UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

DORIS W. BLOOMER Plaintiff *v.* TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED; AND ELI LILLY AND COMPANY. Defendants	CIVIL ACTION NO. COMPLAINT JURY TRIAL DEMANDED SECTION MAGISTRATE

COMPLAINT AND REQUEST FOR JURY TRIAL

NOW INTO COURT, comes Plaintiff, Doris W. Bloomer, who by and through her counsel, brings this action against the Defendants Takeda Pharmaceuticals America, Inc. ("Takeda America"), Takeda Pharmaceuticals North America, Inc. ("Takeda North America"), Takeda Pharmaceutical Company Limited ("Takeda Limited") (collectively "Takeda" or "Defendants"), and Eli Lilly and Company ("Lilly" or "Defendants") and allege the following upon information and belief and investigation of counsel:

NATURE OF THE ACTION

1. This action seeks to recover damages for injuries sustained by the Plaintiff as the direct and proximate result of the wrongful conduct of the Defendants in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Actos (pioglitazone), and for medical monitoring for the current and/or latent injuries she sustained as a result of the prescription drug Actos.

2. Actos is a prescription medication used in the treatment of type II diabetes.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds $75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between the Plaintiff and Defendants. Plaintiff is a resident of the State of Louisiana. All Defendants are corporations of states other than the State of Louisiana, and all Defendants have their principal place of business in a state other than the State of Louisiana.

4. This Court has personal jurisdiction over the Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in the State, including, but not limited to, the marketing, advertising, selling and distributing drugs, including Actos, to resident in this State.

5. Venue is proper in this District pursuant to 28 U.D.C. § 1391(a) because the Defendant marketed, advertised, and distributed the dangerous product in this Federal District, and caused harm to the Plaintiff who resides within this District. The Plaintiff resides in this Federal District and the damages occurred in this federal District. The Defendants do substantial business in the State of Louisiana and within this Federal District, and at all times relevant hereto, the Defendants developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Actos in interstate commerce.

PARTIES

6. Plaintiff, Doris W. Bloomer, is and was at all relevant times, an adult resident of the State of Louisiana. She was prescribed Actos and did ingest Actos. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct described below.

7. Defendant Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware Corporation, which has its principle place of business at One Takeda Parkway, Deerfield, IL 60015.

8. At all times material to this lawsuit, Takeda America was engaged in business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

9. At all times material to this lawsuit, Takeda America was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

10. Defendant Takeda Pharmaceuticals North America, Inc. ("Takeda North America") is a Delaware Corporation, which has its principle place of business at One Takeda Parkway, Deerfield, IL 60015

11. At all times material to this lawsuit, Takeda North America was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

12. At all times material to this lawsuit, Takeda North America was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of

Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

13. Defendant Takeda Pharmaceutical Company Limited ("Takeda Limited") is a foreign corporation, which has its principle place of business in Osaka, Japan.

14. At all times material to this lawsuit, Takeda Limited was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

15. At all times material to this lawsuit, Takeda Limited was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derive substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

16. Defendant Eli Lilly and Company ("Lilly") is an Indiana Corporation, which has its principle place of business located at Lilly Corporate Center, Indianapolis, Indiana, 46285.

17. At all times material to this lawsuit, Lilly was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug Actos to the general public, including Plaintiff.

18. At all times material to this lawsuit, Lilly was authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derive

substantial revenue from goods and products used in the State of Louisiana; and supply Actos within the State of Louisiana.

FACTUAL ALLEGATIONS

19. At all relevant times, Defendants were and remain in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired the defendant(s) who designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Actors for use as a prescription treatment for type II diabetes, to wit:

20. Actos is in a class of insulin-sensitizing drugs known as thiazolidinediones (TZDs) or glitazones. Actos is used to treat type II diabetes.

21. Actos acts upon the insulin-sensitive genes involved in the control of glucose and lipid metabolism in muscle and the liver. As such, Actos is supposed to reduce insulin resistance; increase the body's expense of insulin-dependent glucose; decrease withdrawal of glucose from the liver; and reduce the amount of glucose, insulin, and glycated hemoglobin in the bloodstream.

22. Actos is used in monotherapy and in combination with metformin (Actoplus Met, Actoplus Met XR) and glimepiride (Duetact).

23. The United States Food and Drug Administration ("FDA") approved Actos for the treatment of type II diabetes on July 15, 1999. From before its approval and thereafter, Defendants collaborated to design, research, manufacture, test, advertise, promote, market, sell and distribute Actos in the United States.

24. In June 2011, the FDA, as well as the FDA's counterpart agencies in France and Germany, took action against Actos because of revelations of increased incident of bladder

cancer in patients taking Actos. The French agency ordered Actos withdrawn from the market. The German agency advised doctors not to put new patients on Actos. The FDA announced that information about an increased risk of bladder cancer will be added to Actos' labeling. However, from the time of Actos' launch in 1999 until the government actions were taken in 2011 and the present, patients who were prescribed Actos developed bladder cancer because the Defendants concealed, and continue to conceal, their knowledge that Actos can cause bladder cancer.

25. For example, before its approval by the FDA, drug-induced tumors were observed in rats receiving Actos in levels equivalent to clinical dose.

26. Also, in 2005, the results of a three-year study which investigated the impact in total mortality and macrovascular morbidity (*i.e.*, cardiovascular events and outcomes) in Actos, the PROactive (PROspective PioglitAzone Clinical Trial in Macro Vascular Events) Study, were released.[1] In this study, researchers found a statistically significant increase in the incidents of bladder cancer in patients taking Actos.

27. In addition, on September 17, 2010, the FDA issued a Safety Announcement that identified a three-year "liver safety study" performed in regard to Actos that also showed an increased incident of bladder cancer in patients taking Actos. This study was not released or fully identified by the Safety Announcement.

28. Moreover, another unpublished study designed to further "address the long-term risk of bladder cancer associated with Actos use" by Defendant Takeda and Kaiser Permanente has also been reported by the FDA. Although intended as a ten-year study, a "planned five-year interim analysis was performed with data collected from January 1, 1997 through April 30,

[1] Dormandy J.A., et. Al., *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial in MacroVascular Events): a Randomised Control Trial, Lancet, 255:1279-1289-(2005).*

2008," and that data showed "the risk of bladder cancer increased with increasing dose and duration of Actos use, reaching statistical significance after 24 months of exposure."[2]

29. Furthermore, in 2011, the American Diabetes Association reviewed the adverse event reports made to the FDA concerning Actos between 2004 and 2009.[3] This study concluded that "AERS analysis is consistent with an association between pioglitazone and bladder cancer."

30. And, on June 15, 2011, the FDA issued another Safety Announcement in regard to Actos in which it unequivocally stated that "use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer." Information about this risk was ordered to be placed in the *Warnings and Precautions* section of the Actos label.

31. Clearly, the relationship between Actos and bladder cancer has been know, or should have been known, to Defendants. Despite their knowledge, Defendants refused to inform patients, doctors, or the medical community about the risks and put their profits before people.

32. Actos is one of the top selling drugs for Defendants. It has been listed as one of the top ten best selling medication in the United States in various years, and it had global sales of $4.8 billion world-wide last year. Actos also accounts for a significant percentage of Defendant's revenue, despite the significant risk of bladder cancer that it poses.

33. Defendants, through fraud, negligence, misrepresentation, and/or omission have concealed from patients, doctors, the medical community, and the general public the true and significant risks of Actos use. As a result of these actions by Defendants, Plaintiff Doris

[2] Lewis JD, Ferrara A, Strom BL, Selby JV, Bilker W., Peng T, et al., submitted to FDA, unpublished results.
[3] Piccinni, et. Al., Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting, Diabetes Cares, 34:1369-1371 (June 2011).

Bloomer was unaware of, and exposed to, significant risks, and in fact Plaintiff has been *diagnosed with bladder disorders.*

FEDERAL REQUIREMENTS

34. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Actos.

35. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21U.S.C. §301, et seq.

36. With respect to the prescription drug Actos, Defendants, upon information and belief, have or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violation:

A. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 US.SC. § U.S.C. § 351.

B. The prescription drug Actos is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Actos and such deviations are not plainly stated on their labels.

C. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

D. The prescription drug Actos 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.

E. The prescription drug Actos 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 warnings against use where its use my be dangerous to health or against unsafe dosage or methods of duration of administration or application, in such manner and form as are necessary for the protection of users.

F. The prescription drug Actos is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage of manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

G. The prescription drug Actos does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions,, (c) frequency of

administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

H. The Defendant violated 21 CFR § 201.56 because the labeling was not informative and accurate.

I. The prescription drug Actos is misbranded pursuant to 210 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

J. The Defendant violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Actos cause and the need for regular and/or consistent monitoring to ensure that a potential fatal bladder cancer has not developed.

K. The Defendant violated 21 CFR § 201.57 because it failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

L. The Defendant violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug Actos are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

M. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, imitations in use imposed by it, and steps that should be taken if they occur.

N. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evident of an association of a serious hazard with the drug.

O. The defendant violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Actos and other drugs in the same pharmacologically active and chemically related class.

P. The Defendant violated 21 CFR § 201.57 because the possibility that a patient could develop bladder cancer, while significantly more severe than the other reactions listed in the adverse reactions section, was not listed by Defendant before the other less serious adverse reactions on the labeling of the prescription drug Actos.

Q. The prescription drug Actos is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

R. The prescription drug Actos violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

S. The prescription drug Actos violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

T. The prescription drug Actos violates 21 CFR § 211.165 because the test methods employed by the Defendant are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

U. The prescription drug Actos violates 21 CFR § 211.165 in that the prescription drug Actos fails to meet established standards or specifications and any other relevant quality control criteria.

V. The prescription drug Actos violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Actos were not followed.

W. The prescription drug Actos violates 21 CFR § 310.303 in that the prescription drug Actos is not safe and effective for its intended use.

X. The Defendant violated 21 CFR § 310.303 because the Defendant failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

Y. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to report adverse events associated with the prescription drug Actos as soon as possible

or at least within 15 days of the initial receipt by the Defendant of the adverse drugs experience.

Z. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Actos, and evaluating the cause of the adverse event

AA. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experience and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

BB. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

CC. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or 15-day Alert report follow up."

DD. The Defendant violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug Actos or otherwise received by the Defendant from sources, foreign or domestic, including information derived by 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 authorities that have not already been previously reported to the agency by the sponsor.

EE. The Defendant violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (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 Postmarking 15-Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

FF. The Defendant violated 21 CFR § 314.80 by failing to submit a copy of published articles from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

37. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendant negligent *per se.*

FACTS REGARDING PLAINTIFF DORIS W. BLOOMER

38. With Actos, the Defendant negligently produced and manufactured an unreasonably dangerous product and placed it in the stream of commerce. Through the negligence of Defendants and through their acts and/or failures to act, Plaintiff was prescribed and ingested the prescription drug Actos, which upon information and belief, caused Plaintiff to suffer physical and mental condition for which she seeks and is entitled to be compensated.

39. Plaintiff, Doris W. Bloomer, suffered bladder injury subsequent to taking Actos.

40. As a direct and proximate result of using Actos, Plaintiff suffered general and special damages, past and future pain and suffering, emotional distress, loss of enjoyment of life,

inconvenience, disability, disfigurement, increased risk of death, deterioration or disease, fear of death, past and future surgical expenses, hospital bills, doctors' fees, prescription drug costs, the costs of diagnostic tests, and other medical costs and expenses, loss of consortium, loss of society, and/or loss of support, and loss of earning and/or earning capacity.

41. Plaintiff's healthcare providers were at the time of her injuries, unaware, and could not have reasonably known or have learned through reasonable diligence that such injury directly resulted form the Defendants' negligent and other culpable acts and/or failures to act, omission, and misrepresentations or from Plaintiff's ingestion of Actos.

42. The Actos ingested by Plaintiff was designed, manufactured, distributed and sold by Defendants, and was intended to safely and effectively treat type II diabetes, and Defendants represented Actos to be an appropriate product for such purposes.

43. Plaintiff used Actos in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

44. Plaintiff would not have used Actos had the Defendants properly disclosed the risks associated with this drug.

45. By reason of the foregoing, Plaintiff has suffered personal injuries which are permanent and lasting in nature; has suffered physical pain and mental anguish, including diminished enjoyment of life; and will require lifelong medical treatment, monitoring and/or medications.

46. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered serious and dangerous side effects, as well al other severe and personal injuries which are permanent and lasting in

nature; suffered physical pain and mental anguish, including diminished enjoyment of life; requires lifelong medical treatment, monitoring and/or medications; and lives in fear of developing any of the above named health consequences.

47. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' drug Actos.

48. Despite having actual notice of the dangerous propensities associated with Actos, prior to the date of Plaintiff's purchase and use of Actos, the Defendants took inadequate steps to advise consumers of medical providers, including Plaintiffs, of the know dangers of Actos consumption, including but not limited to the increased risk of bladder cancers. The Defendants failed to take adequate steps to ensure that the Actos it sold was safe for the public and would function in the manner intended.

49. Even after being made aware of the increased incidents of bladder cancer, Defendants still failed to take all reasonable and necessary steps to ensure that the consuming public, including Plaintiff, was aware of the increased risk of suffering these injuries.

50. Defendants were aware of the dangerous properties of Actos described herein, and knew the risks and dangers posed to patients ingesting Actos, and Defendants acted with willful and wanton disregard for the safety of the public, including Plaintiff's.

51. Despite this knowledge, Defendants have widely promoted the use of Actos as a safe and effective treatment for type II diabetes.

52. As a result of Defendants' efforts and actions, the sales of Actos have become an enormous source of profits for Defendants.

53. Accordingly, the Defendants had a significant financial incentive to suppress, misrepresent, and/or conceal any potential dangers or risks associated with Actos. Defendants maximized profits at the expense of the health of patients taking Actos, including Plaintiff, and Defendants failed to adequately or appropriately disclose material information relating to the dangers associated with Actos. As a result, users of Actos, including Plaintiff, were unaware of these dangers, did not have adequate information to know the risks of ingesting Actos and were therefore unable to avoid injury caused by ingesting this defective drug product.

54. As a direct and proximate result of Defendants' defective design and manufacture, inadequate warnings, fraud, misrepresentation, omission, and other acts as described herein regarding Actos, Plaintiff sustained injuries.

55. As a result of her ingestion of Actos, Plaintiff Doris W. Bloomer has sustained the following non-exclusive list of damages:

A. Physical Injuries;

B. Past and future emotional distress;

C. Loss of enjoyment of life;

D. Past and future mental pain and suffering;

E. Inconvenience;

F. Past and future physical pain, suffering and disability;

G. Medical expenses;

H. Other damages to be proven at the trial of this matter.

FRAUDULENT CONCEALMENT

56. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions,

actively concealed from Plaintiff, physicians, the medical community, and the general public the true risks associated with Actos.

57. As a result of Defendants' actions, Plaintiff and physicians were unaware, and could not reasonably have know or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

COUNT ONE

LOUISIANA PRODUCTS LIABILITY ACT

58. Plaintiff hereby restates and realleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

59. Actos proximately caused damage to the Plaintiff, which damage was caused by a characteristic of the product that rendered it unreasonably dangerous arising from a reasonably anticipated use of the product by Plaintiff, thus rendering Defendant liable to Plaintiff pursuant to LSA R.S. 9:2800.55;

60. Actos is unreasonably dangerous for the following reasons:

A. It is unreasonably dangerous in construction or composition as provided in LSA R.S. 9:2800.56.

B. It is unreasonably dangerous to design as provided in LSA R.S. 9:2800.56.

C. It is unreasonably dangerous because an accurate warning about the product was not provided as required by LSA R.S. 9:2800.57

D. It is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in LSA R.S. 9:2800.58.

61. The characteristics of Actos that render it unreasonably dangerous under LSA R.S. 9:2800.55, LSA R.S. 9:2800.56, and LSA R.S. 9:2800.57 et seq. existed at the time the product left the control of the manufacturer or resulted from a reasonably anticipated alteration or modification of the product.

62. For all of the reasons alleged herein, Actos was unreasonably dangerous in design at the time the product left the manufacturer's control in that:

A. There existed an alternate design for the product that was capable of preventing the Plaintiff's damages; and

B. The likelihood that the product's design would cause the Plaintiff's damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

63. For all of the reasons alleged herein, Actos was unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacture's control, the product possessed a characteristic that my cause damage and the manufacturer failed to use reasonably care to provide adequate warning that such characteristic and its dangers to users of the product.

64. Further, Defendants, before, during, and after the product left its control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

65. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that Actos was safe, effective, fit and proper for its intended use.

66. In using Actos, Plaintiff and her physicians relied on the skill, judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

COUNT TWO

VIOLATION OF WARRANTY OF REDHIBITION

67. Plaintiff hereby restates and realleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

68. Defendants were aware of the substantial risks from using Actos but failed to fully disclose the same.

69. Defendants, as the manufacturers of Actos, are deemed to be aware of its redhibitory defects pursuant to LSA-C.C. Article 2545.

70. Had Plaintiff been aware of the defects contained in Actos, Plaintiff would not have purchased or ingested Actos. This characteristic rendered it unfit for its intended purposes.

71. Defendant is liable to Plaintiff under the theory of redhibition as a consequence of the sale to Plaintiff of a product unfit for its intended use.

72. Plaintiff is entitled to the return of any purchase price paid, including but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys

fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiff may be entitled.

JURY DEMAND

73. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

a) that process issue according to law;

b) that the defendants be served with a copy of Plaintiff's Complaint and show cause why the prayers for relief requested by Plaintiff should not be granted;

c) that Plaintiff be granted a trial by jury in this matter;

d) that the Court enter judgment against the Defendants, jointly and severally, for all general and compensatory damages allowable to Plaintiff;

e) that the Court enter judgment against the Defendants for all special damages allowable to Plaintiff;

f) that the Court enter judgment against the Defendants for all equitable relief allowable to Plaintiff;

g) that the Court enter judgment against the Defendants for all declaratory relief allowable to Plaintiff;

h) that the Court enter judgment against the Defendants for all other relief allowable to Plaintiff;

i) that the Court award Plaintiff prejudgment interest on all damages;

j) that the Court award Plaintiff the costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

k) that the Court award Plaintiff such and further monetary, medical, equitable and declaratory relief as may be just and proper under the circumstances.

Dated: January 3, 2012

Respectfully submitted,
SINGLETON LAW FIRM

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JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

/s/ W. JAMES SINGLETON
W. James Singleton
THE SINGLETON LAW FIRM