UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF KENTUCKY
PADUCAH DIVISION
CIVIL ACTION NO.: 5:16-cv-65-TBR

KATHERINE MILAN,
individually and as a representative of all similarly situated persons **PLAINTIFF**

v.

BOSTON SCIENTIFIC CORPORATION **DEFENDANT**

COMPLAINT

Comes the Plaintiff, Katherine Milan, by counsel and for her Complaint herein states as follows:

PARTIES, JURISDICTION, VENUE

1. The Plaintiff, Katherine Milan, is an individual and a citizen of the Commonwealth of Kentucky residing in McCracken County, Kentucky.

2. Defendant Boston Scientific Corporation is a Delaware Corporation, with its corporate headquarters located in Malborough, Massachusetts and which conducts business throughout the United States, including in the State of Kentucky.

3. Boston Scientific Corporation designs, develops, produces, manufactures, assembles, markets, distributes, and sells medical devices across the country and in Kentucky.

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

5. Venue is proper within the Western District Paducah Division 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

6. Defendant Boston Scientific at all times relevant designed, developed, produced, manufactured, assembled, marketed, distributed, and sold a medical device known as the Greenfield Vena Cava Filter, a device implanted and utilized for the purposes of controlling pulmonary embolism.

7. In 2005, Plaintiff came under the medical care and attention of Dr. Mark W. Shelton, a vascular surgeon, whose practice is located in Paducah, McCracken County, Kentucky.

8. On May 4, 2005, Plaintiff was admitted to Western Baptist Hospital in Paducah, Kentucky with a diagnosis of right lower extremity deep vein thrombosis ("DVT").

9. As part of her care and treatment for the DVT, Plaintiff had a procedure performed on May 6, 2005, by Dr. Mark Shelton, during which a clot extraction was performed on her right leg and a Boston Scientific Greenfield Vena Cava Filter was placed within her left inferior vena cava.

10. Upon information and belief, the Boston Scientific Greenfield Filter implanted by Dr. Shelton was implanted and utilized in accordance with Defendant's specific instructions, guidelines, and directives.

11. Plaintiff's hospital course was complicated by fever of unknown etiology.

12. Plaintiff remained at Western Baptist Hospital for a total of ten (10) days before being transferred to Dr. Raul Guzman at Vanderbilt University in Nashville, Tennessee on May 13, 2005.

13. While at Vanderbilt University Plaintiff underwent an Angio Jet thrombectomy.

14. Plaintiff was discharged from Vanderbilt University on May 24, 2005.

15. On June 7, 2005, Plaintiff was taken to the emergency room at Western Baptist Hospital complaining of left thigh and lower abdomen pain.

16. On June 8, 2005, Plaintiff was admitted to Western Baptist Hospital due to extensive clots in the right lower extremity and acute DVT of the left lower extremity.

17. On July 16, 2010, Dr. Joseph Mayo, a surgeon at Western Kentucky Surgical Associates in Paducah, Kentucky, saw Plaintiff due to a possible IVC filter occlusion.

18. On July 30, 2010, Plaintiff returned to Dr. Joseph Mayo still complaining of IVC filter occlusion.

19. On August 10, 2015, Dr. Joseph Mayo performed a CAT scan that revealed Plaintiff's IVC filter was occluded.

20. As a result, Plaintiff must continue to be on blood thinners for the rest of her life.

21. Upon information and belief, on the day of and prior to the implantation of the Greenfield Vena Cava Filter within Plaintiff, Defendant knew or should have known that its Greenfield Vena Cava 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.

22. Upon information and belief, Defendant Boston Scientific negligently, recklessly, wantonly, and carelessly failed to properly design and manufacture the Greenfield Vena Cava Filter implanted in Plaintiff.

23. Upon information and belief, Defendant's negligent, reckless, wanton, and careless failure to notify patients, including Plaintiff, of the defective nature of its Greenfield Vena Cava Filter, was the cause of the Plaintiff's injuries.

24. Upon information and belief, at the time of the implantation of the Greenfield Vena Cava Filter, the Defendant 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

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

26. Plaintiff brings her claim for relief against Defendant Boston Scientific Corporation under Kentucky's Product Liability Act, KRS § 411.300, et seq.

27. Defendant is the "manufacturer" of the Greenfield Vena Cava Filter because it is engaged in the business of designing, formulating, producing, creating, making, constructing, assembling or rebuilding the product.

28. In the alternative, the Defendant was a "supplier" of the Greenfield Vena Cava Filter because it sold, distributed, prepared, labeled or otherwise participated in the placing of the

Greenfield Vena Cava Filter in the stream of commerce, where it repaired or maintained the aspect of the vena cava filter that caused harm.

29. The Defendant is liable for the Greenfield Vena Cava 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.

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

31. The defective aspects of the Greenfield Vena Cava Filter were the direct and proximate cause of Plaintiff's injuries.

32. To the extent the Defendant is a "supplier" rather than a "manufacturer," it is liable as though it were a manufacturer because it altered, modified, or failed to maintain the Greenfield Vena Cava Filter after it came into its possession, or it marketed the Greenfield Filter under its own label or trade name.

33. To the extent the Defendant is a "supplier" rather than a "manufacturer," it is liable for its own negligence, which proximately caused Plaintiff's injuries, as well as the failure of the Greenfield Filter to conform to its representations of safety and the appropriate use of the Greenfield Filter, which proximately caused Plaintiff's injuries.

34. As a direct and proximate result of the Defendant's 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 Defendant expressly warranted that the Greenfield Filter was safe for ordinary and foreseeable use in patients like Plaintiff as a treatment for pulmonary embolism. In actuality, the Greenfield Filter was not safe for such use.

37. The Defendant also impliedly warranted that the Greenfield Filter was safe and fit for ordinary and foreseeable use as a treatment for pulmonary embolism. In actuality, the Greenfield 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 Greenfield Filter left Defendant Boston Scientific's 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 Defendant transferred or sold the Greenfield 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 Greenfield Filter, the Plaintiff suffered injuries, for which the Defendant is 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. Defendant owed Plaintiff a duty of care and breached this duty of care and was thereby negligent in each of the following respects:

a. by failing to give adequate warnings to purchasers and users of the Greenfield 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 Greenfield 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 Defendant, Plaintiff sustained injury for which Defendant is 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. Defendant owed Plaintiff a duty of care, breached this duty of care, and was 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 Defendant's misconduct and gross negligence was 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 Greenfield Vena Cava Filter including, but not limited to, safety, testing, and warnings.

49. Pursuant to Kentucky common law, punitive damages against the Defendant as a manufacturer or supplier is 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 Defendant 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_____

Mark P. Bryant
Emily Ward Roark
BRYANT LAW CENTER, PSC
601 Washington St.
Paducah, KY 42002
Phone: (270) 442-1422
Fax: (270) 443-8788
mark.bryant@bryant.law
emily.roark@bryant.law
sam.bussey@bryant.law