

MDLPradaxa@butlersnow.com or by U.S. Mail to Keishunna Randall, Bulter, Snow, O'Mara, Stevens & Cannada, PLLC, Post Office Box 6010, Ridgeland, MS 39158-6010.

3. Boehringer Ingelheim International GmbH ("BII") is a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Pursuant to CMO No. 12 dated October 19, 2012 by Honorable Chief Judge David R. Herndon, Defendant BII has agreed to accept service by forwarding this Complaint and a Waiver of Service via email to vlodato@sillscummis.com or by U.S. Mail to Vincent Lodato, Esq., Sills Cummis & Gross, P.C., One Riverfront Plaza, Newark, New Jersey 07102.

4. Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim International GmbH are collectively referred to in this Complaint as "Defendants."

5. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

JURISDICTION AND VENUE

6. Jurisdiction is proper in this court pursuant to 28 USC §1332 for the reason that there is complete diversity of citizenship between Plaintiffs and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars (\$75,000.00), exclusive of interest and costs.

7. Defendants are subject to *in personam* jurisdiction in this United States District Court because they placed a defective product into the stream of commerce and that product caused personal injuries to Plaintiff at his residence in the State of Missouri, and cases involving these claims have now been consolidated in this District pursuant to 28 U.S.C. §1407.

8. Defendants have sufficient minimum contacts with the forum state such

that it is subject to personal jurisdiction within said district.

9. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district. Venue is further proper under the order on the judicial panel on multidistrict litigation and Case Management Order #7 dated October 3, 2012 by Honorable Chief Judge David R. Herndon.

FACTUAL BACKGROUND

Background of the Case

10. At all relevant times, Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa® (dabigatran etexilate mesylate).

11. Pradaxa® is a direct thrombin inhibitor that is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Patients with atrial fibrillation have an increased risk of stroke.

12. Pradaxa® was approved by the Food and Drug Administration (“FDA”) on October 19, 2010. The FDA approved two dosages: 75 mg and 150 mg, to be taken twice daily. Pradaxa® was the first anticoagulation medication approved in the U.S. in more than 50 years for patients with non-valvular atrial fibrillation.

13. Prior to the FDA’s approval of Pradaxa®, warfarin was the only oral anticoagulation available in the U.S. for reducing stroke and systemic embolism in patients with atrial fibrillation. Unlike patients who use Pradaxa®, users of warfarin must follow dietary restrictions and regularly monitor their level of anti-coagulation by undergoing blood tests (INR) and potentially adjusting the dose of their medication to maintain adequate anticoagulation.

Defendants' over promotion of Pradaxa®

14. Defendants promoted Pradaxa® as a novel medicine for patients with non-valvular atrial fibrillation. Defendants' marketing campaign for Pradaxa® included promoting it as being more effective than warfarin in preventing stroke and systemic embolism, providing a convenient alternative to warfarin therapy because it does not require blood monitoring or dose adjustments, and does not require any dietary restrictions.

15. Defendants spent significant money in promoting Pradaxa®, which included \$67,000,000.00 spent during 2010 (although Pradaxa® was not approved for sale until October 19, 2010).¹

16. During 2011, Defendants reportedly undertook 1.5 million Pradaxa® "detailing sessions" (marketing/sales visits by Defendants' sales force) with U.S. primary care physicians, internists, group practitioners, cardiologists, and practice nurses, spending approximately \$464,000,000.00 during this 12 month period to promote Pradaxa® in the United States.²

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

18. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Pradaxa® with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent or means

¹ Deborah Weinstein, *Study: Sales Support is Dwindling, Not Dead*, March 14, 2012, Medical Marketing and Media.

² *Id.*

to reverse the anticoagulation effects of Pradaxa®, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

19. Prior to Plaintiff's prescription of Pradaxa®, Plaintiff became aware of the promotional materials described herein.

20. Prior to Plaintiff's prescription of Pradaxa®, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Pradaxa® was more effective than warfarin in reducing strokes in patients with non-valvular atrial fibrillation 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 Pradaxa®.

21. 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 Pradaxa®, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Pradaxa®.

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

23. From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa® were written in the United States. During that same period, there were 932 Pradaxa®-associated "Serious Adverse Event" ("SAE") Medwatch

reports filed with the U.S. Food and Drug Administration, including at least 120 deaths and over 500 reports of severe, life-threatening bleeding.

24. From April 1 until the end of June 2011, there were an additional 856 Pradaxa®-associated “SAE” Medwatch reports filed with the U.S. Food and Drug Administration including at least 117 deaths and over 510 reports of severe, life-threatening bleeding.

25. During the Defendants’ 2011 fiscal year, worldwide Pradaxa® sales eclipsed the \$1 billion threshold, achieving what is commonly known in the pharmaceutical industry as “blockbuster” sales status.³

26. Defendants’ original labeling and prescribing information for Pradaxa®:
- a. failed to disclose in the “Warnings” Section that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;
 - b. 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 Pradaxa®;
 - c. failed to investigate, research, study and consider, fully and adequately, patient age, weight and/or kidney function as a variable factors in establishing recommended dosages of Pradaxa®;
 - d. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;
 - e. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®;

³ Heide Oberhauser-Aslan and Tapan Sharma, *Boehringer Sees Sales Rising Further as 2011 Profits Surge* April 24, 2012 [WSJ.com](http://www.wsj.com)

- f. failed to warn that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;
- g. failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa®;
- h. failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Pradaxa® and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa®;
- i. failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Pradaxa® users;
- j. failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Pradaxa®, especially, in those patients with a prior history of gastrointestinal issues and/or upset;
- k. failed to include a “**BOXED WARNING**” about serious bleeding events associated with Pradaxa®;
- l. failed to include a “**Bolded Warning**” about serious bleeding events associated with Pradaxa®; and
- m. in their “Medication Guide” intended for distribution to patients to whom Pradaxa® has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

27. During March, 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa®, which included additional information regarding the use of Pradaxa® in patients taking certain medications. Despite being aware of: (I) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; and (II) almost 1800 SAE Medwatch reports filed with the U.S. Food and Drug Administration, including at least 237 deaths and over 1,000 reports of severe, life-threatening bleeding, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

28. On July 1, 2011, Pradaxa® was approved for sale in New Zealand with a lower dosing option of 110mg twice a day for high risk patient populations such as those patients over 80 years of age and for patients with moderate renal impairment. This was based on dosing studied in actual patient populations as part of the RE-LY trial.

29. On July 25, 2011, the Archives of Internal Medicine published *The Use of Dabigatran [Pradaxa®] in Elderly Patients*. [Vol 171, No. 14] which concluded that “The risk of major overdosage of...[Pradaxa®] in this [elderly] population is, however, much increased owing to frequent renal function impairment, low body weight, drug interactions that cannot be detected with a routine coagulation test and no antagonist available.”

30. On January 21, 2011, Pradaxa® (under the brand name Prazaza®), in 75mg and 110mg doses only, is approved for sale in Japan to treat non-valvular atrial fibrillation.

31. On August 11, 2011, Japan’s pharmaceutical regulatory authority announced that it was requiring a “**BOXED WARNING**” be added to Pradaxa®

(marketed as Prazaza® in Japan) to call attention to reports of severe hemorrhages in patients treated with Pradaxa® (Prazaza®).

32. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued a “Prescriber Update” entitled “Dabigatran – Is there a Bleeding Risk” in which physicians were alerted that Pradaxa® had a higher incidence of gastrointestinal bleeds than warfarin and that there was no reversal agent to neutralize the anticoagulation effects of Pradaxa®. A follow-up report issued in December 2011, indicated that among 10,000 New Zealanders who had taken Pradaxa®, there were 78 reports of serious bleeding events associated with Pradaxa® including 60 reports of gastrointestinal and rectal bleeding. Among the 78 serious events were 10 patient deaths and 55 hospitalizations. Three months later in March, 2012 the New England Journal of Medicine published two letters from physicians in New Zealand addressing bleeding events associated with Pradaxa®. In one letter, physicians wrote, “We are concerned that the potential risks of this medication are not generally appreciated. The serious consequences of a lack of an effective reversal agent should not be underestimated.”

33. During November 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa® adding additional information regarding the use of Pradaxa® in patients with kidney disease despite being aware of: (I) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (II) the July 25, 2011 article in the *Archives of Internal Medicine*; (III) the addition of a “**BOXED WARNING**” to Pradaxa® in Japan; and, (IV) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

34. On December 7, 2011, the U.S. Food and Drug Administration issued a Drug Safety Communication announcing that it was undertaking a “Drug Safety Review” of Post-Marketing Reports of Serious Bleeding Events with the anticoagulant Pradaxa. The purpose of the FDA’s review is to determine if serious bleeding events associated with the use of Pradaxa® are more common than expected based on the Defendants’ data submitted to the FDA.

35. As of December 31, 2011, the U.S. Food and Drug Administration received over 500 reports of deaths of people in the U.S. linked to Pradaxa® which, at that point, had been available in the U.S. for approximately 14 months. In addition, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa®.

36. In January 2012, the Defendants modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a “**BOXED WARNING**” to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; and (v) the Drug Safety Communication published by the FDA in December, 2011, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

37. During March 2012, in response to a directive from Health Canada, the governmental agency responsible for regulating pharmaceuticals in Canada, the Defendants’ Canadian affiliate issued a “Dear Healthcare Provider” letter in which it advised Canadian healthcare providers of certain risks associated with the use of

Pradaxa® (marketed as Pradax® in Canada) in elderly patients and patients with impaired kidney function and prosthetic heart valves. No such similar communication was sent to healthcare providers in the United States.

38. In April 2012, the Defendants modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the Archives of Internal Medicine; (iii) the addition of a “**BOXED WARNING**” to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; (v) the Drug Safety Communication published by the FDA in December, 2011; and (vi) the “Dear Healthcare Provider” letter Defendants were required to provide in Canada, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

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

Plaintiff’s use of Pradaxa® and resulting injuries

40. As a result of Defendants' claims regarding the effectiveness, safety, and benefits of Pradaxa®, Plaintiff and Plaintiff’s physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Plaintiff would be exposed to the risk of excessive and/or uncontrollable bleeding and the other risks and injuries described herein.

41. Therefore, Plaintiff was prescribed Pradaxa® on March 12, 2012 for treatment of her medically necessary blood thinning needs. Shortly thereafter, Plaintiff presented to the emergency room on July 5, 2012 with complaints of black stools and a presyncopal episode followed by emesis of large amounts of blood with large clots. She was admitted with an upper GI bleed and transfused with 5 units of blood. Plaintiff was ultimately discharged 6 days later and Pradaxa was discontinued. Plaintiff experienced excessive and/or uncontrollable bleeding, which was caused and/or worsened by Plaintiff's use of Pradaxa®.

42. Prior to Plaintiff's use of Pradaxa®, Defendants knew or should have known that the original labeling of the drug did not adequately warn Plaintiff of the risks associated with using the drug as described above.

43. Prior to Plaintiff's use of Pradaxa®, Defendants knew or should have known of the defective nature of Pradaxa® and persons who were prescribed and ingested Pradaxa® for even a brief period of time, including the Plaintiff, were at increased risk for developing life-threatening bleeds. Defendants, through their affirmative misrepresentations and omissions, concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Pradaxa® use.

44. Plaintiff was unaware of the increased risk for developing life-threatening injuries as compared to warfarin. Had Plaintiff and/or Plaintiff's healthcare provider known of the risks and dangers associated with Pradaxa®, as well as the lack of additional benefits, and had Defendants provided adequate warnings that there is no agent to reverse the anticoagulation effects of Pradaxa®, Plaintiff would not have used Pradaxa®.

45. As a direct and proximate result of using Pradaxa®, Plaintiff has suffered severe personal injuries, physical pain and mental anguish, including diminished

enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences all resulting from Plaintiff's ingestion of Pradaxa®.

CAUSES OF ACTION

**COUNT I
STRICT LIABILITY-FAILURE TO WARN**

46. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

47. At all times relevant to this suit, Defendants engaged in the business of designing, manufacturing, testing, marketing, labeling and placing into the stream of commerce Pradaxa® for sale to, and use by, members of the public.

48. At all times relevant to this suit, the dangerous propensities of Pradaxa® were known to Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

49. The Pradaxa® manufactured by Defendants reached Plaintiff without substantial change and was ingested as directed.

50. Defendants marketed Pradaxa® in multiple ways, including but not limited to direct-to-consumer advertisements, which were misleading in that Defendants overstated the safety and efficacy of Pradaxa® and understated its risks.

51. The Pradaxa® was defective and unreasonably dangerous in that the labeling was insufficient to adequately warn physicians and users of the increased risk of excessive and/or uncontrollable bleeding.

52. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to Pradaxa® and suffered personal injuries, economic and non-economic damages including pain and suffering.

53. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT II
STRICT PRODUCTS LIABILITY - DESIGN DEFECT

54. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

55. Defendants are the manufacturers, designers, distributors, sellers and suppliers of Pradaxa®, who sold Pradaxa® in the course of business.

56. The Pradaxa® manufactured, designed, sold, marketed, distributed, supplied and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

57. The Pradaxa™ administered to Plaintiff was defective in design or formulation in the following respects:

- a. When it left the hands of the Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;
- b. Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;
- c. The dosages and/or formulation of Pradaxa™ sold by the Defendants was unreasonably dangerous;

- d. There are no patients for whom the benefits of Pradaxa™ outweighed the risks;
- e. The subject product was not made in accordance with the Defendants' specifications or performance standards;
- f. There are no patients for whom Pradaxa™ is a safer and more efficacious drug than other drug products in its class; and/or
- g. There were safer alternatives that did not carry the same risks and dangers that Defendants' Pradaxa™ had.

58. The Pradaxa™ administered to Plaintiff was defective at the time it was distributed by the Defendants or left their control.

59. The foreseeable risks associated with the design or formulation of the Pradaxa® include, but are not limited to, the fact that the design or formulation of Pradaxa® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

60. The defective and unreasonably dangerous design and marketing of Pradaxa® was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case.

61. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of Pradaxa®, Plaintiff suffered personal injuries, economic and non-economic damages, including pain and suffering.

62. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT III
NEGLIGENCE

63. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

64. Defendants owed a duty to the general public and specifically to the Plaintiff to exercise reasonable care in the design, study, development, manufacture, promotion, sale, labeling, marketing and distribution of Pradaxa® at issue in this lawsuit.

65. Defendants breached their duty and failed to exercise reasonable care in the developing, testing, designing and manufacturing of Pradaxa® because, it was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

66. Defendants breached their duty and also failed to exercise reasonable care in the marketing of Pradaxa® because they failed to warn, that as designed, Pradaxa® was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

67. Defendants breached their duty and also failed to exercise ordinary care in the labeling of Pradaxa® and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Pradaxa®. Moreover, Defendants over-promoted the benefits of Pradaxa® for anticoagulation therapy in patients suffering from atrial fibrillation and understated the risk of excessive and/or uncontrollable bleeding.

68. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiffs:

- a. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;
- b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa®;
- c. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent; and
- d. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff.

69. Despite the fact that Defendants knew or should have known that Pradaxa® posed a serious risk of bodily harm to consumers and/or did not provide any additional benefits, Defendants continued to manufacture and market Pradaxa® for use by consumers.

70. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

71. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, labeling, and/or manufacturing of Pradaxa® was a proximate cause of Plaintiff's injuries and damages.

72. Defendants' conduct as described above, including but not limited to its failure to adequately test Pradaxa®, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of

the serious health risks it created, evidences actions and/or intentional disregard of the rights of Plaintiff so as to warrant the imposition of punitive damages.

COUNT IV
NEGLIGENT MISREPRESENTATION AND/OR FRAUD

73. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

74. Defendants represented that Pradaxa® was just as safe or safer and as effective or more effective than other anticoagulation alternatives and had additional benefits compared to other anticoagulation medications available on the market.

75. Defendants made these misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Pradaxa® had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiff and the consuming public, among other things, that:

- a. Pradaxa® had statistically significant increases in irreversible bleeds and other side effects which could result in serious, permanent injury or death;
- b. Pradaxa® had not been fully or adequately tested;
- c. Pradaxa® does not have any known reversal agents;
- d. Pradaxa® bleeds cannot be stopped or controlled by any effective medical processes or medical intervention;
- e. Failed to warn that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®; and
- f. Pradaxa® was not as safe as blood thinners such as warfarin.

76. Defendants negligently and/or intentionally misrepresented or omitted this information in their product labeling, promotions and advertisements and instead labeled, promoted and advertised their product as safer and more effective than other types of anticoagulation alternatives and understated the risk of excessive and/or uncontrollable bleeding associated with Pradaxa®.

77. The aforementioned misrepresentations were untrue and misleading.

78. Defendants knew or should have known that these representations were false and made the representations with the intent that Plaintiff and/or Plaintiff's prescribing physicians would rely on them, leading to the use of Pradaxa®.

79. At the time of Defendants' fraudulent misrepresentations, Plaintiff and/or Plaintiff's prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiff and/or Plaintiff's prescribing physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendants did suppress, conceal or failed to disclose, to Plaintiff's detriment.

80. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiff suffered personal injuries, economic and non-economic damages, including pain and suffering.

81. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT V
BREACH OF EXPRESS WARRANTY

82. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

83. Defendants expressly warranted, through their direct-to-consumer marketing, label, and sales representatives, that Pradaxa® was a safe and effective prescription blood thinner. The safety and efficacy of Pradaxa® constitute a material fact in connection with the marketing, promotion, and sale of Pradaxa®.

84. Pradaxa® manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

85. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

86. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT VI
BREACH OF IMPLIED WARRANTY – MERCHANTABILITY

87. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

88. Defendants were at the time of the acts forming the basis of this lawsuit, and now are, merchants with respect to the Pradaxa™ at issue in this lawsuit. Defendants have impliedly warranted to the public generally and specifically to Plaintiff that Pradaxa™ was merchantable and fit for safe use for preventing strokes and/or blood clots in patients with AF, the purpose for which Defendants marketed Pradaxa™. Pradaxa™ was not merchantable as warranted because, as designed, Pradaxa™ was capable of causing serious personal injuries such as those suffered by

Plaintiff during foreseeable use. Therefore, Defendants have breached the implied warranty of merchantability with respect to Pradaxa™.

89. As a direct and proximate result of Defendants' breach of the warranty of merchantability, Plaintiff sustained serious and permanent injuries and damages.

COUNT VII
BREACH OF IMPLIED WARRANTY - FITNESS FOR A PARTICULAR PURPOSE

90. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

91. Defendants knew that consumers such as Plaintiff would require Pradaxa™ for safe use for treatment of AF, and that consumers would rely on Defendants' skill and judgment to select suitable medications. Defendants provided such skill and judgment by marketing and selling Pradaxa™ for that purpose. Plaintiff relied on Defendants' skill and judgment when selecting and purchasing the Pradaxa™ at issue. The Pradaxa™ used by Plaintiff was not fit for its particular purpose because, as designed, Pradaxa™ was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Therefore, Defendants have breached the implied warranty of fitness for a particular purpose with respect to Pradaxa™.

92. As a direct and proximate result of Defendants' breach of the warranty of fitness for a particular purpose, Plaintiff sustained the injuries and damages discussed herein.

COUNT VIII
NEGLIGENCE PER SE - DEFENDANTS' VIOLATION OF 21 U.S.C. §§ 331(a) & 352

93. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

94. As part of their duty to exercise reasonable care, Defendants were obligated to follow public laws and regulations enacted and promulgated to protect the

safety of persons such as Plaintiff, including 21 U.S.C. §§ 331(a) & 352, and other statutes and regulations, which make it unlawful to misbrand prescription drug products.

95. The labeling, including package inserts, for Pradaxa® failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (t), and the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

96. Specifically, the product label and package insert for Pradaxa® is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe Pradaxa®.

97. Pradaxa® is misbranded pursuant to 21 U.S.C. § 352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

98. Pradaxa® is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

99. Pradaxa® is misbranded pursuant to 21 U.S.C. § 352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

100. Because the Defendants each had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to misbrand Pradaxa®, and because each of them violated this duty, they were guilty of negligence per se.

101. Pradaxa® is further misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

102. Defendants also violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Pradaxa®.

103. Defendants violated 21 C.F.R. § 201.57 because the safety considerations regarding Pradaxa® are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

104. Pradaxa® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

105. Pradaxa® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., irreversible bleeding).

106. Pradaxa® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling does not state an upper limit dosing beyond which safety and effectiveness have not been established.

107. Pradaxa® violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

108. Pradaxa® violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

109. Defendants violated 21 C.F.R. §§ 310.305 & 314.80 by failing to report adverse events associated with Pradaxa® as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

110. Defendants violated 21 C.F.R. §§ 310.305 & 314.80 by failing to conduct an investigation of each adverse event associated with Pradaxa®, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

111. Defendants violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the IS-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing IS-day Alert report, (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) and/or (d) a copy of the published article from scientific or medical journals along with one or more IS-day Alert reports based on information from the scientific literature.

112. Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of Pradaxa® or otherwise received by Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

113. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making Defendants liable to Plaintiff, and further, because each of them violated the above referenced duties required by these statutes and regulations, they are guilty of negligence per se.

114. Defendant's failure to adequately warn about the magnitude of the risk associated with use of Pradaxa® constitutes negligence per se. This negligence per se proximately caused injury to Plaintiff as described more fully herein.

COUNT IX
FRAUDULENT CONCEALMENT

115. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

116. At all times during the course of dealings between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Pradaxa® for its intended use.

117. Defendants knew or were reckless in not knowing that their representations were false.

118. 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 Pradaxa® was not as safe or effective as other forms of anticoagulation medication for atrial fibrillation patients;
- b. that Defendants failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

- c. that Defendants failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;
- d. that Defendants failed to provide adequate warnings that there was no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;
- e. that Defendants failed to include an adequate warning about serious bleeding events associated with Pradaxa®;
- f. that Defendants failed to warn it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;
- g. that Defendants failed to adequately instruct physicians on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa®;
- h. that it is critical to fully assess renal functioning prior to starting a patient on Pradaxa® and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa®;
- i. that there is an increased risk of bleeding events associated with aging patient populations of Pradaxa® users;
- j. that there is an increased risk of gastrointestinal bleeds in those taking Pradaxa®, especially, in those patients with a prior history of gastrointestinal issues and/or upset;
- k. that Pradaxa® was defective, and that it caused dangerous side effects, including but not limited to higher incidence of excessive and/or uncontrollable bleeding;
- l. that Pradaxa® was manufactured negligently;
- m. that Pradaxa® was manufactured defectively;

- n. that Pradaxa® was manufactured improperly;
- o. that Pradaxa® was designed negligently;
- p. that Pradaxa® was designed defectively; and
- q. that Pradaxa® was designed improperly.

119. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Pradaxa®, including but not limited to the heightened risks of excessive and/or uncontrollable bleeding.

120. 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 Pradaxa®, including the Plaintiff, in particular.

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

122. 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 Pradaxa®, as set forth herein.

123. 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.

124. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, excessive and/or uncontrollable 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.

125. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

126. By reason of the foregoing, Plaintiff has been damaged.

COUNT X
PUNITIVE DAMAGES

127. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

128. At all material times, the Defendants knew or should have known that Pradaxa® was inherently dangerous.

129. Despite their knowledge, the Defendants continued to aggressively market Pradaxa® to consumers, including Plaintiff, without disclosing its dangerous side effects when there existed safer alternative products.

130. Despite Defendants' knowledge of Pradaxa®'s defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff, in conscious disregard of the foreseeable harm caused by Pradaxa®.

131. Defendants' conduct was intentional and/or wanton.

132. Defendants' conduct as described above, including, but not limited to, their failure to adequately test their product, to provide adequate warnings, and their continued manufacture, sale, and marketing of their products when they knew or should have known of the serious health risks created, evidences a flagrant disregard of human life as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Actual damages as alleged, jointly and/or severally against Defendants, in excess of \$75,000.00;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;
5. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of \$75,000.00;
6. Interest on the judgment at the highest legal rate from the date of judgment until collected;
7. Attorneys' fees, expenses, and costs of this action; and
8. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated this 6th day of February, 2013

Respectfully submitted,

s/ Ryan L. Thompson

Ryan L. Thompson

Federal Bar No. 602642

Mikal C. Watts

Federal Bar No. 12419

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ATTORNEYS FOR PLAINTIFF

CIVIL COVER SHEET

The JS 44 civil coversheet 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

Georgia Primus

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

(c) Attorneys (Firm Name, Address, and Telephone Number) Ryan L. Thompson, Watts Guerra Craft LLP, 5250 Prue Rd, Suite 525, San Antonio, TX 78240, 210.448.0500

DEFENDANTS

Boehringer Ingelheim Pharmaceuticals, Inc., et al

County of Residence of First Listed Defendant Fairfield (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, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Property, etc.

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 US Section 1332

Brief description of cause:

Personal injury; product liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$

CHECK YES only if demanded in complaint: JURY DEMAND: X Yes O No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Judge David Herndon

DOCKET NUMBER 3:12-md-02385

DATE February 6, 2013 SIGNATURE OF ATTORNEY OF RECORD

/s/ Ryan L. Thompson

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE