

IN THE TWELFTH JUDICIAL CIRCUIT OF THE STATE OF FLORIDA
IN AND FOR SARASOTA COUNTY, FLORIDA

LAWRENCE HAMMERS,

Plaintiff,

v.

CASE NO. 2011CA003641NC

BAYSIDE ORTHOPAEDICS, INC.,

Defendant.

_____ /

COMPLAINT

COMES NOW, the Plaintiff, LAWRENCE HAMMERS, by and through his undersigned attorneys and hereby sues Defendant, BAYSIDE ORTHOPAEDICS, INC., and alleges as follows:

1. This is an action for damages in excess of \$15,000.00, exclusive of attorney's fees and costs, resulting from Defendant's promoting, marketing, distributing, supplying, selling, and servicing defective hip replacement components that were subsequently recalled by the United States Food and Drug Administration

PARTIES AND JURISDICTION

2. At all times material to this Complaint, LAWRENCE HAMMERS, was and continues to be a resident of Sarasota County in the State of Florida.

3. Defendant is a Florida corporation with its principal place of business at 14450 46th Street North, Suite 112, Clearwater Florida 33762, in Pinellas County, Florida, and as such is a citizen of the State of Florida.

4. At all times material to this Complaint, Defendant BAYSIDE ORTHOPAEDICS, INC., was a corporation organized and existing pursuant to the laws of the state of Florida and operating within the State of Florida.

5. At all times relevant to this action, Defendant promoted, marketed, distributed, supplied, sold, and serviced the recalled defective hip replacement components in the state of Florida, including Sarasota County, Florida.

6. Defendant utilized and employed sales representatives that were responsible for educating Plaintiff's orthopedic surgeons regarding the supposed advantages of the hip replacement components, answering any questions Plaintiff's orthopedic surgeons had regarding the hip replacement components, providing the Plaintiff's orthopedic surgeons with information regarding the proper surgical technique to employ in implanting the hip replacement components, providing the Plaintiff's orthopedic surgeons with information concerning the hip replacement components appropriate for the patient, providing the Plaintiff's orthopedic surgeons with the tools to be used to implant the hip replacement components, assisting Plaintiff's orthopedic surgeons at surgery regarding the hip replacement components, and selling the hip replacement components to Plaintiff's orthopedic surgeons in Sarasota County, Florida.

7. Plaintiff and his surgeons, nurses, and hospital staff relied on information from Defendant in selecting, purchasing, implanting, and servicing the hip replacement components.

VENUE

8. Venue is proper in Sarasota County in that at present and at all times relevant to this action, the primary residence of Plaintiff was in Sarasota County, Florida, and the acts of Defendant took place in Sarasota County, Florida.

HIP REPLACEMENT COMPONENTS

9. In 2005, Defendant began promoting and selling in Florida hip replacement components with the model identification of “ASR” manufactured by DePuy International, LTD of the United Kingdom.

10. In addition to other means, Defendant used brochures and other printed literature to promote the ASR hip replacement components.

11. Defendant disseminated literature to the orthopedic community in Florida stating that the ASR hip replacement components were “large diameter, high performance metal-on-metal bearings [are] designed and manufactured within fine tolerances to facilitate a state of fluid film lubrication” and “designed to reduce wear and provide high function for all patients.”

12. Defendant also claimed in information provided to the Florida orthopedic community that the ASR hip replacement components were “based on a strong clinical history” and “reduces wear compared to traditional hip replacement.”

WARNINGS FROM INDEPENDENT ORTHOPEDIC EXPERTS

13. The same year Defendant began selling the ASR hip replacement components, independent experts from around the world were warning that the design of the ASR hip replacement components was defective.

14. Orthopedic experts warned that some of the ASR hip replacement components were too thin and thus prone to deformation.

15. Orthopedic experts warned that the clearance between the ASR hip replacement component cup and heads was too small and in some patients could lead to jamming of components.

16. Orthopedic experts warned that the treatment of the metal used for the ASR hip replacement components rendered them prone to increased wear.

17. By 2005, ASR hip replacement components were shown to have a 4-fold higher rate of revision than similar components in the Australian Joint Registry.

DEFENDANT'S RESPONSE TO WARNINGS

23. When questioned by members of the orthopedic community about independent expert warnings that the ASR hip replacement components were defective, Defendant's sales representatives were instructed how to argue that the independent experts were mistaken and to continue to heavily promote the ASR hip replacement components.

24. Defendant, through its employees and agents, was also aware of the problems with the design of the ASR hip replacement components based upon complaints of orthopedic surgeons.

25. Defendant was additionally aware of excessive failures necessitating revision of ASR hip replacement components due to revision surgeries in which Defendant's sales representatives participated, but failed to convey this information to the Plaintiffs' orthopedic surgeons.

SUSPENSION

26. From 2005 to 2009, numerous complaints of premature failure of ASR hip replacement components were made by orthopedic surgeons and hospitals to Defendant and the United States Food and Drug Administration.

27. Independent studies showed numerous problems with ASR hip replacement components, including failure of ASR hip replacement cups to achieve proper fixation due to the lack of bony ingrowth into the back of the cup, fracture resulting from loose ASR hip

replacement components, significant metal debris in patients with ASR hip replacement components, and the formation of pseudotumors in patients with ASR hip replacement components.

28. In the fall of 2009, DePuy International, LTD. announced that the company would be phasing our sales of the ASR hip replacement components worldwide, citing slowing sales as the only reason for the change.

29. Unfortunately, this action came far too late for the Plaintiff to this action

BACKGROUND OF PLAINTIFF LAWRENCE HAMMERS

30. Plaintiff, LAWRENCE HAMMERS, is a resident of the Sarasota County, Florida.

31. Just a few months prior to the announced phase out, Plaintiff was implanted with an ASR hip replacement component on June 15, 2009 in his right hip by his orthopedic surgeon, Vance Askins, M.D., at Sarasota Memorial Hospital in Sarasota County, Florida.

32. Little more than a month later, on July 28, 2009, Dr. Askins implanted Plaintiff with an ASR hip replacement component in his left hip at Sarasota Memorial Hospital in Sarasota County, Florida.

33. Plaintiff underwent treatment successfully and was without symptoms for approximately one year.

34. On July 6, 2010, Plaintiff returned to Dr. Askins with sharp pain in his right thigh and back. Dr. Askins treated him with a sacral epidural steroid injection. The injection failed to resolve the pain, and the pain subsequently spread to his left hip.

35. On August 31, 2010, Plaintiff received a letter from Dr. Askins informing him that the ASR hip replacement components implanted in both of his hips had been recalled.

36. Plaintiff sought out a second opinion from orthopedic surgeon Edward Stolarski, MD, on September 28, 2010. At that time Dr. Stolarski ordered blood tests for chromium and cobalt to determine if the ASR hip replacement components were releasing metal debris as well as an MRI and bone scan to test for prosthetic loosening.

37. The results of these tests revealed levels of cobalt over ten times the highest acceptable limit, and chromium levels at over 30 times the highest acceptable limit. The bone scan revealed early stages of prosthetic loosening. At this time Dr. Stolarski recommended revision surgery of both hips.

38. Revision surgery of Plaintiff's left hip took place on December 1, 2010 at the Sarasota Memorial Hospital in Sarasota, Florida. In the operative report, Dr. Stolarski reported the following:

The acetabular component had some rim fit and overgrowth and we used the Explant Osteotomes to just free of that overgrowth and the cup came out rather readily. There was no bony attachment to the cup and no bony ingrowth.

39. On January 19, 2011, Plaintiff returned to Sarasota Memorial Hospital to undergo revision surgery for his right hip. During this surgery, Dr. Stolarski noted the following:

The acetabular fluid was a significant serous and irritative joint fluid. We sent some of the thickened capsule to pathology. Using explant osteotomes, the cup was easily removed with minimal difficulty on which side he had fibrous on-growth.

40. Plaintiff is now in the slow process of recovering from multiple traumatic surgeries.

EFFECT ON PLAINTIFF

41. The Plaintiff to this action had ASR hip replacement components that were promoted, marketed, distributed, supplied, sold, and serviced by Defendant.

42. The Plaintiff to this action had ASR hip replacement components that were defective when implanted in his body and were subsequently recalled by the FDA.

43. In the instance of the Plaintiff to this action, the ASR hip replacement cups failed to achieve proper bone ingrowth into the cup and thus failed to achieve proper fixation.

44. In the instance of the Plaintiff to this action, the ASR hip replacement components generated excessive metal debris.

45. In the instance of the Plaintiff to this action, the recognition that ASR hip replacement components had failed was delayed by the failure of Defendant to convey to Plaintiff's orthopedic surgeons the warnings regarding the product made by independent orthopedic experts and information regarding other failures of ASR hip replacement components throughout the United States and worldwide.

46. As a result of this significant delay in the recognition that the ASR hip replacement components had failed, Plaintiff needlessly suffered pain and damage to the bones and tissues of his hips.

47. The defective ASR hip replacement components implanted and allowed to remain in the body of the Plaintiff caused extreme pain and suffering to Plaintiff.

48. Despite Defendant's knowledge of extensive problems with and defects in the ASR hip replacement components, Defendant continued to heavily promote the components.

49. Plaintiff's orthopedic surgeon relied on the misinformation provided by Defendant and used, continued to use, and failed to suspect the premature failure of the ASR hip replacement components

COUNT ONE – NEGLIGENCE

50. Plaintiff re-alleges and incorporates by reference paragraphs 1-49 above as if fully stated herein.

51. Defendant, as the promoter, marketer, seller, distributor, and servicer of the ASR hip replacement components, owed a duty to Plaintiff to provide accurate information to Plaintiff, his orthopedic surgeon, and the orthopedic community.

52. Defendant, in breach of the duty described above, negligently and carelessly promoted, marketed, sold, distributed, and serviced the ASR hip replacement components implanted in Plaintiff.

53. As a direct and proximate result of the conduct of Defendant, Plaintiff needlessly suffered severe pain and weakness.

54. As a direct and proximate cause of the breaches set forth herein, Plaintiff has suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead a normal life; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiff are permanent in nature and Plaintiff will continue to suffer such losses in the future.

COUNT TWO STRICT LIABILITY

55. Plaintiff re-alleges and incorporates by reference paragraphs 1-49 above as if fully stated herein.

56. At the time that Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components, they contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and was unfit for its intended use.

57. The ASR hip replacement components reached Plaintiff without substantial change in the condition in which they were sold.

58. The ASR hip replacement components, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

59. At the time and on the occasions in question, the ASR hip replacement components were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

60. As a direct and proximate cause of the nature of the ASR hip replacement components, Plaintiff has suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead a normal life; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiff are permanent in nature and Plaintiff will continue to suffer such losses in the future.

**COUNT THREE
BREACH OF IMPLIED WARRANTY**

61. Plaintiff re-alleges and incorporates by reference paragraphs 1-49 above as if fully stated herein.

62. Defendant promoted, marketed, distributed, supplied, sold, and serviced the ASR hip replacement components at issue in this case.

63. Defendant impliedly warranted that the ASR hip replacement components were reasonably fit for their intended use as hip replacement components.

64. Plaintiff was a foreseeable user of the ASR hip replacement components.

65. Plaintiff purchased the ASR hip replacement components from Defendant.

66. The ASR hip replacement components failed while being used for their intended purpose, causing serious injury to Plaintiff.

67. As a direct and proximate cause of this breach, Plaintiff has suffered severe physical distress and injury, emotional distress and injury; incurred medical and other expenses; lost wages and income; suffered shame, humiliation and the inability to lead a normal life; and have suffered loss of enjoyment of life. The injuries and losses of Plaintiff are permanent in nature and Plaintiff will continue to suffer such losses in the future.

**COUNT FOUR
FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICE ACT VIOLATION OF
DEFENDANT BAYSIDE**

68. Plaintiff re-alleges and incorporates by reference paragraphs 1-49 as if fully stated herein.

69. At all times relevant to this action, Plaintiff was a consumer as described in the Florida Deceptive and Unfair Trade Practices Act, Florida Statute Section 501.203(7).

70. In violation of the Florida Deceptive and Unfair Trade Practices Act, Defendant advertised and promoted its DePuy ASR Hip Replacement System using representations that it knew to be false.

71. This false and deceptive advertising and promotion constitutes “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices” pursuant to Florida Statutes Section 501.204.

72. Based upon the false and deceptive advertising and promotion of Defendant, Plaintiff purchased the hip replacement systems.

73. As a result of the DePuy ASR Hip Replacement Systems purchased by Plaintiff being other than as represented by Defendant, it was thus unfit for its intended purpose and therefore valueless.

74. As a direct and proximate result of the deceptive and unfair trade practices of Defendant, Defendant sold and Plaintiff purchased valueless hip replacement systems.

75. These violations of the DTPA were a producing cause of Plaintiff damages as alleged herein below.

WHEREFORE Plaintiff demands judgment against the Defendant, for the difference in value between the DePuy ASR Hip Replacement System advertised and promoted by Defendant and the hip replacement system actually delivered by Defendant together with reasonable attorneys’ fees and costs of suit pursuant to Florida Statutes, Section 501.211(2), and for any further relief that the court deems just and proper.

DEMAND FOR JURY TRIAL

76. Plaintiff respectfully requests that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

[/S/ Altom M. Maglio](#)

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