of the plaintiffs on the disputed issues of the existence of a defect and causation. Nothing more is necessary at the summary judgment stage. The defendant's theory that Dr. Pringle failed to squeeze the trigger fully is also believable, but it is the job of a jury in a trial, not the court on summary judgment, to resolve those factual disputes.

IV. *Conclusion*

The defendant's motion for summary judgment is denied. Dkt. No. 37. The defendant's motion to seal defendant's exhibit D is denied, and Exhibit D is ordered unsealed after a seven-day delay to permit the defendant to seek emergency review from the Court of Appeals if it wishes to do so. Dkt. No. 42.

The plaintiffs' request for evidentiary hearing is denied. Dkt. No. 51. The plaintiffs' motion to supplement their designation of evidence is granted. Dkt. No. 64.

So ordered.

Date: January 5, 2009

DAVID F. HAMILTON, CHIEF JUDGE
United States District Court
Southern District of Indiana

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