IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

MARK A. JACKSON, on behalf of himself and those similarly situated, Plaintiff,	§	
vs.	§	Case No. _____
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BIDACHEM S.P.A.	§	JURY TRIAL DEMANDED
Defendants.	§	

PLAINTIFF'S ORIGINAL CLASS ACTION COMPLAINT FOR DAMAGES

Plaintiff, Mark A. Jackson, on behalf of himself and those similarly situated, by and through his attorney, brings this action for personal injuries suffered as a result of Plaintiff ingesting the defective and unreasonably dangerous drug Pradaxa™ (dabigatran etexilate), a prescription medication used as a blood thinner, which at all times relevant hereto, was manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed, and sold by Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Bidachem S.p.A. (Collectively, "Boehringer Ingelheim" or "Defendants").

Plaintiff alleges as follows:

PARTIES

1. Plaintiff Mark A. Jackson (hereinafter referred to as "Plaintiff"), is a natural person. At

all times relevant hereto, Plaintiff was a resident and citizen of Gretna, Jefferson Parish, Louisiana.

2. Boehringer Ingelheim Pharmaceuticals, Inc ("Boehringer US") is a Delaware corporation, which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer US may be served at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer US has conducted business and derived substantial revenue from within the State of Louisiana.

3. Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer Pharma") is a foreign corporation with its principal place of business located at Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Boehringer International has transacted and conducted business within the State of Louisiana. Boehringer Pharma has derived substantial revenue from goods and products disseminated and used in the State of Louisiana, and Boehringer Pharma expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from commerce within the State of Louisiana.

4. Boehringer Ingelheim International GmbH & Co. KG ("Boehringer International") is a foreign corporation with its principal place of business located at Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Boehringer International has transacted and conducted business within the state of Louisiana. Boehringer International has derived substantial revenue from goods and products disseminated and used in the State of Louisiana, and Boehringer International expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from

commerce within the State of Louisiana.

5. Bidachem S.p.A. ("Bidachem") is a foreign corporation with its principal place of business located at Bidachem S.p.A., Strada Statale 11, (Padana Sup.) N.8 24040 Fornovo S. Giovanni, Bergamo, Italy. Bidachem has transacted and conducted business within the state of Louisiana. Bidachem has derived substantial revenue from goods and products disseminated and used in the State of Louisiana, and Bidachem expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from commerce within the State of Louisiana.

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 Plaintiff 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. This Court has jurisdiction over the non-resident Defendants because they have done business in the State of Louisiana, have committed a tort in whole or in part in the State of Louisiana, and have continuing contacts with the State of Louisiana.

8. Venue of this case is proper in the Eastern District of Louisiana pursuant to 28 U.S.C. §1391(b)(1) because Plaintiff is a resident of this state.

9. Venue is further proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Eastern District of Louisiana.

STATEMENT OF FACTS

10. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa™ as a blood-thinning medicine primarily used to reduce the risk of stroke and blood clots in people with atrial fibrillation not caused by a heart valve problem.

11. Pradaxa™ was launched by Defendants in North America in 2010.

12.Pradaxa™ was approved by the Food and Drug Administration ("FDA") in October of 2010 for prevention of stroke in patients with non-valvular atrial fibrillation. Pradaxa™ is the first new treatment alternative to warfarin (Coumadin) in nearly 60 years.

13. According to Defendants' marketing and informational materials, referenced in the paragraphs below, and widely disseminated to the consuming public, atrial fibrillation ("AF") is the most common sustained heart rhythm condition in the world, with one in four adults over the age of 40 developing the condition in their lifetime.[1]

14. As the Defendants state on their website, "[AF] is a type of irregular heartbeat. It occurs when one or both of the upper chambers of the heart–called the atria–beat erratically. This puts them out of sync with the heart's 2 lower chambers–called the ventricles."[2] Because the atria are primer pumps for the two large ventricles, AF normally causes only a modest reduction in

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[1] http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2011/04_aug_2011_dabigatran.html

[2] http://www.pradaxa.com/understanding-afib.jsp

cardiac output. But in the "dead zone" of the malfunctioning atria, blood clots may form and then travel to the lungs or brain, where irreversible and potentially life-threatening damage may occur.[3]

15. The Defendants claim that approximately one percent of the total populations I affected by AF worldwide, or approximately 70+ million people in the world, and more than 2 million people in the United States alone have AF. AF is a disease that typically has an impact on aging populations, and indeed, its prevalence increases with age.

16. While some cases of AF have no apparent or known cause, various conditions and/or lifestyle factors are believed to trigger or increase the odds of devloping AF. For example, the following are believed to trigger AF in adults: high blood pressure; being obese or overweight; diabetes; having an overactive thyroid gland; lung cancer; and drinking too much alcohol or binge drinking.

17. Defendants posit that AF is not a directly life-threatening condition, but in their marketing materials, Defendants state that AF can have serious and even deadly consequences for patients.

18. Defendants further declare that patients with AF are more likely to experience the development of a blood clot in their heart, especially if their condition is left untreated. If such a clot were to form, the blood clot could break loose, and after breaking loose, the clot can be washed into the brain, where it can block an artery and cause a stroke. Defendants state that patients with AF thus "have a five-fold increased risk of stroke when compared to people without atrial fibrillation. Up to three million people worldwide suffer strokes related to AF each year.

[3]Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

Strokes due to AF tend to be severe, with an increased likelihood of death and disability."[4]

19. Defendants claim their medication, Pradaxa™, is the answer to the worldwide problem of strokes and blood clots in those with AF. They claim, "Many AF-related strokes can be prevented with appropriate medicinal therapy. For this, substances are used which act on the blood clotting system and shall prevent blood clots from forming.[5]

20. Historically, conditions such as AF have been treated with the prescription drug warfarin, which is a form of rat poison. Warfarin blocks the formation of the tiny fibrin threads that help hold together the platelets that collect in a person's blood to form a blood clot. Like all blood thinners, warfarin can cause bleeds. Warfarin has two other noteworthy limitations: (1) it requires blood tests every 1 to 4 weeks to establish the optimal level of anticoagulation, and (2) it interacts (negatively) with scores of other drugs, including drugs frequently used in heart patients. In spite of these apparent limitations, however, warfarin also has an important benefit; if an overdose or unexpected bleed occurs, an antidote (e.g., vitamin K) is readily available and highly effective. [6]

21. Pradaxa™ is administerred as an oral anticoagulant and is from the class of the direct thrombin inhibitors ("DTI").

22. According to the Defendants' website, Pradaxa™ is "at the forefront of a new generation of oral blood thinning treatments, which prevent blood clots from forming in the body

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[4]Http://www.boehringer-ingelheim.com/products/prescription_medicines/stroke_prevention.html

[5]Id.

[6]Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

that can lead to devastating strokes in patients with atrial fibrillation. Potent antithrombotic effects are achieved with DTIs by specifically blocking the activity of thrombin (both free and clot-bound), the central enzyme in the process responsible for thrombus formation."[7]

23. According to Defendants testing and marketing materials, which extol the supposed benefits and virtues of Pradaxa™ , Pradaxa™ had fewer drug interactions than warfarin, and the frequent laboratory tests needed to manage warfarin blood levels were not recommended for patients taking Pradaxa™. Moreover, unlike warfarin, which is adjusted for individual patient blood levels on an ongoing basis, Pradaxa™ was approved in an allegedly easy "one size fits all" dose of 150 mg twice a day. This "one size fits all" characteristic of the drug, while simple for physicians to follow, means that a lower (or personalized) dose is unavailable and patients ingesting Pradaxa™ are not routinely monitored to see if they are getting too much of the drug's active ingredient, as are patients on other blood thinning medications like warfarin.

24. Moreover, the "RE-LY Clinical Trial" (Randomized Evaluation of Long-term anticoagulant therapy) sponsored by Defendants concluded that vitamin K antagonists such as warfarin are cumbersome to use because of their multiple interactions with food and drugs and because these drugs require frequent laboratory monitoring.

25. The RE-LY Clinical Trial went on to suggest that there is a need for new anticoagulant agents that are affective, safe and convenient to use (i.e., Defendants' product, Pradaxa™). The Defendants' marketing materials suggest that Pradaxa™ represented a therapeutic simplification and therapeutic progress because it does not require patients to

[7] http://www.boehringer-ingelheim.com/products/prescription_medicines/stroke_prevention.html

undergo periodic monitoring with blood tests. A fundamental tenet of the RE-LY Clinical Trial was a claim by Defendants that Pradaxa™ was apparently safe to use as compared to warfarin. As the Defendants highlight on their website in claim Pradaxa generally has similar, but lower overall total bleeds vs. warfarin[8]:

26. What the RE-LY Clinical Trial seemed to prove was quite simple: With Pradaxa™ there is (1) a higher rate of major GI bleeds (1.6% vs 1.1%) as compared to warfarin; and (2) a similar rate of major bleeds (3.3% vs 3.6%) as compared to warfarin. Additionally, Pradaxa™ appears to be particularly dangerous when used in older patients, as the label states: "The risk of major bleeds was similar with PRADAXA 150 mg and warfarin across major subgroups defined by baseline characteristics, with the exception of age, where there was a trend towards a higher incidence of major bleeding on PRADAXA (HR 1.2, 95% CI: 1.0 to 1.4) for patients >75 years of age."[9]

27. In essence, the Defendants have created a new drugs, Pradaxa™, that is no better than warfarin from a safety perspective, and at best, perhaps slightly easier to use and administer. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing by the Defendants, but it ignores patient safety.

28. On February 14, 2011, the American College of Cardiology Foundation and American Heart Association added Pradaxa™ to their guidelines for management of non-valvular atrial fibrillation with a "Class I" recommendation. The endorsement, along with heavy marketing

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[8] http://www.prdaxapro.com/safety.jsp

[9] http://www.accessdata.fda.gov/drugsatfda_docs/lable/2012/022512s009lbl.pdf

from the Defenants, caused sales of Pradaxa to skyrocket. By the end of the first quarter of 2011, IMS Health's National Prescription Audit data showed 272,119 dispensed outpatient prescriptions. But, as prescriptions mounted, reports of serious adverse drug events also surged.[10]

29. As a result of the defective nature of Pradaxa™ , persons who were prescribed and ingested Pradaxa™ for even a brief period of time, including Plaintiff herein, were at increased risk for developing life-threatening bleeds. Due to the flawed formulation of Pradaxa™ (and unlike any of the traditional blood thinners on the market, Pradaxa™ has a questionable "one size fits all" dose), its levels in the blood are difficult or impossible to assess and bleeds cannot be stopped since there is no known reversal antidote for this dangerous drug.

30. In November 2011, Defendants confirmed at least 260 fatal bleeding events were reported in patients taking Pradaxa™ worldwide between March 2008 and October 2011. The actual number of Pradaxa™ related deaths remain unknown at this time. Moreover, The Institute for Safe Medication Practices, reported that:

> In the first quarter of 2011 [Pradaxa™] produced two different kinds of signals of major drug risk: a large volume of total serious reports, and large numbers of reports for a specific adverse event, hemorrhage. Overall [the study] identified 932 serious adverse drug events of all types in which [Pradaxa™] was the primary suspect drug, including 120 patient deaths, 25 cases of permanent disability, and 543 cases requiring hospitalization. For the quarter, this was a higher total than for any drug ["The Institute for Safe Medication Practices] monitor[s] with one exception. In the Standardized

[10]Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

> MedDRA Query ("SMQ") for Hemorrhage, [Pradaxa™] accounted for 505 cases, more than any other drug. (Warfarin ranked second with 176 cases.) The 932 overall [Pradaxa™] cases in the first quarter [of 2011] included 293 cases that were also classified in the narrower gastrointestinal hemorrhage SMQ, more than any other regularly monitored drug. An additional 120 cases contained event terms in the Hemorrhagic stroke SMQ. The strokes are of particular concern because if treatment intended to prevent ischemic strokes than causes hemorrhagic strokes the risk/benefit balance is called into fundamental question. In 65 hemorrhage cases overall, the patients died.[11]

In other words, the deadly consequences of Pradaxa™ use did not go unnoticed.

31. On December 7, 2011, the FDA initiated an investigation into the serious bleeding events associated with Pradaxa™ stating the "FDA is working to determine whether the reports of bleeding in patients taking Pradaxa are occurring more commonly than would be expected, based on observations in the large clinical trial that supported the approval of Pradaxa [RE-LY trial]."

32. Defendants concealed their knowledge that Pradaxa™ can cause life threatening, irreversible bleeds from Plaintiff, other consumers, the general public, and the medical community. Indeed, the Defendants did not warn of the irreversible nature of Pradaxa™ in the "Warnings and Precautions" section of the products initial warning label. The only warnings provided by Defendants were as follows:

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[11]Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

WARNINGS AND PRECAUTIONS

- Risk of bleeding: PRADAXA can cause serious and, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1)
- Temporary discontinuation: Avoid lapses in therapy to minimize risk of stroke (5.2)
- P-gp inducers and inhibitors: Avoid coadministration of rifampin with PRADAXA because of effects on dabigatran exposure.

33. Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of uncontrollable bleeds associated with Pradaxa™ usage, nor did Defendants warn or otherwise advise on how to intervene and stabilize a patient should a bleed occur. Even in the expanded "Warnings and Precautions" section of the initial label only the following meager and unacceptably inadequate information was given:

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Bleeding

PRADAXA increases the risk of bleeding and can cause significant, and, sometimes, fatal bleeding. Risk factors for bleeding include the use of drugs that incase the risk of bleeding in general (e.g., anti-platelet agents, heparin, fibroinolytic therapy, and chronic use of NSAIDs) and labor and delivery. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding.

In the REL-LY (randomized Evaluation of Long-term Anticoagulant Therapy) study, a life-threatening bleed (bleeding that met one or more of the following criteria: fatal, symptomatic intacranial, reduction in hemoglobin of at least 5 grams per deciliter, transfusion of at least 4 units of blood, associated with hypotension requiring the use of intravenous inotropic agents, or necessitating surgical intervention) occurred at an annualized rate of 1.5% and 1.8% for PRADAXA 150 mg and warfarin, respectively [*see adverse reactions (6.1)]*.

34. In fact, the only section of Defendants original label that references the fact that Pradaxa™ has no known "reversal agent" is buried in section 10 o the "Full Prescribing Information" section of the Pradaxa™ label, which discusses "Overdosage" on the medication. The language in section 10 is effectively no warning at all as the "warning" is both inadequate and misplaced, as shown below:

10 OVERDOSAGE

Accidental overdose may lead to hemorrhagic complications. There is no reversal agent for dabigatran. In the event of hemorrhagic complications, initiate appropriate clinical support, discontinue treatment of PRADAXA, and investigate the source of bleeding. Dabigatran is primarily excreted in the urine and shows low plasma protein binding. Therefore, dabigatran can be dialyzed with the removal of about 60% of drug use over 2 to 3 hours; however, data supporting this approach are limited. Measurement of a PTT or ECT may help guide therapy *[see Warnings and Precautions (5.1) and Clinical Pharmacology (12.2)]*.

35. Finally, in January of 2012, after thousands of Pradaxa™ users had been killed or injured as a result of their ingestion of Pradaxa™, the Defendants belatedly initiated an extremely modest, and wholly inadequate, label change.

36. Importantly, Pradaxa™ still does not have a "black box" warning letting patients or their prescribing doctors know that Pradaxa™ can cause sudden and irreversible bleeds. Indeed, the relevant part of the "Warnings and Precautions" section itself remains unchanged (with no reference to the irreversible nature of Pradaxa™ bleeds) on the current Pradaxa™ label as shown below:

WARNINGS AND PRECAUTIONS

- Risk of bleeding: PRADAXA can cause serious and, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1)
- Temporary discontinuation: Avoid lapses in therapy to minimize risk of stroke (5.2)
- P-gp inducers and inhibitors: Effects on dabigatran exposure.

37. The only labeling modification Defendants' made in January 2012 regarding the irreversible nature of Pradaxa™ bleeds was made in the "Warnings and Precautions" part of the "Full Prescribing Information"section of the Pradaxa™ label, buried in small print on the fifth and sixth pages of the label. It reads:

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Bleeding

PRADAXA increases the risk of bleeding and can cause significant, and, sometimes, fatal

bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding [*see dosage and Administration 2.2]*

Risk factors for bleeding include the use of drugs that incase the risk of bleeding in general (e.g., anti-platelet agents, heparin, fibroinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment [*see Clinical Pharmacology 12.2)]*

A specific reversal agent for dabigatran is not available. Dabigatran can be dialyzed (protein binding is low, with the removal of about 60% of drug over 2-3 hours); however the amount of data supporting this approach is limited. Activated prothrombin complex concentrates (aPCCs, e.g., FEIBA), or recombinant Factor Villa, or concentrates of coagulation factors II, IX or X may be considered but their use has not been evaluated in clinical trials. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of dabigatran. Consider administration of platelet concentrates in cases where thrombocytopenia is present or long-acting antiplatelet drugs have been used.

38. The current warning is simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including the Plaintiffs herein.

39. Even if the warnings were sufficient, which Plaintiffs strongly deny, Pradaxa™ still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug.

Pradaxa™ is quite simply dangerous and defective as formulated. The Defendants should withdraw Pradaxa™ from the market.

40. Indeed, a FDA analysis showed that with Pradaxa™ treatment, life-threatening bleeds (a drug adverse effect) occurred at a higher rate than the strokes or systemic embolisms Pradaxa™ is intended to prevent (1.5% per year versus 1.1% a year), suggesting that Pradaxa™ created an extreme risk for patients and provides no benefit whatsoever.[12] Pradaxa™, under the guise of providing a safe defense against strokes and/or embolisms in AF patients, subjects unsuspecting patients to new dangers of death and injury.

41. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of irreversible bleeds in users of Pradaxa™ to prevent any chance of their product's registrations being delayed or rejected by FDA.

42. As the manufacturers and distributors of Pradaxa™, Defendants knew or should have known that Pradaxa™ use was associated with irreversible bleeds.

43. With the knowledge of the true relationship between use of Pradaxa™ and irreversible bleeds, rather than taking steps to pull the drug off the market, provide strong warnings, or create an antidote, Defendants promoted and continue to promote Pradaxa™ as a safe and effective treatment for AF and alternative to warfarin.

44. Pradaxa™ is expected to be one of Defendants' top selling drugs. Upon information and belief, Defendants "expect[s] sales of blood thinner Pradaxa to reach 450 million euros

[12] Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

($603 million) this year."[13]

45. While Defendants enjoy great financial success from their expected blockbuster drug, Pradaxa™, they continue to place American citizens at risk of severe bleeds and death.

46. Consumers, including Plaintiffs, who have used Pradaxa™ for treatment of AF and blood thinning, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits, associated with Pradaxa™ therapy.

47. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Pradaxa™ use.

48. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiffs would be exposed to the risks identified in the Complaint. The increased risks and subsequent medical damages associated with Plaintiff's Pradaxa™ use were the direct and proximate result of Defendants' conduct.

49. In or around 2010, Plaintiff was first prescribed and began taking Pradaxa™ upon direction of Plaintiff's physician as a blood thinner. Subsequently, as a direct result of Plaintiff's ingestion of Pradaxa™, Plaintiff had and was treated for a serious bleeding event in or around February 2012.

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[13]http://www.bloomberg.com/news/2011-11-28/boehringer-expects-2011-pradaxa-sales-of-603-million-dpa-says.html

50. As a direct result of being prescribed Pradaxa™, Plaintiff has suffered severe and life altering injuries.

51. Plaintiff, as a direct and proximate result of Pradaxa™ use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses.

52. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described herein above due to Plaintiff's ingestion of Pradaxa™. Plaintiff accordingly seeks damages associated with these injuries.

53. Plaintiff would not have used Pradaxa™ had Defendants properly disclosed the risks associated with its use.

CLAIMS FOR RELIEF

COUNT I: STRICT LIABILITY – FAILURE TO WARN: LA. R.S. 9:2800.57

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

55. Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and are now, engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Pradaxa™ at issue in this lawsuit. The Pradaxa™ was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

56. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that

warnings and other clinically relevant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with the use of Pradaxa™ were inadequate.

57. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

58. Defendants had a continuing duty to provide consumers, including Plaintiff, and Plaintiff's physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with Pradaxa™, as it became or should have become available to Defendants.

59. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription rug, Pradaxa™, to health care providers empowered to prescribe and dispense Pradaxa™ to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Pradaxa™, which resulted in injury to Plaintiff.

60. Despite the fact that Defendants knew or should have known that Pradaxa™ caused unreasonable and dangerous side effects, they continued to promote and market Pradaxa™ without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

61. Defendants knew or should have known that Pradaxa™ caused unreasonable and dangerous side effects, they continued to promote and market Pradaxa™ without stating that

there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

62. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the following ways:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Pradaxa™ including, among other things, irreversible bleeds;

b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, irreversible bleeds;

c. Defendants continued to aggressively promote and sell Pradaxa™, even after they knew or should have known of the unreasonable risks of irreversible bleeds from this drug.

63. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Pradaxa™, and/or that there existed safer and more or equally effective alternative drug products.

64. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Pradaxa™, and/or that there existed safer and more or equally alternative drug

products, Defendants breached their duty of reasonable care and safety.

65. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

66. Defendants' actions described above violated the federal and state Food, Drug and Cosmetic Acts and rendered Pradaxa™ misbranded.

67. 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 the injuries and damages set forth herein above.

COUNT II: STRICT LIABILITY – DESIGN DEFECT, MARKETING DEFECT, CONSTRUCTION OR COMPOSITION DEFECT & MANUFACTURING DEFECT: LA. R.S. 9:2800.55 AND 9:2800.56

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

69. Pradaxa™ was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Pradaxa™ could cause injuries such as those suffered by Plaintiff during foreseeable use. This facts was known to Defendants at the time Pradaxa™ was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including Plaintiff. Nonetheless, Defendants failed to warn that Pradaxa™ was designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Such a failure to warn rendered the Pradaxa™ unreasonably dangerously defective as designed and marketed.

70. At all times material to these allegations, Defendants manufactured, distributed, tested, packaged, promoted, marketed, labeled, designed, and sold Pradaxa™, as alleged herein.

71. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field.

72. The Pradaxa™ administered to Plaintiff was defective in design and 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.

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

74. The Pradaxa™ administered to Plaintiff was expected to reach user without substantial change in the condition in which it was sold.

75. The Pradaxa™ administered to Plaintiff reached Plaintiff without substantial change in the condition to which it was sold.

76. There were safer alternative methods and designs for Defendants' Pradaxa™.

77. Plaintiff was a patient who the Defendants reasonably expected would be administered Pradaxa™.

78. Defendants were at liberty to withdraw Pradaxa™ from the market at any time, but failed to do so.

79. 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, including punitive damages.

80. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Pradaxa™, Plaintiff was injured as described herein. All of said injuries caused and/or continue to cause Plaintiff's damages, for which Plaintiff is entitled to damages.

81. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Pradaxa™, Plaintiff was required to obtain reasonable and necessary health care treatment and services and incurred expenses for which Plaintiffs are entitled to damages.

82. As a direct and proximate result of the design, marketing and manufacturing defects of Defendants' product, Pradaxa™, Plaintiff suffered serious and permanent injury, and the

harms as previously alleged herein.

COUNT III: NEGLIGENCE

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

84. 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, marketing and distribution of their prescription medications, including the Pradaxa™ at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Pradaxa™ because as designed, it was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Defendants 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.

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

a. Failing to use due care in developing, testing, designing, and manufacturing Pradaxa™ so as to avoid the aforementioned risks to individuals when Pradaxa™ was being used for treatment;

b. Failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Pradaxa™ and the comparative severity and duration of such adverse effects;

c. 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;

d. Failing to accompany their products with proper or adequate rate of incidence or prevalence of irreversible bleeds;

e. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

f. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa™;

g. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

h. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Pradaxa™ and patients taking Pradaxa™;

i. Failing to adequately test and/or warn about the use of Pradaxa™, including, without limitations, the possible adverse side effects and health risks caused by the use of Pradaxa™;

j. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent or antidote;

k. 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;

l. Failing to remove Pradaxa™ from the market when Defendants' knew or should have known of the likelihood of serious side effects and injury to its users;

m. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of bleeds and related dangerous conditions to individuals taking Pradaxa™; and

n. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

86. The Pradaxa™ that injured Plaintiff was in substantially the same condition when Plaintiff ingested it as it was when it left the control of Defendants. Pradaxa's™ ability to cause serious personal injury and damages such as those suffered by plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff consumed the Pradaxa™ as directed and without change in its form or substance.

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

88. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

COUNT IV: NEGLIGENCE PER SE

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

90. As part of their duty to exercise reasonable care, Defendants were obliged to follow public laws and regulations enacted and promulgated to protect the safety of persons such as the Plaintiff, including 21 U.S.C. §§ 331(a) & 352, and other statues and regulations, which make it unlawful to misbrand prescription drug products.

91. The labeling, including package inserts, for Pradaxa™ failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (f), 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, or cosmetic that is adulterated or misbranded."

92. 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™.

93. 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.

94. 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.

95. 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.

96. 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.

97. 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.

98. 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™.

99. 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.

100. 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.

101. 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., reversible bleeding).

102. 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.

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

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

105. 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 drugs experience.

106. 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.

107. 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 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 15-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.

108. 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.

109. 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 Plaintiffs, and further, because each of them violated the above-referenced duties required by these statues and regulations, they are guilty of negligence per se.

110. Defendants' 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 V: BREACH OF WARRANTY – MERCHANTABILITY

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

112. 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 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™.

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

COUNT VI: BREACH OF WARRANTY – FITNESS FOR A PARTICULAR PURPOSE

114. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

115. 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 judgement 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™.

116. 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 VII: BREACH OF WARRANTY

BREACH OF EXPRESS WARRANTY: LA R.S. 9:2800.58

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

118. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Pradaxa™, in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

119. Pradaxa™ materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of Pradaxa™, respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and ingested in direct or indirect reliance upon these express representations. Such failure by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Pradaxa™ sold to Plaintiff.

120. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Pradaxa™. Plaintiff purchased and ingested Pradaxa™ as prescribed and instructed by Plaintiff's physician leading to Plaintiff's injuries.

COUNT VIII: BREACH OF WARRANTY - BREACH OF IMPLIED WARRANTY

121. Plaintiff incorporates by reference each preceding paragraph as through set forth fully at length herein.

122. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Pradaxa™, in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

123. Defendants impliedly warranted their Pradaxa™ product, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

124. Defendants breached their implied warranties of the Pradaxa™ product sold to Plaintiff because this product was not fit for its common, ordinary and intended use.

125. As a direct, foreseeable and proximate result of the Defendants' breaches of implied warranties, Plaintiff suffered grievous bodily injury and consequential economic and other losses, as described above, when Plaintiff ingested Pradaxa™, in reasonable reliance upon the implied warranties.

COUNT IX: REDHIBITION

126. Plaintiff repeats and incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

127. The subject product contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

128. Defendants sold and promoted Pradaxa™, which defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product sold and promoted by Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had they known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the subject product.

129. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product

so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction of the purchase price.

130. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, under Louisiana law, Defendants are deemed to know that Pradaxa™ possessed a redhibitory defect. La. C.C. art. 2545.

COUNT X: BREACH OF WARRANTY – FITNESS FOR ORDINARY USE

131. Plaintiff repeats and incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

132. In addition to warranting against redhibitory defects, Defendants warrant that the subject product is reasonably fit for its ordinary and intended use. La. C.C. art. 2524.

133. The subject product is not safe, has numerous and serious side effects and causes severe and deadly injuries including, but not limited to, developing irreversible bleeds and other serious injuries and side effects. As a result, Pradaxa™ is unfit and inherently dangerous for ordinary use.

134. As a direct and proximate result of Defendants' actions, Plaintiff has sustained serious, significant and permanent injuries. In addition, Plaintiff required and/or will continue to require healthcare and services as a result of Plaintiff's injury. Plaintiff has incurred and/or will continue to incur medical and related expenses as a result of Plaintiff's injury. Plaintiff also has suffered and/or will continue to suffer diminished capacity for the enjoyment of life, a

diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain.

COUNT XI: MISREPRESENTATION, SUPPRESSION OF EVIDENCE AND FRAUD

135. Plaintiff repeats and incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

136. Defendants committed actual fraud by making material representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Plaintiff rely on such material representations; Plaintiff acted in actual and justifiable reliance on such material misrepresentations and was injured as a result.

137. In addition, and in the alternative if necessary, Defendants knowingly omitted and downplayed material information, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff rely on Defendants' misrepresentations; Plaintiff acted in actual and justifiable reliance on Defendants' representations and was injured as a result.

138. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Pradaxa™ at issue in this lawsuit, said breach or breaches constituting fraud because of their prosperity to deceive others or constitute an injury to public interests or public policy.

139. Defendants misrepresented to the FDA, Plaintiff, and the health care industry the safety and effectiveness of Pradaxa™ and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Pradaxa™.

140. 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 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 antidote and/or reversal agents;

d. Pradaxa™ bleeds cannot be stopped or controlled by any effective medical processes or medical intervention; and

e. Pradaxa™ was not as safe as blood thinners such as warfarin.

141. The misrepresentations of and/or active concealments alleged were perpetuated directly and/or indirectly by Defendants. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that 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 had no knowledge of the information concealed and/or suppressed by Defendants, and they 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.

142. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing and treating physicians, and the public about the potential risks and complications associated with Pradaxa™ in a timely manner. The misrepresentations and active fraudulent concealment by the Defendants constitute a continuing tort against Plaintiff, who purchased and/or ingested Pradaxa™. Defendants made the misrepresentations and actively concealed information about the defects and dangers of Pradaxa™ with the intention and specific desire that Plaintiff and the consuming public would rely on such or the absence of information in selecting Pradaxa™ as treatment.

143. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiff suffered the injuries and damages discussed herein.

COUNT XII: DECEPTIVE TRADE PRACTICES

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

145. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Pradaxa™, in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

146. Plaintiff purchased and used Pradaxa™ for personal use and thereby suffered

ascertainable losses as a result of Defendants' actions in violation of consumer protection laws, which include the following violations:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Representing that good have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which they do not have;

d. Failing to disclose information concerning goods which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed;

e. Unconscionable actions and courses of action; and

f. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

147. Defendants uniformly communicated the purported benefits of Pradaxa™ while failing to disclose the serious and dangerous side-effects related to Pradaxa™ and of the true state of Pradaxa™, the regulatory status, its safety, its efficacy and its true usefulness. Defendants made these representations to physicians, the medical community at large and to patients and consumers, such as Plaintiff, in their marketing and advertising.

148. Defendants' conduct in connection with Pradaxa™ was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding because Defendants

misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding the utility, benefits, costs, safety, efficacy and advantages of Pradaxa™.

149. As a direct, proximate and foreseeable result of Defendants' statutory violations, Plaintiff suffered the injuries and consequential economic and other losses, as described above, when Plaintiff ingested Pradaxa™.

COUNT XIII - GROSS NEGLIGENCE

150. Plaintiff restates each and every preceding allegation of the Complaint and incorporates each by reference as though set forth fully.

151. Plaintiff would further show that the negligent acts and/or omissions of Defendants, as set forth above, constitute an entire want of care so as to indicate that the acts and/or omissions in question were th result of conscious indifference and/or malice as to give rise to the award of exemplary damages.

152. Plaintiff would further show that the negligent acts and/or omissions of Defendants, as set forth above, constitute an act or omission,

a. which, when viewed objectively from the standpoint of Defendants, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiff, and

b. of which Defendants had actual, subjective awareness of the risks involved, but nevertheless proceeded with conscious indifference to the rights, safety or welfare of Plaintiff.

153. The gross negligence of the Defendants was a proximate cause of the injuries and damages suffered by Plaintiff.

CLASS ACTION

154. This action is appropriate for determination through the Class Action Procedure for the following reasons:

A. The large number of potential claimants present a level of numerosity better handled through the class action procedure as opposed to a mass joinder of individual claims;

B. The common issues of law and fact pertaining to the determination of fault and the liability for compensatory and exemplary damages predominate over the individual issues of quantum, and such issues are typical of similar claims;

C. The determination of fault and the basis for assessment of compensatory and exemplary damages may be made in the class action without the necessity of proof at that time as to the amount of those damages, thereby establishing guidelines for settlement and/or subsequent trials in individual cases if necessary;

D. Petitioners herein have sustained damages of the nature described hereinabove and are suitable representatives of the class;

E. The Plaintiffs herein are represented by skilled attorneys who are experienced in handling mass torts and class actions, and who can be expected to handle this matter in an expeditious and economical matter to the best interests of the class membership;

F. The class action procedure is the superior vehicle for the efficient disposition of the issues and claims herein presented.

WHEREFORE, Plaintiff prays:

1. That Defendant be required to answer this class action complaint after all legal delays have run, all in accordance with law.

2. That after due proceedings had, that this action be certified as a class action, as alleged above, for the purpose of determining the common issues of liability for appropriate damages.

3. That upon certification of the class action, the Court call for the formulation of a suitable management plan.

4. That after due proceedings had, and a trial by jury, there be judgment herein in favor of Plaintiff and against defendant, for all damages which are reasonable in the premises, together with legal interest thereon from the date of judicial demand until paid, and for all costs of these proceedings.

5. That the rights of the Plaintiff and the members of the class to establish their entitlement to compensatory damages, and the amounts thereof, be reserved for determination in their individual actions when appropriate.

6. That Plaintiff recovers his costs for the prosecution of this class action.

7. That a medical monitoring class be certified, and the Court aware appropriate damages sufficient to establish a medical monitoring program as deemed effective by Plaintiff's medical experts.

8. That the Court render judgment in favor of Plaintiff's class awarding all damages as prayed for herein, including attorneys' fees, with all costs assessed against Defendants.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues.

Date: May 31, 2012

Respectfully submitted:

Michael Hingle & Associates, LLC

By: /s/ Michael Hingle
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Attorneys for Plaintiffs

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Mark A. Jackson

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

(c) Attorney's (Firm Name, Address, and Telephone Number)
Michael Hingle & Associates, LLC
220 Gause Blvd., Slidell, LA 70458
(985) 641-6800

DEFENDANTS

Boehringer Ingelheim Pharmaceuticals, Inc., et al.

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

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

Attorneys (If Known)

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

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

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

(For Diversity Cases Only)

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

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

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

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

TORTS

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

PERSONAL INJURY
- ❒ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

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

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

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition

FORFEITURE/PENALTY
- ❒ 610 Agriculture
- ❒ 620 Other Food & Drug
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 630 Liquor Laws
- ❒ 640 R.R. & Truck
- ❒ 650 Airline Regs.
- ❒ 660 Occupational Safety/Health
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 730 Labor/Mgmt.Reporting & Disclosure Act
- ❒ 740 Railway Labor Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus - Alien Detainee
- ❒ 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
- ❒ 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
- ❒ 810 Selective Service
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 875 Customer Challenge 12 USC 3410
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 892 Economic Stabilization Act
- ❒ 893 Environmental Matters
- ❒ 894 Energy Allocation Act
- ❒ 895 Freedom of Information Act
- ❒ 900Appeal of Fee Determination Under Equal Access to Justice
- ❒ 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 ❒ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

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

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ >$75,000

CHECK YES only if demanded in complaint:

JURY DEMAND: ☑ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
05/31/2012

SIGNATURE OF ATTORNEY OF RECORD
/s/ Michael Hingle

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Mark A. Jackson, et al.

Plaintiff

v.

Boehringer Ingelheim Pharmaceuticals, Inc.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Michael Hingle
Michael Hingle & Associates, LLC
220 Gause Boulevard
Slidell, Louisiana 70458

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: