

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

Tommy G. Thompson and Lua Thompson,

Plaintiff(s),

vs.

Takeda Pharmaceuticals North America, Inc.
c/o CT Corporation System
208 South LaSalle Street
Chicago, Illinois 60604;

and

Takeda Global Research & Development Center, Inc.
c/o CT Corporation System
208 South LaSalle Street
Chicago, Illinois 60604;

and

Takeda Pharmaceutical Company Limited
c/o President Yasuchika Hasegawa
1-1, Doshomachi 4-chome,
Chuo-ku, Osaka 540-8645;

and

Takeda Pharmaceuticals America, Inc.
c/o CT Corporation System
1300 East Ninth Street
Cleveland, Ohio 44114;

and

Takeda San Diego, Inc.
10410 Science Center Drive
San Diego, CA 92121

and

Takeda Pharmaceuticals International, Inc.
One Takeda Parkway
Deerfield, IL 60015

**COMPLAINT AND DEMAND
FOR JURY TRIAL**

and

Eli Lilly and Company
c/o National Registered Agents, Inc.
145 Baker Street
Marion, Ohio 43302

Defendants.

COMPLAINT

Plaintiff(s) Tommy G Thompson and Lua Thompson (alternatively referred to as “Plaintiff”), residing in Terrebonne Parish within the State of Louisiana, by and through the undersigned attorneys, hereby brings this cause of action against Defendants Takeda Pharmaceuticals America, Inc. (“Takeda America”), Takeda Pharmaceuticals North America, Inc. (“Takeda North America”), Takeda Global Research & Development Center, Inc. (“Takeda Global Research”) and Takeda Pharmaceutical Company Limited (“Takeda Limited”) and Takeda Pharmaceuticals LLC and Takeda Pharmaceuticals International Inc., and Takeda San Diego (collectively “Takeda” or “Defendants”) and Eli Lilly and Company (“Lilly” or collectively with Takeda as “Defendants”) and as for his/her Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

INTRODUCTION

1. This is a personal injury action brought for injuries caused to Plaintiff(s) as a result of ingesting Defendants’ defective drug Actos (pioglitazone), a prescription medication used to improve blood sugar (glucose) control in adults with type II diabetes.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

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

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

PLAINTIFF(S)

5. Plaintiff, Tommy G Thompson, is a natural person and a resident of Houma, Louisiana and used the prescription Actos as prescribed and directed by his physician.

6. Plaintiff, Lua Thompson, is the spouse of Plaintiff Tommy G Thompson and also resides in Houma, Louisiana.

7. Plaintiff Tommy G Thompson was injured as a result of his use of Actos, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement of cost of obtaining Actos, reimbursement for all past, present, and future health and medical care costs related to Actos.

8. Plaintiff Lua Thompson was deprived of the care, consideration, compassion, consortium and concern of Plaintiff Tommy G Thompson, and has suffered injuries and damages thereby.

DEFENDANTS

9. Takeda America is a Delaware Corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

10. Takeda America is a wholly owned subsidiary of Takeda North America.

11. Takeda America has transacted and conducted business within the State of Louisiana.

12. Takeda America has derived substantial revenue from goods and products used in the State of Louisiana.

13. Takeda America expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

14. Takeda North America is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

15. Takeda North America is a wholly-owned subsidiary of Takeda Limited.

16. Takeda North America has transacted and conducted business within the State of Louisiana.

17. Takeda North America has derived substantial revenue from goods and products used in the State of Louisiana.

18. Takeda North America expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

19. Takeda Global Research is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

20. Takeda Global Research is a wholly-owned subsidiary of Takeda North America.

21. Takeda Global Research has transacted and conducted business within the State of Louisiana.

22. Takeda Global Research has derived substantial revenue from goods and products used in the State of Louisiana.

23. Takeda Global Research expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

24. Takeda Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan.

25. Takeda Limited is the parent company of Takeda North America, and Takeda America and Takeda Global Research are wholly-owned subsidiary of Takeda North America.

26. Takeda Limited has transacted and conducted business within the State of Louisiana.

27. Takeda Limited has derived substantial revenue from goods and products used in the State of Louisiana.

28. Takeda Limited expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

29. Takeda Pharmaceuticals, LLC is a Delaware corporation which has its principal place of business at One Takeda Parkway Deerfield, IL 60015.

30. Takeda Pharmaceuticals, LLC is a wholly-owned subsidiary of Takeda North America.

31. Takeda Pharmaceuticals, LLC has transacted and conducted business within the State of Louisiana.

32. Takeda Pharmaceuticals, LLC has derived substantial revenue from goods and products used in the State of Louisiana.

33. Takeda Pharmaceuticals, LLC has derived substantial revenue from goods and products used in the State of Louisiana.

34. Takeda Pharmaceuticals, LLC expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

35. Takeda San Diego, Inc. is a Delaware corporation with its principal place of business located at 10410 Science Center Drive San Diego, CA 92121.

36. Takeda San Diego, Inc. is a wholly-owned subsidiary of Takeda North America.

37. Takeda San Diego, Inc. has transacted and conducted business within the State of Louisiana.

38. Takeda San Diego, Inc. has derived substantial revenue from goods and products used in the State of Louisiana.

39. Takeda San Diego, Inc. expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

40. Takeda Pharmaceuticals International, Inc. is a Delaware corporation with its principal place of business located at One Takeda Parkway Deerfield, IL 60015.

41. Takeda Pharmaceuticals International, Inc. is a wholly-owned subsidiary of Takeda North America.

42. Takeda Pharmaceuticals International, Inc has transacted and conducted business within the State of Louisiana.

43. Takeda Pharmaceuticals International, Inc. has derived substantial revenue from goods and products used in the State of Louisiana.

44. Takeda Pharmaceuticals International, Inc. expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

45. Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

46. Lilly has transacted and conducted business within the State of Louisiana.

47. Lilly has derived substantial revenue from goods and products used in the State of Louisiana.

48. Lilly expected or should have expected their acts to have consequences within the State of Louisiana, and derived substantial revenue from interstate commerce.

SUMMARY OF THE CASE

49. As a result of the defective nature of Actos, persons who were prescribed and ingested this product, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

50. Defendants concealed and continue to conceal their knowledge of Actos' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the risk of bladder cancer associated with more than twelve (12) months of Actos ingestion.

51. As a result of Defendants' actions and inaction, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

FACTUAL ALLEGATIONS

52. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted and sold Actos, for the treatment of type two diabetes mellitus.

53. Actos was jointly launched by Takeda North America and Lilly in 1999.

54. On April 20, 2006, Takeda Limited announced the conclusion of its collaboration in the United States between Takeda North America and Lilly to promote and market Actos, a partnership Takeda Limited described as "a great success" and "mutually beneficial to both companies."

55. According to the American Diabetes Association, type II diabetes is the most common form of diabetes. Type II diabetes develops when the body does not produce enough insulin or doesn't efficiently use the insulin that it does produce. Type I diabetes occurs when the body does not produce any insulin at all. Insulin is necessary for the body to be able to use glucose for energy.

56. Actos was approved by the Food and Drug Administration (“FDA”) in July of 1999 to treat type II diabetes. Actos is in a class of insulin-sensitizing diabetes agents known as thiazolidinediones (“TZD”s).

57. Actos exerts its antihyperglycemic effect only in the presence of endogenous insulin. Therefore, Actos is only used to treat type II diabetes and should not be used to treat type I diabetes.

58. Actos is sold as a single ingredient product under the brand name Actos, and it is also sold in combination with metformin (Actoplus Met, Actoplus Met XR) and in combination with glimepiride (Duetact).

59. As a result of the defective nature of Actos, persons who were prescribed and ingested Actos for more than twelve (12) months, including Plaintiff, have suffered and may continue to suffer from bladder cancer.

60. Defendants concealed and continue to conceal their knowledge that Actos can cause bladder cancer from Plaintiff, other consumers, and the medical community. Specifically, Defendants have yet to adequately inform consumers and the prescribing medical community about the risks of bladder cancer with use of Actos for more than twelve (12) months.

61. As a result of Defendants’ actions and inactions, Plaintiff was injured due to his ingestion of Actos, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

62. Prior to Actos being approved by the FDA, a two-year carcinogenicity study was conducted on male and female rats. Drug-induced tumors were observed in male rats receiving doses of Actos that produced blood drug levels equivalent to those resulting from a clinical dose.

63. In 2005, the results of the PROactive (**PRO**spective PioglitAzone **Clinical Trial In MacroVascular Events**) three-year study were published. PROactive prospectively looked at the impact in total mortality and macrovascular morbidity using Actos. 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 Controlled Trial*, Lancet, 266:1279-1289 (2005).

64. The PROactive study was looking at cardiovascular events and outcomes. However, the study demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators. This information was not included in the published Dormandy paper.

65. A three-year liver safety study was also performed, and according to the FDA, that study also demonstrated a higher percentage of bladder cancer cases in patients receiving Actos versus comparators.

66. On September 17, 2010, the FDA issued a Safety Announcement stating it was undertaking a review of the data from an ongoing, ten-year epidemiological study being conducted by Kaiser Permanente to evaluate the association between Actos and bladder cancer. The planned five-year interim analysis demonstrated that the risk of bladder cancer increases with increasing dose and duration of Actos use, reaching statistical significance after 24 months.

67. Despite this finding by the FDA, Robert Spanheimer, Vice President of Medical and Scientific Affairs for Takeda, claimed to Reuters that the Kaiser Permanente study has not shown a risk to patients of bladder cancer or other cancers from Actos.

68. In early 2011, the American Diabetes Association published *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011. This study looked at adverse events reports made to the FDA between 2004 and 2009. The conclusion of that study was that “[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies.”

69. On June 9, 2011, the European Medicines Agency (“EMA”) announced that it had been informed by the French Medicines Agency (“Afssaps”) of its decision to suspend the use of pioglitazone-containing medicines (Actos, Competact) in France while awaiting the outcome of the ongoing European review.

70. France’s decision was based upon a retrospective cohort study in France using the French National Health Insurance Plan which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than a year. The French cohort included 1.5 million patients with diabetes that were followed for 4 years (2006-2009).

71. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos after Germany’s Federal Institute for Drugs and Medical Devices (“BfArM”) reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

72. On June 15, 2011, the FDA issued another Safety Announcement stating that “use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with

an increased risk of bladder cancer.” The FDA ordered information about this risk to be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines.

73. The FDA reported that the risk of bladder cancer increased with increasing dose and duration of pioglitazone use. When compared to persons never exposed to pioglitazone, exposed to pioglitazone therapy for longer than 12 months was associated with a 40% increase in risk. Based on this data, the FDA calculated that therapy with Actos for longer than 12 months was associated with 27.5 excess cases of bladder cancer per 100,000 person-years follow-up, compared to those who never used pioglitazone.

74. On July 12, 2011, Takeda Limited issued a recall on Actos in France.

75. As the manufacturers of Actos, Defendants knew or should have known that Actos use for longer than 12 months was associated with bladder cancer. Instead, Defendants promoted Actos as a safe and effective treatment for type II diabetes.

76. Piccinni, et al. analyzed the association between antidiabetic drugs and bladder cancer by reviewing reports from the FDA Adverse Event Reporting System (“AERS”) between 2004 and 2009. The association was analyzed by the case/noncase methodology. There were 31 recorded reports of bladder cancer in patients using pioglitazone. Piccinni’s results indicated that the reporting odds ratio for pioglitazone was indicative of a “definite risk.” *Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting*, Piccinni, et al. *Diabetes Care*, 34:1369-1371 (June 2011), published ahead of print April 22, 2011.

77. Despite its knowledge of this dangerous side effect that can result from Actos use, Defendants refused to warn patients, physicians and the medical community about the risk of bladder cancer.

78. Actos is one of Defendants' top selling drugs. Upon information and belief, in the last year, the medication had global sales of \$4.8 billion and accounted for approximately 27% of Takeda's revenue. In 2008, Actos was the tenth best-selling medication in the United States.

79. Consumers, including Plaintiff, who have used Actos for treatment of type II diabetes, 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 long-term Actos therapy.

80. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with long-term Actos use.

81. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

82. Plaintiff was prescribed and began taking Actos upon direction of his physicians. Plaintiff subsequently developed bladder cancer.

83. As a direct result of being prescribed Actos for many years Plaintiff has been permanently and severely injured, having suffered serious consequences from long-term Actos use. Plaintiff requires and will in the future require ongoing medical care and treatment.

84. Plaintiff, as a direct and proximate result of long-term Actos 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, and living related expenses due to his new lifestyle.

85. Plaintiff would not have used Actos had Defendants properly disclosed the risks associated with its long-term use.

FEDERAL REQUIREMENTS

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

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

88. With respect to the prescription drug Actos, the Defendants, upon information and belief, has 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 violations:

- 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 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 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.
- 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 or 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 Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.
- i. The prescription drug Actos is misbranded pursuant to 21 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 Defendants 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 cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.
- k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Actos.

- l. The Defendants 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 Defendants 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, limitations 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 evidence of an association of a serious hazard with the drug.
- o. The Defendants 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 Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendants failed to list the development of Cardiac Arrhythmia before the other 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 Defendants 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 Defendants violated 21 CFR § 310.303 because the Defendants 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 Defendants 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 Defendants of the adverse drugs experience.
- z. The Defendants 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 Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and

submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

- bb. The Defendants 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 Defendants 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 followup.”
- dd. The Defendants 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 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.
- ee. The Defendants violated 21 CFR § 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, 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 Defendants violated 21 CFR § 314.80 by failing to submit 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.

89. 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 the Defendants liable under Louisiana law.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

CONSTRUCTION OR COMPOSITION

DEFECT UNDER LA. R.S. 9:2800.55

90. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if more fully set forth herein.

91. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Actos.

92. At all times material to this action, Actos was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Plaintiff herein without substantial change in the condition in which it was sold.

93. At all times material to this action, Actos was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, Actos contained manufacturing defects which rendered the subject product unreasonably dangerous;
- b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;
- c. The subject product was not made in accordance with the Defendants' specifications or performance standards; and
- d. The subject product's manufacturing defects existed before it left the control of the Defendants.

94. The subject product manufactured and/or supplied by Defendant was defective in construction or composition in that, when it left the hands of Defendant, it deviated in a material way from Defendant's manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, developing bladder cancer. The product was unreasonably dangerous in construction or composition as provided by La. R.S. 9:2800.55.

SECOND CAUSE OF ACTION

DESIGN DEFECT UNDER LA. R.S. 9:2800.56

95. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

96. Actos is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonably dangerous in design as provided by La.R.S. 9:2800.56.

97. At all times material to this action, Actos was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Plaintiff herein, without substantial change in the condition in which it was sold.

98. At all times material to this action, Actos was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, Actos contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to permanent personal injuries including, but not

limited to, developing bladder cancer and other serious injuries and side effects;

- b. When placed in the stream of commerce, Actos was defective in design and formulation, making the use of Actos more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type II diabetes;
- c. Actos' design defects existed before it left the control of the Defendants;
- d. Actos was insufficiently tested;
- e. Actos caused harmful side effects that outweighed any potential utility; and
- f. Actos was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

99. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

THIRD CAUSE OF ACTION

INADEQUATE WARNING UNDER LA. R.S. 9:2800.57

100. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

101. Acots was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing bladder cancer and other serious injuries and side effects, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other forms treatment of type II diabetes. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as provided pursuant to La.R.S. 9:2800.57.

102. The subject product manufactured and supplied by Defendant was defective due to inadequate post-marketing warning or instruction because, after Defendant knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendant failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury.

103. Plaintiff was prescribed and used the subject product for its intended purpose.

104. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

105. The Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

106. Takeda Limited and Lilly, as manufacturers and/or distributors of the subject prescription product, are the Reference Listed Drug Company and the New Drug Application Holder and is held to a level of knowledge of an expert in the field.

107. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

108. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, developing type II diabetes and other serious injuries and side effects.

109. Plaintiff, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

110. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

111. Had Plaintiff received adequate warnings regarding the risks of the subject product, he would not have used it.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
UNDER LA. R.S. 9:2800.58

112. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

113. Defendants expressly represented to Plaintiff, other consumers, and the medical community that Actos was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

114. Actos does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, developing bladder cancer and other serious injuries and side effects.

115. At the time of the making of the express warranties, Defendant knew or should have known of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an expressed warranty of the defendant as provided by La.R.S. 9:2800.58.

116. At the time of the making of the express warranties, Defendant knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

117. At all relevant times Actos did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

118. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

FIFTH CAUSE OF ACTION

REDHIBITION

119. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

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

121. Defendants sold and promoted Actos, 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 he 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.

122. 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.

123. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, is 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 Actos possessed a redhibitory defect. La. C.C. art. 2545.

SIXTH CAUSE OF ACTION

BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE

124. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

125. 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.

126. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, developing bladder cancer and other serious injuries and side effects. As a result, Plaintiff's vehicle is unfit and inherently dangerous for ordinary use.

127. As a direct and proximate result of Defendants' actions, Plaintiff has sustained serious, significant and permanent injuries. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and 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.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS

128. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint as detailed above, with the same force and effect as if fully set forth herein.

129. At all relevant times, Defendants knew of the use for which Actos was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

130. Defendants were aware that consumers, including Plaintiff would use Actos for treatment or prevention of type II diabetes.

131. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell Actos only if it was indeed of merchantable quality and safe and fit for its intended use.

132. Defendants breached the implied warranty to consumers, including Plaintiff, as Actos was not of merchantable quality or safe and fit for its intended use.

133. Consumers, including Plaintiff and the medical community, reasonably relied upon Defendants' implied warranty for Actos.

134. Actos reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

EIGHTH CAUSE OF ACTION

LOSS OF CONSORTIUM

135. Plaintiff(s) incorporate by reference each preceding paragraph as though set forth fully at length herein and further alleges as follows.

136. Plaintiff, Lua Thompson, was at all times relevant hereto the spouse of Plaintiff Tommy G Thompson, and as such lives and cohabitates with him.

137. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

138. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of her spouse's companionship, services, society and the ability of the Plaintiff's spouse have in those respects been impaired and depreciated, and the marital association between husband and wife has been altered, and accordingly, the Plaintiff has been caused great mental anguish.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

- a. Awarding actual damages to the Plaintiff incidental to his purchase and use of Actos in an amount to be determined at trial;
- b. Awarding pre-judgment and post-judgment interest to the Plaintiffs;
- c. Awarding the costs and the expenses of this litigation to the Plaintiffs;
- d. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and
- e. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demands a trial by jury on all counts and as to all issues.

Dated: September 9, 2011

Respectfully submitted,
BY: /s/ Richard J. Arsenault

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C. MICHAEL BOLLINGER (LA Bar #01256)

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