UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
PADUCAH DIVISION
CIVIL ACTION NO.: 5:16-cv-66-GNS

OLENDA HOMES,
individually and as a representative of all similarly situated persons **PLAINTIFF**

v.

COOK MEDICAL INCORPORATED,
a/k/a COOK MEDICAL, INC.;
COOK INCORPORATED;
WILLIAM COOK EUROPE ApS; **DEFENDANTS**

COMPLAINT

Comes the Plaintiff, Olenda Homes, by counsel and for her Complaint herein states as follows:

PARTIES, JURISDICTION, VENUE

1. The Plaintiff, Olenda Homes, is an individual and a citizen of the Commonwealth of Kentucky residing in Graves County, Kentucky.

2. Defendant Cook Medical Incorporated, a/k/a Cook Medical, Inc., is a citizen of the State of Indiana, having its principal business at 750 Daniels Way, P.O. Box 1068, Bloomington, Indiana, 47402, and conducts business throughout the United States, including in the State of Kentucky.

3. Defendant, Cook Incorporated, is a citizen of the State of Indiana, having its principal place of business at 750 Daniels Way, P.O. Box 1068, Bloomington, Indiana, 47402, and conducts business throughout the United States, including in the State of Kentucky.

4. Defendant William Cook Europe ApS, is a foreign citizen, whose corporate headquarters and principal place of business is in Bjqaeverskov, Denmark, and conducts business throughout the United States, including in the State of Kentucky.

5. Jurisdiction exists against Defendants pursuant to 28 U.S.C. § 1332, in that there is complete diversity of citizenship between the Plaintiff and Defendants, and the amount in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

6. Venue is proper within the Western District of Kentucky pursuant to 28 U.S.C. § 1391 in that jurisdiction is founded on diversity of citizenship and a substantial part of the events or omissions giving rise to the claim occurred within this District.

FACTUAL ALLEGATIONS

7. Cook is a manufacturer, distributor and marketer of medical devices, including the Cook Celect Vena Cava Filter ("Cook Filter"), a device designed and manufactured to prevent pulmonary embolism.

8. The Cook Filter is designed to filter blood clots, known as "thrombi," that travel from the lower portions of the body to the heart and lungs. The Cook Filter is designed to prevent deep vein thrombosis ("DVT"), from reaching the lungs, where the pulmonary emboli can be fatal.

9. The Cook Filter, a retrievable filter, has four anchoring struts for fixation and eight independent secondary struts to improve self-centering and clot trapping.

10. In 2013, Plaintiff came under the medical care and attention of Dr. Griffin Bicking, a surgeon, whose practice is located in Paducah, McCracken County, Kentucky.

11. On February 20, 2013, Plaintiff was admitted to Western Baptist Hospital in Paducah, Kentucky with a diagnosis of right lower extremity deep vein thrombosis ("DVT").

12. As part of her care and treatment for the DVT, Plaintiff had a procedure performed on February 21, 2013, by Dr. Bicking, during which a Cook Filter was placed within her inferior vena cava.

13. Upon information and belief, the Cook Filter implanted by Dr. Bicking was implanted and utilized in accordance with Defendants specific instructions, guidelines, and directives.

14. On July 18, 2015, Plaintiff noted some chronic low back pain that progressively increased causing the Plaintiff to have significant dyspnea with exertion and a near syncopal episode.

15. On July 25, 2015, Plaintiff was taken to the emergency room at Lourdes Hospital in Paducah, Kentucky complaining of chronic back and lower extremity pain.

16. Plaintiff underwent a CT angiogram, which revealed a significant amount of what appeared to be fresh thrombus in her pulmonary vasculature.

17. Upon further viewing, the CT revealed a large clot burden within the bilateral and upper lobar arteries where the blood passes away from the heart to various parts of the body.

18. Plaintiff was immediately admitted to the ICU and placed on a heparin drip to decrease the clotting ability of the blood and prevent harmful clots from forming in the blood vessels.

19. On July 26, 2015, a CT of the abdomen and pelvis revealed Plaintiff's Cook Filter had tilted causing acute DVT in the left lower extremity.

20. On July 27, 2015, Dr. Timothy Ranval, a vascular surgeon, placed an additional Option suprarenal inferior vena cava filter above the Cook Filter.

21. On July 28, 2015, Plaintiff underwent an insertion of right and left femoral vein catheter placements, as well as lysis of the existing clot.

22. Plaintiff was discharged from Lourdes Hospital on July 31, 2015.

23. As a result, Plaintiff will have to be on long-term anticoagulation medication.

24. Upon information and belief, on the day of and prior to the implantation of the Cook Filter within Plaintiff, Defendants knew or should have known that its Cook Filter when used as expected and intended, had the possibility of shifting, breaking free its implantation site, migrating, perforating the vena cava, and causing serious injury and/or death to patients, including Plaintiff.

25. Upon information and belief, Defendants negligently, recklessly, wantonly, and carelessly failed to properly design and manufacture the Cook Filter implanted in Plaintiff.

26. Upon information and belief, Defendants negligent, reckless, wanton, and careless failure to notify patients, including Plaintiff, of the defective nature of its Cook Filter, was the cause of the Plaintiff's injuries.

27. Upon information and belief, at the time of the implantation of the Cook Filter, the Defendants negligently, recklessly, wantonly, and carelessly failed to provide proper and adequate warnings to the potential users/recipients of the product, including Plaintiff, of the hazards associated with the filter, including, but not limited to failing to properly and adequately warn that a person might suffer personal injury as a result of implantation of the filter.

COUNT ONE – PRODUCT LIABILITY

28. Plaintiff incorporates all of the above paragraphs of the Complaint as if fully rewritten herein.

29. Plaintiff brings her claim for relief against Defendants under Kentucky's Product Liability Act, KRS § 411.300, et seq.

30. Defendants are the "manufacturers" of the Cook Filter because they are engaged in the business of designing, formulating, producing, creating, making, constructing, assembling or rebuilding the product.

31. In the alternative, the Defendants were "suppliers" of the Cook Filter because they sold, distributed, prepared, labeled or otherwise participated in the placing of the Cook Filter in the stream of commerce, where they repaired or maintained the aspect of the vena cava filter that caused harm.

32. The Defendants are liable for the Cook Filter's defective manufacture, design, inadequate warnings, and failure to conform to representations under KRS §§ 411.320, 411.340 of Kentucky's Product Liability Act.

33. The Cook Filter implanted in Plaintiff was not properly manufactured to withstand normal, foreseeable, and intended use for the care and treatment of DVT.

34. The defective aspects of the Cook Filter were the direct and proximate cause of Plaintiff's injuries.

35. To the extent the Defendants are a "supplier" rather than a "manufacturer," they are liable as though they were a manufacturer because they altered, modified, or failed to maintain the Cook Filter after it came into their possession, or they marketed the Cook Filter under its own label or trade name.

36. To the extent the Defendants are a "supplier" rather than a "manufacturer," they are liable for their own negligence, which proximately caused Plaintiff's injuries, as well as the

failure of the Cook Filter to conform to their representations of safety and the appropriate use of the Cook Filter, which proximately caused Plaintiff's injuries.

37. As a direct and proximate result of the Defendants violations of the Kentucky Product Liability Act, Plaintiff sustained injuries or a personal, pecuniary, and permanent nature including, but not limited to, physical injuries, medical bills, pain and suffering, mental anguish, and such other harms and losses that will be proven at trial. As such, Plaintiff is entitled to all remedies provided by Kentucky's Product Liability Act and according to Kentucky common law, which are compensatory, punitive, attorney fees, costs, expenses, and interest.

COUNT TWO – WARRANTY

35. Plaintiff incorporates by reference all of the above allegations in the Complaint as if fully rewritten herein.

36. The Defendants expressly warranted that the Cook Filter was safe for ordinary and foreseeable use in patients like Plaintiff as a treatment for pulmonary embolism. In actuality, the Cook Filter was not safe for such use.

37. The Defendants also impliedly warranted that the Cook Filter was safe and fit for ordinary and foreseeable use as a treatment for pulmonary embolism. In actuality, the Cook Filter was not safe and fit for such use.

38. Plaintiff relied on these express and implied warranties and the breach of these warranties was the direct and proximate cause of her injuries. As such, Plaintiff is entitled to recover under Kentucky common law and other statutory enactments, in addition to the Kentucky Product Liability Act.

COUNT THREE – STRICT LIABILIY

39. Plaintiff incorporates by reference all the above paragraphs in the Complaint as if fully rewritten herein.

40. When the Cook Filter left the Defendants control, it was in a condition that was unsafe, unreasonably dangerous, and defective in that it was defectively manufactured or re-manufactured with inadequate, insufficient, and improper warnings as required by law.

41. Despite the foregoing, the Defendants transferred or sold the Cook Filter for implantation into Plaintiff, either directly or through a supplier in this defective and unsafe condition and without proper warnings.

42. As a direct and proximate cause of the unsafe, unreasonably dangerous or defective condition of the Cook Filter, the Plaintiff suffered injuries, for which the Defendants are strictly liable under Kentucky common law and other statutory enactments, in addition to the Kentucky Product Liability Act.

COUNT FOUR – NEGLIGENCE

43. Plaintiff incorporates by reference each and every allegation set forth in the above paragraphs in the Complaint as if fully rewritten herein.

44. Defendants owed Plaintiff a duty of care and breached this duty of care and were thereby negligent in each of the following respects:

a. by failing to give adequate warnings to purchasers and users of the Cook Filter, including Plaintiff, about its use and the risks associated with its use, including, but not limited to, the risk of migration and perforation and the unreasonably dangerous and defective condition of the filter; and/or

b. by failing to discover the defects in the Cook Filter by not using reasonable care to inspect the filter prior to its being distributed into the chain of commerce and sold for implantation into patients including into the Plaintiff.

45. As a direct and proximate cause of the above-described negligence of the Defendants, Plaintiff sustained injury for which Defendants are liable under Kentucky common law and other statutory enactments, in addition to the Kentucky Product Liability Act.

COUNT FIVE – GROSS NEGLIGENCE

46. Plaintiff incorporates by reference each and every allegation set forth in the above paragraphs in the Complaint as if fully rewritten herein.

47. Defendants owed Plaintiff a duty of care, breached this duty of care, and were grossly negligent in their breach of the reasonable and expected standard of care, which requires the imposition of punitive damages in this matter.

48. The Defendants misconduct and gross negligence were a flagrant disregard for the safety of person(s) who might be harmed by the product in question, especially in light of the fact that substantial and debilitating injury and/or death would occur from a breach of the standard of care required in the design, manufacture, and sale of the Cook Filter including, but not limited to, safety, testing, and warnings.

49. Pursuant to Kentucky common law, punitive damages against the Defendants as a manufacturer or supplier are warranted and should be imposed in order to send a message to the public and prohibit similar conduct by other manufacturers and suppliers of similar medical devices in the future and to protect consumers in the State of Kentucky.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendant in an amount in excess of $75,000.00 for compensatory damages, together with interest, attorney fees, costs of suit, and any other relief this Court deems just and proper, including any punitive damages for the willful and wanton misconduct and gross negligence of the Defendants pursuant to Kentucky common law and Kentucky's Product Liability Act.

JURY DEMAND

Plaintiff demands a trial by jury.

Respectfully submitted,

/S/ Emily Ward Roark

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