UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: PRADAXA (DABIGATRAN ETEXILATE) PRODUCTS LIABILITY LITIGATION	3:12-MD-02385-DRH-SCW **MDL No. 2385** Judge David R. Herndon
Adalaine Nancy Kohn individually and as personal representative of the estate of Ronald Kohn, Deceased, Susan Kohn, an individual, Michael Kohn, an individual, Jon Kohn, an individual by and through his legal guardian, Adalaine Nancy Kohn Plaintiffs	COMPLAINT AND JURY DEMAND Civil Action No.: 3:13-cv-50023-DRH-SCW
vs.	
Boehringer Ingelheim Pharmaceuticals, Inc.; Defendant.	

COMPLAINT

Plaintiff Adalaine Nancy Kohn, individually and as personal representative of the Estate of Ronald Kohn, Deceased, Susan Kohn, Michael Kohn, and Jon Kohn (hereinafter "Plaintiffs"), by and through Plaintiffs' attorneys, brings this action for personal injuries and wrongful death against Defendant Boehringer Ingelheim Pharmaceuticals, Inc., (hereinafter "Defendant"). Plaintiffs allege as follows:

PARTIES

1. Plaintiff Adalaine Nancy Kohn is the surviving spouse of Ronald Kohn (hereinafter "Decedent") and the personal representative of the Estate of Ronald Kohn, Deceased. She brings individual claims, including her claim for the wrongful death of Ronald Kohn, as well as claims of the Estate. At the time of filing this Complaint and at all times relevant hereto, Plaintiff Adalaine Nancy Kohn was a resident and citizen of Albany County,

New York. She was married to Decedent until his death on September 21, 2012.

2. At the time of his injury and subsequent death, Decedent was a resident and citizen of Albany County, New York.

3. Plaintiff Susan Kohn is an adult child of Decedent and brings a claim for loss of consortium. At all times relevant hereto, Plaintiff Susan Kohn was a resident and citizen of Orleans Parish, Louisiana.

4. Plaintiff Michael Kohn is an adult child of Decedent and brings a claim for loss of consortium. At all times relevant hereto, Plaintiff Michael Kohn was a resident and citizen of Albany County, New York.

5. Plaintiff Jon Kohn is an adult child of Decedent and is legally incapacitated. Through his legal guardian, Adalaine Nancy Kohn, he brings a claim for loss of consortium. At all times relevant hereto, Plaintiff Jon Kohn was a resident and citizen of Albany County, New York.

6. Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut, 06877. Boehringer has conducted business and derived substantial revenue from within the State of Illinois, and may be served by email through its designated agent for service of process, Keishunna Randall, Butler, Snow, O'Mara, Stevens & Cannada, PLLC, P.O. Box 6010, Ridgeland, MS 39158-6010, as directed in Case Management Order 7, Case 3:12-MD-02385-DRH-SCW (Doc. 43).

JURISDICTION AND VENUE

7. Jurisdiction is proper in this Court pursuant to 28 USC § 1332 because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business in states other than the state in which the named Plaintiffs' reside.

8. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 US.C. § 1367.

9. Venue is proper in the Southern District of Illinois pursuant to Case Management

Order Number 7 Regarding Direct Filing and Waiver of Service of Process for Direct Filed Case for *In re: Pradaxa (Dabigatran Etexilate) Products Liability Litigation*^ MDL No. 23

FACTUAL BACKGROUND

Background of the Case

10. At all relevant times, Defendant, directly or through its 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 medication 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 blood levels (INR) by undergoing blood tests and potentially adjusting the dose of their medication.

Defendant's Over Promotion of Pradaxa®

14. Defendant promoted Pradaxa® as a novel medicine for patients with non-valvular atrial fibrillation. Defendant's 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. Defendant 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, Defendant reportedly undertook 1.5 million Pradaxa® "detailing sessions" (marketing/sales visits by Defendant's 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 its marketing of Pradaxa®, Defendant widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Plaintiffs' decedent 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, Defendant 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 to reverse the anticoagulation effects of Pradaxa®, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

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

20. Prior to Plaintiffs' decedent's prescription of Pradaxa®, Plaintiffs' decedent's prescribing physician received Promotional materials and information from sales representatives of Defendant 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, Defendant 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

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

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 Defendant 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 Defendant's 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. Defendant's 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 Plaintiffs' decedent'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 weight as a variable factor in establishing recommended dosages of Pradaxa®;

[3] Heide Oberhauser-Aslan and Tapan Sharma, Boehringer See Sales Rising Further as 2011 Profits Surge April 24, 2012 WST.com.

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®;

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 its "Medication Guide" intended for distribution to patients to whom Pradaxa® has been prescribed, Defendant 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, Defendant 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®; (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, Defendant nonetheless failed to provide adequate disclosures or warnings in its label as detailed in Paragraphs 26 (a -m).

28. On July 1, 2011, Pradaxa® was approved for sale in New Zealand with lower dosing (lowered from 150mg to HOmg twice a day) required for patients over 80 years of age and recommended for patients with moderate renal impairment.

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 over dosage 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 150mg doses only, was 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 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, Defendant 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"**[1] to Pradaxa® in Japan; and, (IV) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®, Defendant nonetheless failed to provide adequate disclosures or warnings in its 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 Defendant's 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 Defendant 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, Defendant nonetheless failed to provide adequate disclosures or warnings in its 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 Defendant's 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 Pradaxa® 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 Defendant 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 Defendant was required to provide in Canada, Defendant nonetheless failed to provide adequate disclosures or warnings in its label as detailed in Paragraphs 26 (a - m).

39. At all times relevant hereto, Defendant 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®.

Plaintiffs' Decedent's use of Pradaxa® and Resulting Injuries

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

41. Therefore, Plaintiffs' decedent was prescribed Pradaxa® on or about April 25, 2011, for treatment of his medically necessary blood thinning needs. Shortly thereafter, on or about September 20, 2012 Plaintiffs' decedent was hospitalized for two days at St. Peter's Hospital due to abdominal pain and abdominal bleeding. Plaintiffs' decedent experienced excessive and/or uncontrollable bleeding, which was caused and/or worsened by Plaintiffs' decedent's use of Pradaxa®. As a result, Plaintiffs' decedent died on September 21, 2012.

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

43. Prior to Plaintiffs' decedent use of Pradaxa®, Defendant 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 Plaintiffs' decedent, were at increased risk for developing life-threatening bleeds. Defendant, through its affirmative misrepresentations and omissions, concealed from Plaintiffs' decedent and Plaintiffs' decedent's physicians the true and significant risks associated with Pradaxa® use.

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

45. As a direct and proximate result of using Pradaxa®, Plaintiffs' decedent, up until his death, suffered severe personal injuries, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications, and imminent fear of death, all of which resulted from Plaintiffs' decedent's ingestions of Pradaxa®.

46. As a direct and proximate result of using Pradaxa®, Plaintiffs' decedent, suffered fatal injuries, and died on September 21, 2012

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-FAILURE TO WARN

47. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

48. At all times relevant to this suit, Defendant was 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.

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

50. The Pradaxa® manufactured by Defendant reached Plaintiffs' decedent without substantial change and was ingested as directed.

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

52. 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.

53. As a direct and proximate result of the actions and inactions of the Defendant as set forth above, Plaintiffs' decedent was exposed to Pradaxa® and suffered personal injuries, economic and non-economic damages including pain and suffering.

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

COUNT II

STRICT PRODUCTS LIABILITY - DESIGN DEFECT

55. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

56. Defendant are the manufacturers, designers, distributers, sellers and suppliers of Pradaxa®, who sold Pradaxa® in the course of business.

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

58. The Pradaxa® administered to Plaintiffs' decedent was defective in design or formulation in at least the following respects:

a. When it left the hands of the Defendant, this drug was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Plaintiffs' decedent or Plaintiffs' decedent'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 Defendant intended;

c. The dosages and/or formulation of Pradaxa® sold by the Defendant was unreasonably dangerous;

d. There are no patients for whom the benefits of Pradaxa® outweighed the risks;

e. The product was not made in accordance with the Defendant' 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 Defendant's Pradaxa® had.

59. The Pradaxa® administered to Plaintiffs' decedent was defective at the time it was distributed by the Defendant or left its control.

60. 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.

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

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

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

COUNT III

NEGLIGENCE

64. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

65. Defendant owed a duty to the general public and specifically to the Plaintiffs' decedent to exercise reasonable care in the design, study, development, manufacture, promotion, sale, labeling, marketing and distribution of Pradaxa® at issue in this lawsuit.

66. Defendant breached its 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 Plaintiffs' decedent during foreseeable use.

67. Defendant breached its 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 Plaintiffs' decedent during

foreseeable use.

68. Defendant breached its 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, Defendant 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.

69. Defendant breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiffs' decedent:

a. In disseminating information to Plaintiffs' decedent and Plaintiffs' decedent's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Decedent;

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 Plaintiffs' decedent.

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

71. Defendant knew or should have known that consumers, including Plaintiffs' decedent, would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

72. Defendant failure to exercise reasonable care in the design, dosing information,

marketing, warnings, labeling, and/or manufacturing of Pradaxa® was a proximate cause of Plaintiffs' decedent's injuries and damages.

73. Defendant's 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 Plaintiffs' decedent so as to warrant the imposition of punitive damages.

COUNT IV

NEGLIGENT MISREPRESENTATION AND/OR FRAUD

74. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

75. Defendant 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.

76. Defendant made these misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Pradaxa® had defects, dangers, and characteristics that were other than what Defendant had represented to and Plaintiffs' decedent the health care industry generally. Specifically, Defendant misrepresented to and/or actively concealed from Plaintiffs' decedent 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.

77. Defendant's negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its 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®.

78. The aforementioned misrepresentations were untrue and misleading.

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

80. At the time of Defendant's fraudulent misrepresentations, Plaintiffs' decedent and/or Plaintiffs' decedent's prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs' decedent and/or Plaintiffs' decedent'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 Defendant did suppress, conceal or failed to disclose, to Plaintiffs' decedent detriment.

81. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendant, Plaintiffs' decedent suffered personal injuries, economic and non-economic damages, including pain and suffering.

82. Defendant's actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiffs' decedent's rights so as to warrant the imposition of punitive damages.

COUNT V

BREACH OF EXPRESS WARRANTY

83. Plaintiffs' incorporates by reference each preceding paragraph as though set forth fully at length herein.

84. Defendant expressly warranted, through its 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®.

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

86. As a direct and proximate result of Defendant's breach of warranty, Plaintiffs' decedent suffered harm, damages and economic loss and Plaintiffs' will continue to suffer such harm, damages and economic loss in the future.

87. Defendant's actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of Plaintiffs' decedent rights so as to warrant the imposition of punitive damages.

COUNT VI

BREACH OF IMPLIED WARRANTY

88. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

89. At the time Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and /or otherwise released Pradaxa® into the stream of commerce, Defendant knew of the use for which Pradaxa® was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

90. Defendant breached its implied warranties of the Pradaxa® product sold to Plaintiffs' decedent because this product was not fit for its common, ordinary, and intended use.

91. As a direct, foreseeable and proximate result of Defendant's breaches of implied warranties, Plaintiffs' decedent suffered grievous bodily injury and consequential economic and other losses, as described above, when Plaintiffs' decedent ingested Pradaxa®, in reasonable reliance upon the implied warranties.

92. Defendant's actions and omissions as identified in this Complaint demonstrate malicious actions and /or intentional disregard of Plaintiffs' decedent's rights so as to warrant the imposition of punitive damages.

COUNT VII

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

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

94. As part of its duty to exercise reasonable care, Defendant were obligated to follow public laws and regulations enacted and promulgated to protect the safety of persons such as Plaintiffs' decedent, 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 Defendant 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. Defendant 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. Defendant 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 Defendant 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. Defendant 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 Defendant of the adverse drug experience.

110. Defendant 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. Defendant 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 15-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 15-day Alert reports based on information from the scientific literature.

112. Defendant violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of Pradaxa® or otherwise received by Defendant 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. Defendant 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 Plaintiffs' decedent, making Defendant liable to Plaintiffs', 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 Plaintiffs' decedent as described more fully herein.

COUNT VIII

FRAUDULENT CONCEALMENT

115. Plaintiffs hereby incorporate by reference all of the above allegations as a fully set forth herein.

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

117. Defendant knew or was reckless in not knowing that its representations were false.

118. In representations to Plaintiffs' decedent and/or Plaintiffs' decedent's healthcare providers, and/or the FDA, Defendant 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 Defendant failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

c. that Defendant failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

d. that Defendant failed to provide adequate warnings that there was no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;

e. that Defendant failed to include an adequate warning about serious bleeding events associated with Pradaxa®;

f. that Defendant failed to warn it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;

g. that Defendant 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. Defendant was under a duty to disclose to Plaintiffs' decedent and Plaintiffs' decedent'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. Defendant 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 Plaintiffs' decedent, in particular.

121. Defendant's concealment and omissions of material facts concerning, *inter alia,* the safety of Pradaxa® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiffs' decedent and Plaintiffs' decedent'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. Defendant knew that Plaintiffs' decedent and Plaintiffs' decedent's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding Pradaxa®, as set forth herein.

123. Plaintiffs' decedent as well as Plaintiffs' decedent'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 Defendant.

124. As a result of the foregoing acts and omissions the Plaintiffs' decedent was caused to suffer serious and dangerous side effects including, *inter alia,* excessive and /or uncontrollable bleeding, which ultimately led to his death, 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 Plaintiffs' decedent did incur medical, health, incidental and related expenses.

126. By reason of the foregoing, Plaintiffs' decedent has been damaged.

COUNT IX

ILLINOIS CONSUMER FRAUD AND DECEPTIVE PRACTICES ACT

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

128. At all times relevant, the Illinois Consumer Fraud & Deceptive Practices Act, 815 ILCS 505/1 et seq., (hereinafter "IFCA") 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.

129. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released Pradaxa® into the stream of commerce and in the course of same, directly advertised or marketed the product to health care professionals and consumers, including Plaintiffs' decedent.

130. Defendant violated the IFCA by the use of deceptive, false, and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Pradaxa®. Defendant communicated, and continue to communicate, the purported benefits and safety of Pradaxa® while failing to disclose the serious and dangerous side effects related to the use of Pradaxa® with the intent that consumers, like Plaintiffs' decedent and Plaintiffs' decedent's healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Pradaxa®, respectively.

131. Defendant intended that consumers like Plaintiff s' decedent rely on its deceptive, false and misleading misrepresentations or omissions of material fact in order to increase its sales and profit of Pradaxa®, which was done in the ordinary course of its business.

132. As a result of violating the ICFA, Defendant caused Plaintiffs' decedent to be prescribed and to use Pradaxa®, causing severe injuries and damages as previously described herein.

133. As a result of Defendant's violation of the ICFA, Decedent suffered pecuniary loss and damages, when Plaintiffs' decedent failed to get the benefit of Plaintiffs' decedent bargain by purchasing Pradaxa® in reliance on Defendant's deceptive, false, and misleading representations concerning its benefits and safety, and instead suffered actual severe injuries as previously described herein.

134. Defendant's actions and omissions as identified in this Complaint demonstrate malicious actions and /or intentional disregard of Plaintiffs' decedent rights so as to warrant the imposition of punitive damages. Plaintiffs' decedent relied on Defendant's deceptive, false and misleading misrepresentations or omissions of material fact in order to increase its sales and profits of Pradaxa®, which was done in the ordinary course of its business.

COUNT X

WRONGFUL DEATH

135. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

136. Defendant, as previously described herein, failed to exercise reasonable care in the design, dosing information, marketing, warnings, labeling, and/or manufacturing of Pradaxa®, failed to adequately test Pradaxa®, and fraudulently concealed and intentional omitted material information in the sale and marketing of the product when it knew or should have known of the serious health risks it created.

137. As a direct and proximate cause of Defendant's conduct, Plaintiffs' decedent sustained injuries of a personal, permanent, and pecuniary nature, and died on September 21, 2012.

138. Had the Plaintiffs' decedent survived the serious injuries and internal bleeding resulting from his Pradaxa® usage, Decedent would be entitled to recover damages for such injuries from the Defendant for the reasons described herein.

139. As a direct and proximate result of Decedent's death, Decedent's family members, including Plaintiffs, Adalaine Nancy Kohn, individually and as legal guardian for Jon Kohn, Michael Kohn, individually, and Susan Kohn, individually have suffered damages and harm, including but not limited to, emotional distress, and have incurred other medical expenses and economic harm, as well as loss of consortium, services, society, companionship, love, and comfort, and will continue to suffer such harm in the future.

COUNT XI

PUNITIVE DAMAGES

140. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

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

142. Despite its knowledge, the Defendant continued to aggressively market Pradaxa® to consumers, including Plaintiffs' decedent, without disclosing its dangerous side

effects when there existed safer alternative products.

143. Despite Defendant's knowledge of Pradaxa®'s defective and unreasonably dangerous nature, Defendant 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 Plaintiffs' decedent, in conscious disregard of the foreseeable harm caused by Pradaxa®.

144. Defendant's conduct was intentional and/or wanton.

145. Defendant's conduct as described above, including, but not limited to, its failure to adequately test its product, to provide adequate warnings, and their continued manufacture, sale, and marketing or its 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 Plaintiffs' and Decedent

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

I. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Wrongful death;
5. Burial and funeral expenses;
6. Loss of companionship and society;
7. Loss of consortium;
8. Punitive damages alleged against Defendant, including Plaintiffs' attorneys fees, in excess of $75,000.00;
9. Prejudgment interest at the highest lawful rate allowed by law;
10. Interest on the judgment at the highest legal rate from the date of judgment

until collected;

11. Attorneys' fees, expenses, and costs of this action; and

12. 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 23th day of January 2013.

RESPECTFULLY SUBMITTED,

By: /s/ Ellen A. Presby
Ellen A Presby, #16249600
NEMEROFF LAW FIRM
2626 Cole Ave. Suite 450
Dallas, TX 75204
Telephone: 214-774-2258
Facsimile: 214-393-7897
ellenpresby@nemerofflaw.com
ATTORNEY FOR PLAINTIFFS

JS 44 (Rev. 09/11)

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
Adalaine Nancy Kohn, Susan Kohn, Michael Kohn and Jon Kohn

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Ellen A. Presby
Nemeroff Law Firm
2626 Cole Ave., Suite 450, Dallas, TX 75204, (214) 774-2258

DEFENDANTS
Boehringer Ingelheim Pharmaceuticals, Inc.

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

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

Attorneys *(If Known)*
Keishunna Randall Butler
Snow, O'Mara, Stevens & Cannada, PLLC
Post Office Box 6010 Ridgeland, MS 39158-6010

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) (For Diversity Cases Only) and One Box for Defendant)*

	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 (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

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 - Med. 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

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

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
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 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/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 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; CMO 7, in re Pradaxa (Dabigatran Etexilate) Product Liability Litigation, MDL No. 23

Brief description of cause:
product liability involving Pradaxa

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $ 75,000.00

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

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE David R. Herndon DOCKET NUMBER MDL 2385

DATE 01/23/2013

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE