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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
URBANA DIVISION

ANN HARTMAN, Plaintiff, v. JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG, Defendants.	**COMPLAINT AND DEMAND FOR JURY TRIAL** **Civil Action No.: 2:14-cv-2285**

Plaintiff ANN HARTMAN ("Plaintiff"), by and through her undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and the Defendants.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants' conduct substantial business in this District.

3. This Court has personal jurisdiction over the Defendants because they have

done business in the State of Illinois, have committed a tort in whole or in part in the State of Illinois, have substantial and continuing contact with the State of Illinois, and derive substantial revenue from goods used and consumed within the State of Illinois. The Defendants actively sell, market, and promote their pharmaceutical product Xarelto to physicians and consumers in this state on a regular and consistent basis.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff ANN HARTMAN. Plaintiff used Xarelto, also known as rivaroxaban, which is a medication used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (hereinafter referred to as "DVT") and pulmonary embolism (hereinafter referred to as "PE"), to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

5. Defendants, JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC, JANSSEN ORTHO LLC, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Xarelto.

6. When warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug

Administration (hereinafter referred to as the "FDA"), to Plaintiff and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

7. Defendants concealed their knowledge of Xarelto's defects from Plaintiff, the FDA, the public in general, and/or the medical community specifically.

8. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Xarelto for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Plaintiff, and Plaintiff's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Xarelto whatsoever.

10. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer serious and dangerous side effects including inter alia life-threatening bleeding,

as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for

hospitalization and medical treatment, and loss of earnings. Plaintiff herein has sustained certain of the above health consequences due to Plaintiff's use of Xarelto.

11. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

12. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of the Xarelto, which has caused Plaintiff to suffer from life-threatening bleeding, as well as other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications, and loss of earnings.

PARTY PLAINTIFF

13. Plaintiff ANN HARTMAN (hereinafter "Plaintiff"), is currently a citizen and resident of the State of Georgia, but suffered Xarelto related injuries while in the state of Illinois.

14. Upon information and belief, Plaintiff was prescribed Xarelto upon direction of her physician for the treatment of DVT and pulmonary embolism.

15. Upon information and belief, as a direct and proximate result of the use of Defendants' Xarelto, Plaintiff experienced a dysfunctional rectal bleed on or about September 12 2014 and was caused to suffer a life-threatening bleed requiring blood transfusions and extensive hospitalization from the use of Xarelto.

16. As a direct and proximate result of the use of Defendants' Xarelto, Plaintiff suffered serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature,

physical pain and mental anguish, including, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

17. The injuries and damages sustained by Plaintiff were caused by Defendants' Xarelto.

PARTY DEFENDANTS

18. Upon information and belief, Defendant JANSSEN RESEARCH & DEVELOPMENT LLC F/K/A JOHNSON & JOHNSON RESEARCH & DEVELOPMENT LLC (hereinafter referred to as "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JANSSEN R&D is the holder of the approved New Drug Application ("NDA") for Xarelto as well as the supplemental NDA.

19. As part of its business, JANSSEN R&D is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

20. Upon information and belief, Defendant JANSSEN R&D has transacted and conducted business in the State of Illinois.

21. Upon information and belief, Defendant JANSSEN R&D has derived substantial revenue from good and products used in the State of Illinois.

22. Upon information and belief, Defendant, JANSSEN R&D, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

23. Upon information and belief, and at all relevant times, Defendant, JANSSEN R&D, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non- valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

24. Upon information and belief, Defendant JANSSEN PHARMACEUTICALS, INC. F/K/A JANSSEN PHARMACEUTICAL INC. F/K/A ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter referred to as "JANSSEN PHARM") is a Pennsylvania corporation, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

25. As part of its business, JANSSEN PHARM is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

26. Upon information and belief, Defendant, JANSSEN PHARM has transacted and conducted business in the State of Illinois.

27. Upon information and belief, Defendant, JANSSEN PHARM, has derived substantial revenue from goods and products used in the State of Illinois.

28. Upon information and belief, Defendant, JANSSEN PHARM, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

29. Upon information and belief, and at all relevant times, Defendant, JANSSEN PHARM, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non- valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

30. Upon information and belief, Defendant JANSSEN ORTHO LLC (hereinafter referred to as "JANSSEN ORTHO") is a limited liability company organized under the laws of Delaware, having a principal place of business at 933 Km 0.1. Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

31. As part of its business, JANSSEN ORTHO is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

32. Upon information and belief, Defendant, JANSSEN ORTHO has transacted and conducted business in the State of Illinois.

33. Upon information and belief, Defendant, JANSSEN ORTHO, has derived substantial revenue from goods and products used in the State of Illinois.

34. Upon information and belief, Defendant, JANSSEN ORTHO, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois more particularly.

35. Upon information and belief, and at all relevant times, Defendant,

JANSSEN ORTHO, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non- valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

36. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

37. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

38. As part of its business, BAYER HEALTHCARE PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

39. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has transacted and conducted business in the State of Illinois.

40. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has derived substantial revenue from goods and products used in the State of Illinois.

41. Upon information and belief, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

42. Upon information and belief, and at all relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

43. Upon information and belief, Defendant BAYER PHARMA AG is a pharmaceutical company domiciled in Germany.

44. Defendant BAYER PHARMA AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

45. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

46. Upon information and belief, Bayer Schering Pharma AG was renamed BAYER PHARMA AG effective July 1, 2011.

47. As part of its business, BAYER PHARMA AG is involved in the

research, development, sales, and marketing of pharmaceutical products including Xarelto and rivaroxaban.

48. Upon information and belief, Defendant, BAYER PHARMA AG, has transacted and conducted business in the State of Illinois.

49. Upon information and belief, Defendant, BAYER PHARMA AG, has derived substantial revenue from goods and products used in the State of Illinois.

50. Upon information and belief, Defendant, BAYER PHARMA AG, expected or should have expected its acts to have consequence within the United States of America and the State of Illinois, and derived substantial revenue from interstate commerce within the United States and the State of Illinois, more particularly.

51. Upon information and belief, and at all relevant times, Defendant, BAYER PHARMA AG, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

52. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

53. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE

PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

54. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Xarelto.

55. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of Illinois, by selling and distributing its products in the State of Illinois and engaged in substantial commerce and business activity in the State of Illinois.

56. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New Jersey.

57. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Illinois, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC.

58. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America and in the State of Illinois, and derived substantial revenue from interstate commerce.

59. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

60. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER PHARMA AG.

61. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Illinois, and derived substantial revenue from interstate commerce.

62. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Illinois, and derived substantial revenue from interstate commerce.

63. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG.

64. Upon information and belief, Defendant BAYER AG is a German

chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

65. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

66. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

67. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Illinois, and derived substantial revenue from interstate commerce.

68. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, and in the State of Illinois, and derived substantial revenue from interstate commerce.

69. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Xarelto for use as an oral anticoagulant, the primary purposes of which are to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

FACTUAL BACKGROUND

70. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Xarelto

and rivaroxaban to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

71. Defendants received FDA approval for Xarelto, also known as rivaroxaban, on July 1, 2011 for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries (NDA 022406).

72. Defendants then received additional FDA approval for Xarelto to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation on November 4, 2011 (NDA 202439).

73. The additional indication for treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE was added to the label on November 2, 2012.

74. Defendants launched Xarelto in the United States (hereinafter referred to as the "U.S.") in 2011.

75. Xarelto is an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15mg, and 10mg.

76. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition), accompanied by similar rates of bleeding.

However, the studies also showed a greater incidence with Xarelto of bleeding leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty*. N.Engl.J.Med. 2008;358:2776-86; Kakkar, A.K., et al. *Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomised controlled trial*. Lancet 2008;372:31-39; Ericksson, B.I., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty*. N.Engl.J.Med. 2008;358:2765-75.)

77. Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as "ROCKET AF"). The study's findings showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion." (Patel, M.R., et al. *Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation*. N.Engl.J.Med. 2011;365:883-91.)

78. Approval of Xarelto for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The

EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to placebo. (The EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous Thromboembolism*. N.Engl.J.Med. 2010;363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. *Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study)*. Expert Rev. Cardiovasc. Ther. 2011;9(7):841-844). The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEIN- PE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism*. N.Engl.J.Med. 2012;366:1287-97.)

79. Defendants use the results of the ROCKET AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including the Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

80. Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto

Difference – namely, that Xarelto does not require periodic monitoring with blood tests and does not limit a patient's diet.

81. However, in its QuarterWatch publication for the first quarter of the 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could be eliminated by twice-a-day dosing."

82. Importantly, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

83. Defendants spent significant money in promoting Xarelto, which included at least$11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

84. As a result of Defendants' aggressive marketing efforts, in its first full year of being on the market, Xarelto garnered approximately $582 million in sales globally.

85. Defendants' website for Xarelto claims that over seven million people worldwide have been prescribed Xarelto. In the U.S., approximately 1 million Xarelto prescriptions had been written by the end of 2013.

86. During the Defendants' 2012 fiscal year, Xarelto garnered approximately $658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to more than clear the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

87. As part of their marketing of Xarelto, Defendants widely disseminated direct-to- consumer advertising campaigns that were designed to influence patients, including Plaintiff, to make inquiries to their prescribing physician about Xarelto and/or request prescriptions for Xarelto.

88. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Xarelto with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Xarelto, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

89. On June 6, 2013, Defendants received an untitled letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

90. Prior to Plaintiff's prescription of Xarelto, Plaintiff became aware of

the promotional materials described herein.

91. Prior to Plaintiff's prescription of Xarelto, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

92. At all times relevant hereto, Defendants also failed to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation effects of Xarelto, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Xarelto.

93. At all times relevant to this action, The Xarelto Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Xarelto has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, it may be irreversible, permanently disabling, and life-threatening.

94. In the year leading up to June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related

death with warfarin.

95. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

96. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

97. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

98. Moreover, on a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related averse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

99. Despite the clear signal generated by the SAE data, Defendants failed to either alert the public and the scientific community, or perform further investigation into the safety of Xarelto.

100. Defendants original, and in some respects current labeling and prescribing information for Xarelto:

(a) failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto;

(b) failed to provide adequate warnings about the true safety risks associated with the use of Xarelto;

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient;

(d) failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto;

(e) failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;

(f) failed to advise prescribing physicians, such as the Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;

(g) failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;

(h) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto users;

(i) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

(j) failed to provide adequate warnings regarding the increased risk of

suffering a bleeding event, requiring blood transfusions in those taking Xarelto;

(k) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto;

(l) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto;

(m) failed to include a "**BOXED WARNING**" about serious bleeding events associated with Xarelto;

(n) failed to include a "**BOLDED WARNING**" about serious bleeding events associated with Xarelto; and

(o) in their "Medication Guide" intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

101. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain

medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 103 (a – o).

102. Prior to applying for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of life-threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidence Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

103. Upon information and belief, despite life-threatening bleeding findings in a clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Xarelto prior to filing their New Drug Application for Xarelto.

104. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Xarelto was associated with and/or could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

105. Upon information and belief, Defendants concealed and failed to

completely disclose its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

106. Upon information and belief, Defendants ignored the association between the use of Xarelto and the risk of developing life-threatening bleeding.

107. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for life-threatening bleeding risk further rendered warnings for this medication inadequate.

108. By reason of the foregoing acts and omissions, the Plaintiff was caused to suffer from life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENCE)

109. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

110. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Xarelto into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

111. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing,

quality assurance, quality control, and/or distribution of Xarelto into interstate commerce in that Defendants knew or should have known that using Xarelto created a high risk of unreasonable, dangerous side effects, including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

112. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Xarelto without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Xarelto was safe for use; in that Defendants herein knew or should have known that Xarelto was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Xarelto without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Xarelto;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who

would reasonably and foreseeably come into contact with, and more particularly, use, Xarelto;

(g) Failing to test Xarelto and/or failing to adequately, sufficiently and properly test Xarelto.

(h) Negligently advertising and recommending the use of Xarelto without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Xarelto was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that Xarelto had equivalent safety and efficacy as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(k) Negligently designing Xarelto in a manner which was dangerous to its users;

(l) Negligently manufacturing Xarelto in a manner which was dangerous to its users;

(m) Negligently producing Xarelto in a manner which was dangerous to its users;

(n) Negligently assembling Xarelto in a manner which was dangerous to its users;

(o) Concealing information from the Plaintiff in knowing that Xarelto

was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Xarelto compared to other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non- valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

113. Defendants under-reported, underestimated and downplayed the serious dangers of Xarelto.

114. Defendants negligently compared the safety risk and/or dangers of Xarelto with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

115. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Xarelto in that they:

(a) Failed to use due care in designing and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was used for treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing

the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Xarelto;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Xarelto;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Xarelto;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Xarelto;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of Xarelto, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

116. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Xarelto to consumers, including the Plaintiff.

117. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

118. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered.

119. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

120. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS (STRICT PRODUCTS LIABILITY)

121. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

122. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Xarelto as hereinabove described

that was used by the Plaintiff.

123. That Xarelto was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

124. At those times, Xarelto was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

125. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Xarelto.

126. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

127. At all times herein mentioned, Xarelto was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

128. Defendants knew, or should have known that at all times herein mentioned, their Xarelto was in a defective condition, and was and is inherently dangerous and unsafe.

129. At the time of the Plaintiff's use of Xarelto, Xarelto was being used for the purposes and in a manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

130. Defendants with this knowledge voluntarily designed its Xarelto in a dangerous condition for use by the public, and in particular the Plaintiff.

131. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

132. Defendants created a product unreasonably dangerous for its normal, intended use.

133. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Xarelto left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

134. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Xarelto was manufactured.

135. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

136. The Plaintiff could not, by the exercise of reasonable care, have discovered Xarelto's defects herein mentioned and perceived its danger.

137. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

138. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

139. The Xarelto designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, life-threatening bleeding, as well as other severe and permanent health consequences from Xarelto, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Xarelto.

140. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Xarelto.

141. Defendants' defective design, manufacturing defect, and inadequate warnings of Xarelto were acts that amount to willful, wanton, and/or reckless conduct by

Defendants.

142. That said defects in Defendants' drug Xarelto were a substantial factor in causing Plaintiff's injuries. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

143. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF EXPRESS WARRANTY)

144. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

145. Defendants expressly warranted that Xarelto was safe and well accepted by users.

146. Xarelto does not conform to these express representations because Xarelto is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

147. Plaintiff did rely on the express warranties of the Defendants herein.

148. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants

for use of Xarelto in recommending, prescribing, and/or dispensing Xarelto.

149. The Defendants herein breached the aforesaid express warranties, as their drug Xarelto was defective.

150. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and/or the FDA that Xarelto was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

151. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Xarelto was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

152. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

153. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

154. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

155. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Xarelto, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

156. At the time Defendants marketed, sold, and distributed Xarelto for use by Plaintiff, Defendants knew of the use for which Xarelto was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

157. The Defendants impliedly represented and warranted to the users of Xarelto and their physicians, healthcare providers, and/or the FDA that Xarelto was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

158. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Xarelto was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

159. Plaintiff, and/or members of the medical community and/or healthcare

professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

160. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Xarelto was of merchantable quality and safe and fit for its intended use.

161. Xarelto was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

162. The Defendants herein breached the aforesaid implied warranties, as their drug Xarelto was not fit for its intended purposes and uses.

163. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

164. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)

165. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

166. The Defendants falsely and fraudulently represented to the medical and

healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, Xarelto, had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

167. That representations made by Defendants were, in fact, false.

168. When said representations were made by Defendants, they knew those representa- tions to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

169. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Xarelto, for use to reduce the risk of stroke and systemic embolism in patients with non- valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

170. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Xarelto, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

171. In reliance upon said representations, the Plaintiff was induced to and did use Xarelto, thereby sustaining severe and permanent personal injuries.

172. Said Defendants knew and were aware or should have been aware that Xarelto had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

173. Defendants knew or should have known that Xarelto had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

174. Defendants brought Xarelto to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

175. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

176. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

177. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

178. At all times during the course of dealing between Defendants and Plaintiff,

and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Xarelto for its intended use.

179. Defendants knew or were reckless in not knowing that its representations were false.

180. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Xarelto was not as safe as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(b) that the risks of adverse events with Xarelto were higher than those with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(c) that the risks of adverse events with Xarelto were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in Xarelto, in addition to and above and beyond those associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients

with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(e) that Xarelto was defective, and that it caused dangerous side effects, including but not limited to life-threatening bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery;

(f) that patients needed to be monitored more regularly than normal while using Xarelto;

(g) that Xarelto was manufactured negligently;

(h) that Xarelto was manufactured defectively;

(i) that Xarelto was manufactured improperly;

(j) that Xarelto was designed negligently;

(k) that Xarelto was designed defectively; and

(l) that Xarelto was designed improperly.

181. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Xarelto, including but not limited to the heightened risks of life-threatening bleeding.

182. Defendants had sole access to material facts concerning the defective

nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Xarelto, including the Plaintiff, in particular.

183. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Xarelto was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Xarelto, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Xarelto and/or use the product.

184. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Xarelto, as set forth herein.

185. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

186. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

187. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

188. Plaintiff repeat, reiterate and reallege each and every allegation of this

Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

189. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA, and the public in general that said product, Xarelto, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

190. The representations made by Defendants were, in fact, false.

191. Defendants failed to exercise ordinary care in the representation of Xarelto, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Xarelto's high risk of unreasonable, dangerous side effects.

192. Defendants breached their duty in representing Xarelto's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

193. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

194. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

195. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

196. Defendants conducted research, or lack thereof, and used Xarelto as part of their research.

197. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Xarelto was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

198. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

199. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

200. The information distributed to the public, the FDA, and the Plaintiff, by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

201. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Xarelto was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

202. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Xarelto carried the same risks, hazards, and/or dangers as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

203. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Xarelto was not injurious to the health and/or safety of its intended users.

204. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Xarelto was as potentially injurious to the health and/or safety of its intended users, as other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

205. These representations were all false and misleading.

206. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that

demonstrated that Xarelto was not safe as a means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and/or was not as safe as other means of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

207. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Xarelto, specifically but not limited to Xarelto not having dangerous and serious health and/or safety concerns.

208. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of Xarelto, specifically but not limited to Xarelto being a safe means of reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

209. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Xarelto and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Xarelto.

210. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

211. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Xarelto was fit and safe for use as treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

212. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Xarelto did not present serious health and/or safety risks.

213. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Xarelto did not present health and/or safety risks greater than other oral forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-

valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

214. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

215. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Xarelto.

216. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Xarelto to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

217. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Xarelto by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Xarelto.

218. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations made by Defendants, and purchase, use and rely on Xarelto and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

219. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

220. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Xarelto.

221. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, reducing the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery, and were thereby induced to purchase, use and rely on Defendants' drug Xarelto.

222. That at the time the representations were made, the Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Xarelto.

223. That the Plaintiff did not discover the true facts with respect to the

dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

224. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Xarelto, Plaintiff would not have purchased, used and/or relied on Defendants' drug Xarelto.

225. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

226. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

227. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (VIOLATION OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE PRACTICES ACT)

228. Plaintiff repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

229. Defendants have a statutory duty to refrain from making false or fraudulent representations and/or from engaging in deceptive acts or practices in the sale

and promotion of Xarelto pursuant to the Illinois Consumer Fraud & Deceptive Practices Act, 815 ILCS 505/1 *et seq*. (hereinafter "the Act"), which prohibits "the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact…in the conduct of any trade or commerce" and declares such acts or practices as unlawful.

230. Defendants engaged in unfair, deceptive, false and/or fraudulent acts and/or practices in violation of the Act through its false and misleading promotion of Xarelto designed to induce Plaintiff to purchase and use Xarelto.

231. Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

(a) Publishing instructions and product material containing inaccurate and incomplete factual information;

(b) Engaging in fraudulent or deceptive conduct that creates a likelihood of Misrepresenting the nature, quality, and characteristics about the product; and

(c) confusion or misunderstanding.

232. Defendants misrepresented the alleged benefits of Xarelto, failed to disclose material information concerning known side effects of Xarelto, misrepresented the quality of Xarelto, and otherwise engaged in fraudulent and deceptive conduct which induced Plaintiff to purchase and use Xarelto.

233. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side-effects related to the use of Xarelto, its safety, its efficacy, and its usefulness. Defendants made these representations

to physicians, the medical community at large, and to patients and consumers such as Plaintiff in the marketing and advertising campaign described herein.

234. Defendants' conduct in connection with Xarelto was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

235. Defendants' conduct as described above was a material cause of Plaintiff's decision to purchase Xarelto.

236. As a direct, foreseeable and proximate cause of Defendants' conduct in violation of the Act, Plaintiff suffered damages, including personal injuries, economic damages, and non- economic damages. Defendants' conduct was further wanton, egregious, and reckless so as to warrant the award of punitive damages.

237. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings.

238. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Prejudgment interest;

5. Postjudgment interest;

6. Awarding Plaintiff reasonable attorneys' fees;

7. Awarding Plaintiff the costs of these proceedings; and

8. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: November 21, 2014

/s/ Trent B. Miracle

Trent B. Miracle #6281491
SIMMONS, HANLY, CONROY LLC
One Court Street
Alton, IL 62002
Tel. (618) 259-2222
Fax (618) 259-2251
tmiracle@simmonsfirm.com

Attorneys for the Plaintiff

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Ann Hartman

(b) County of Residence of First Listed Plaintiff Spalding, GA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Simmons Hanly Conroy, One Court Street, Alton, IL 62002
618-259-2222

DEFENDANTS

Janssen Research & Development LLC, et al.

County of Residence of First Listed Defendant Middlesex, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

❒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332

Brief description of cause:
Pharmaceutical Personal Injury Product Liability

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER JPML MDL 2592

DATE 11/21/2014

SIGNATURE OF ATTORNEY OF RECORD Trent B. Miracle

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

E-FILED
Friday, 21 November, 2014 09:23:58 AM
Clerk, U.S. District Court, ILCD

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of Illinois

ANN HARTMAN

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC

Defendant(s)

Civil Action No. 2:14-cv-2285

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research & Development LLC f/k/a Johnson & Johnson Pharmaceutical Research & Development LLC
1 Johnson & Johnson Plaza
New Brunswick, NJ 08993

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Trent Miracle
Simmons Hanly Conroy
One Court Street
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:14-cv-2285

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

E-FILED
Friday, 21 November, 2014 09:23:59 AM
Clerk, U.S. District Court, ILCD

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of Illinois

ANN HARTMAN

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC

Defendant(s)

Civil Action No. 2:14-cv-2285

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Pharmaceutical Inc. f/k/a Janssen Pharmaceutica Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.
1 Johnson & Johnson Plaza
New Brunswick, NJ 08993

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Trent Miracle
Simmons Hanly Conroy
One Court Street
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:14-cv-2285

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

E-FILED
Friday, 21 November, 2014 09:24:00 AM
Clerk, U.S. District Court, ILCD

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of Illinois

ANN HARTMAN

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC

Defendant(s)

Civil Action No. 2:14-cv-2285

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Healthcare Pharmaceuticals, Inc.
c/o Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Trent Miracle
Simmons Hanly Conroy
One Court Street
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:14-cv-2285

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of Illinois

ANN HARTMAN

Plaintiff(s)

v.

JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC

Defendant(s)

Civil Action No. 2:14-cv-2285

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Corporation
c/o Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Trent Miracle
Simmons Hanly Conroy
One Court Street
Alton, IL 62002

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:14-cv-2285

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: