

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

THELMA HAWTHORNE	§	
Plaintiff	§	
	§	
vs.	§	Cause No. _____
	§	
BOEHRINGER INGELHEIM	§	
PHARMACEUTICALS, INC.,	§	
BOEHRINGER INGELHEIM PHARMA	§	
GMBH & CO. KG, BOEHRINGER	§	JURY TRIAL DEMANDED
INGELHEIM INTERNATIONAL	§	
GMBH, BIDACHEM S.P.A.	§	
Defendants	§	

PLAINTIFF’S ORIGINAL COMPLAINT

Comes now Plaintiff, by and through his undersigned attorney, and files this Complaint against 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”) for selling, distributing, and manufacturing the defective and unreasonably dangerous drug Pradaxa™ (dabigatran etexilate), a prescription medication used as a blood thinner in the United States, which has proximately caused personal injuries to Plaintiff as further set forth below.

PARTIES

1. Plaintiff, Thelma Hawthorne, is a citizen and resident of Thibedeaux, Lafourche Parish, Louisiana, who suffered personal injuries as a result of ingesting Pradaxa™. As a direct and proximate result of ingesting Pradaxa™, Plaintiff Hawthorne suffered severe internal bleeding. Plaintiff Hawthorne specifically avers that Defendants’ Pradaxa was defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the

true danger associated with its use, and that Thelma Hawthorne suffered injury as a result of his ingestion of Pradaxa™.

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 has conducted business and derived substantial revenue from within the State of Louisiana. Boehringer US may be served at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

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 Pharma 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 (“Boehringer International”) is a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, 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.

6. Hereinafter, the above-referenced parties will be referred to as “Defendants.”

JURISDICTION AND VENUE

7. 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. 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 is further proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events giving rise to Plaintiff’s claims occurred, in part, in the Eastern District of Louisiana. Specifically, Plaintiff suffered injuries in the State of Louisiana and in Lafourche Parish as a result of ingestion of or exposure to Pradaxa™. Defendants promoted and sold Pradaxa™ in this State and in Lafourche Parish. Accordingly, venue is appropriate in this Court.

UNDERLYING COMMON FACTS

9. Defendants, directly or through their agents, apparent agents, servants or employees, are and at all relevant times have been engaged in the business of formulating, designing, manufacturing, licensing, testing, advertising, marketing, warranting, selling, distributing, and introducing into the stream of commerce a drug compound known as “dabigatran etexilate,” which Defendants have sometimes marketed under the brand name “Pradaxa.” Regardless of the name under which Defendants marketed, sold, and distributed the drug, all of its forms were and are, for all purposes relevant to Plaintiff’s claims, chemically and pharmacologically identical. Plaintiff, for purposes of this Complaint, will refer to the drug compound by the common brand name, “Pradaxa™.”

10. 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 an oral anticoagulant and is from the class of the direct thrombin inhibitors (“DTI”). 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 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.”¹ Indeed, Pradaxa™ is the first new treatment alternative to warfarin (Coumadin) in nearly 60 years.

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

¹ http://www.boehringer-ingenelheim.com/products/prescription_medicines/stroke_prevention.html

12. According to the 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.²

13. 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."³ Because the atria are primer pumps for the two large ventricles, AF normally causes only a modest reduction in 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.⁴

14. Defendants claim that approximately one percent of the total population is 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.

15. 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. 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

² http://www.boehringer-ingenelheim.com/news/news_releases/press_releases/2011/4_aug_2011_dabigatran.html

³ <http://www.pradaxa.com/understanding-afib.jsp>

⁴ Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

without atrial fibrillation. Up to three million people worldwide suffer strokes related to AF each year. Strokes due to AF tend to be severe, with an increased likelihood of death and disability.”⁵ 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.”⁶

16. 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.⁷

17. 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

⁵ http://www.boehringer-ingelheim.com/products/prescription_medicines/stroke_prevention.html

⁶ *Id.*

⁷ Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

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.

18. Moreover, the “RE-LY Clinical Trial” (Randomized Evaluation of Longterm 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. The RE-LY Clinical Trial went on to suggest that there is a need for new anticoagulant agents that are effective, 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 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 claiming Pradaxa™ generally has similar, but lower overall total bleeds versus warfarin.⁸

19. 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 In spite of this reference regarding age, the label is still wholly inadequate because, among other reasons, this information was not conveyed in the warnings

⁸ <http://www.pradaxapro.com/safety.jsp>

⁹ http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022512s009lbl.pdf

section. In essence, the Defendants have created a new drug, 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 and promotion by the Defendants, but it ignores patient safety.

20. 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 from the Defendants, 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

21. 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, was 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.

22. 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 remains unknown at this time.

23. 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

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

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 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 then 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.

24. On December 7, 2011, the FDA initiated an investigation into serious bleeding events associated with Pradaxa™ stating that 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].”

25. Defendants concealed their knowledge that Pradaxa™ can cause life threatening, reversible 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:

-----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 stroke (5.2)
- P-gp inducers and inhibitors: avoid co-administration of rifampin with PRADAXA because of the effects of dabigatran exposure (5.3).

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

26. 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 increase the risk of bleeding in general (e.g. anti-platelet agents, heparin, fibrinolytic 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 RE-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, intracranial, 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.)*].

27. 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 of 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 with 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 over 2 to 3 hours; however, data supporting this approach are limited. Measurement of PTT or ECT may help guide therapy. [*see Warnings and Precautions (5.1) and Clinical Pharmacology 12.2*].

28. 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. 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. Discontinue PRADAXA in patients with active pathological bleeding. [*see Dosage and Administration (2.2)*].

Risk factors for bleeding include the use of drugs that increase the risk of bleeding in general (e.g. anti-platelet agents, heparin, fibrinolytic 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, the removal of about 60% of drug over 2-3 hours); however, the amount of data supporting such an approach is limited. Activated prothombin complex concentrates (aPCCs, e.g. FEIBA), or recombinant Factor VIIa, or concentrates of coagulation factors II, IX or X may be considered but their use has not be 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.

29. 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 stroke (5.2)
- P-gp inducers and inhibitors: Effects of dabigatran exposure (5.3).

30. 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 Plaintiff herein.

31. Even if the warnings were sufficient, which Plaintiff strongly denies, 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. Defendants should withdraw Pradaxa™ from the market.

32. 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™ creates an extreme risk for patients and provides no benefit whatsoever. 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.¹² Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of irreversible bleeds in users of Pradaxa™ to prevent any chances of their product's registrations being delayed or rejected by FDA. As the

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

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

33. 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. 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 (\$603 million) this year."¹³

34. 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. Consumers, including Plaintiff, 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.

35. Defendants, through their affirmative misrepresentations and omissions, failed to warn Plaintiff and Plaintiff's physicians of the true and significant risks associated with Pradaxa™ use.

36. 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 Plaintiff would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiff's Pradaxa™ use was the direct and proximate result of Defendants' conduct.

¹³ <http://www.bloomberg.com/news/2011-11-28/boehringer-expects-2011-pradaxa-sales-of-603-million-dpasays>

37. Pradaxa™ was and is a defective product, unreasonably dangerous in light of its nature and intended use. That defect existed when the product left Defendants' control and has been the proximate cause of injuries to Plaintiff, whose injuries was caused by the use of Pradaxa™ in its intended or foreseeable manner or in the manner recommended by Pradaxa™.

38. Defendants knew or should have known of the dangerous condition of its product, Pradaxa™, but failed to adequately warn or instruct physicians and consumers of the risks, dangers, and proper uses of the drug.

39. Defendants have breached their duty of reasonable care in connection with the design, testing, manufacture, marketing, and/or labeling of Pradaxa™.

40. Plaintiff continues to suffer permanent injury, pain, loss of normal life, and other non-economic damage. As a direct and proximate result of the aforesaid acts of and/or omissions by Defendants, Plaintiff has, *inter alia*,

- a. suffered severe and permanent injuries, which he will be forced to endure for the remainder of his life;
- b. suffered physical impairment and disfigurement;
- c. suffered physical pain and suffering;
- d. suffered mental pain and suffering;
- e. suffered loss of enjoyment of life;
- f. incurred substantial costs for medical care in the past, and will in reasonable medical probability incur substantial costs for medical care in the future; and
- g. suffered a loss of earnings and future earning capacity.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

41. Defendants failed to disclose a known defect and affirmatively misrepresented that Pradaxa™ was safe for its intended use. Further, Defendants actively concealed the true risks associated with the use of Pradaxa. Neither Plaintiff nor Plaintiff's prescribing physicians had knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of Defendants' concealment of and misrepresentations regarding the true risks associated with Pradaxa, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

42. Thus, because Defendants fraudulently concealed the defective nature of Pradaxa™ and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

CAUSES OF ACTION

43. Defendants were at all times relevant to this suit, and is now, engaged in the business of designing, manufacturing, testing, marketing, and/or placing in 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™ placed into the stream of commerce by Defendants reached Plaintiff without substantial change and was ingested as directed. The Pradaxa™ was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

44. Defendants are believed to be a "manufacturer" under Louisiana Revised Statute 9:2800.53(1).

45. Plaintiff hereby sets forth that the Defendants are liable to Plaintiff under the Louisiana Products Liability Act, LA. R.S. 9:2800.54, *et seq.*:

- a. At the time Pradaxa™ left the control of the Defendants it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or in the alternative, because the product breached an express warranty or failed to conform to the other expressed factual representations upon which Plaintiff and/or Plaintiff's physician's justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein;
- b. Pradaxa™ was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the product left the possession of the Defendants, and that such risks clearly outweighed the utility of the product or its therapeutic benefits;
- c. At the time Pradaxa™ left the control of the Defendants it possessed a dangerous characteristic that may cause damage, and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the product left the possession of the Defendants. Specifically, although the Defendants were well aware that Pradaxa™ could potentially cause irreversible bleeding, and in fact, had significantly greater prevalence and severity of these side effects in the elderly, warnings of such adverse health conditions were either not included on the package insert for these products or they were not adequate to inform consumers. The Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of Pradaxa™.
- d. The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicated sufficient information on the dangers and safe use of the product taking into account the characteristics of the product, and/or the ordinary knowledge common to the consumer, such as the Plaintiff.

46. At all times pertinent and material hereto, there existed alternative feasible drugs to provide comparable benefits of Pradaxa™ to Plaintiff without the attendant risks of irreversible bleeding.

37. At all times pertinent and material hereto, Defendants knew that Pradaxa™ was unreasonably dangerous and/or defective as set forth herein.

38. In the alternative, Defendants should have, at all times pertinent and material hereto, known of the unreasonably dangerous and/or defective characteristics and/or conditions

of Pradaxa™, had they reasonably employed then-existing scientific and/or technical knowledge, reasonable testing, and/or other reasonable and then-accepted methods of quality assurance and/or quality control.

39. The Pradaxa™ manufactured by Defendants is unreasonably dangerous due to an inadequate warning that, at the time the drug left Defendants' control, possessed a characteristic that might cause damage or injury to Plaintiff, and yet Defendants failed to use reasonable care to provide an adequate warning of such characteristics and/or dangers to prescribing physicians and/or users of the drug.

40. In addition, and in the alternative, the Pradaxa™ manufactured by Defendants is unreasonably dangerous in design, in that at the time the drug left the Defendants' control, there existed, upon information and belief, an alternative design for the drug that was capable of preventing Plaintiff's injuries, and the likelihood of causing the Plaintiff's injuries and the gravity of that harm outweighed the burden (if any) on Defendants in adopting such alternative design and the adverse effect (if any) on the utility of the drug.

41. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger that caused the injuries for which Plaintiff seeks recovery. Despite this knowledge, Defendants failed 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 could have become available to Defendants.

42. A reasonably ordinary consumer who ingested Pradaxa™ would not readily recognize ingestion of the drug involved substantial dangers.

43. The Plaintiff did not know, nor had reason to know, at the time of her usage of Pradaxa™, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

44. Those defects caused serious injuries to Plaintiff when the product was used in its intended and foreseeable manner, and in the manner recommended by Defendants or in a non-intended manner that was reasonably foreseeable.

45. Defendants failed to provide adequate warnings based on what it knew or should have known about the adverse effects of Pradaxa™.

46. Defendants are therefore liable to Plaintiff for any and all damages arising from irreversible, internal bleeding, and/or other purchase and/or use of the drug.

JURY DEMAND

47. Plaintiff hereby demands a trial by jury.

DAMAGES

48. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs. The facts set out above demonstrate that, as a direct and proximate result of Defendants' conduct, Plaintiff has suffered severe economic and non-economic losses and injuries for which they are entitled to recover damages.

49. Plaintiff is entitled to recover the following damages, including without limitation the following:

- (a) past and future disfigurement, conscious pain, suffering, mental anguish, mental suffering, embarrassment, shame, loss of enjoyment of life, loss of association, loss of earnings, loss of profits, loss of salary;
- (b) the reasonable and necessary expenses for the medical treatment rendered to Plaintiff in the past and that will be medically probable in the future;

- (c) compensation for Plaintiff's permanent past and future mental and physical impairment;
- (d) all other actual damages available under applicable law;
- (e) future economic damages, including lost wages of Plaintiff;
- (f) pre- and post-judgment interest, and
- (f) costs of this suit.

PRAYER

WHEREFORE, Plaintiff asks that Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Bidachem S.p.A. be cited to appear and answer herein. That upon final trial, Plaintiff have judgment against Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Bidachem S.p.A. for actual damages, costs of court, and any other relief to which Plaintiff may be entitled.

Respectfully submitted,

BY: /s/Robert L. Salim
ROBERT L. SALIM
SALIM-BEASLEY, LLC
ATTORNEY AT LAW
1901 Texas Street
Natchitoches, LA 71457
Phone: (318) 352-5999
Fax: (318) 354-1227
Email: robertsalim@cp-tel.net

ATTORNEY FOR PLAINTIFF

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
THELMA HAWTHORNE

DEFENDANTS

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, ET AL

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

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 LAND INVOLVED.

Attorneys (If Known)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Robert L. Salim, SALIM-BEALSEY, LLC, 1901 TEXAS ST.,
NATCHITOCHE, LA 71457 (318) 352-5999

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

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

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

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location. Includes categories like Citizen of This State, Citizen of Another State, and Foreign Nation.

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

Large table with columns: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER 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 sec. 1332

Brief description of cause:

Product Liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND \$
CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

05/11/2012 /s/Robert L. Salim

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

THELMA HAWTHORNE

Plaintiff

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL

Defendant

)
)
)
)
)
)
)

Civil Action No.

SUMMONS IN A CIVIL ACTION

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

Robert L. Salim
SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, LA 71457

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:

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

THELMA HAWTHORNE

Plaintiff

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL

Defendant

)
)
)
)
)
)
)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

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:

Robert L. Salim
SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, LA 71457

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:

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

THELMA HAWTHORNE

Plaintiff

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL

Defendant

)
)
)
)
)
)
)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Boehringer Ingelheim International GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

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:

Robert L. Salim
SALIM-BEASLEY, LLC
1901 Texas Street
Natchitoches, LA 71457

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:

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

THELMA HAWTHORNE

Plaintiff

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Bidachem S.p.A. Strada Statale 11 (Padana Sup.) N.8 24040 Fornovo S. Giovanni Bergamo Italy

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:

Robert L. Salim SALIM-BEASLEY, LLC 1901 Texas Street Natchitoches, LA 71457

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: