UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

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TERRENCE ALLEN and SUSAN ALLEN,

Docket No.:

Plaintiffs,

-against-

COMPLAINT AND DEMAND FOR JURY TRIAL

TAKEDA PHARMACEUTICALS NORTH AMERICA INC., TAKEDA PHARMACEUTICALS INTERNATIONAL INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC., TAKEDA SAN DIEGO INC.,

Defendants.

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Plaintiffs, by their attorneys, **WEITZ & LUXENBERG, P.C** allege as follows:

SUBJECT MATTER JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiffs are citizens of New York, which is different from the states where the Defendants are incorporated and have their principal places of business. Plaintiffs are citizens of the United States of America, and residents of the City of Attica, in Wyoming County in the State of New York.

2. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c).

NATURE OF THE CASE

3. This is an action for personal injury on behalf of the Plaintiff Terrence Allen and loss of consortium on behalf of his spouse, Susan Allen, against Defendants who were responsible for the prescription drug Actos, a diabetes medication used by Plaintiff Terrence Allen that caused Plaintiff Terrence Allen's bladder cancer.

PARTY DEFENDANTS AND PERSONAL JURISDICTION

4. Upon information and belief, Defendant TAKEDA PHARMACEUTICALS NORTH AMERICA INC. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMACEUTICALS NORTH AMERICA INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

5. Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan. As part of its business, TAKEDA PHARMACEUTICAL COMPANY LIMITED is involved in the research, development, sales, and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

6. Defendant TAKEDA PHARMACEUTICALS LLC. is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TAKEDA PHARMACEUTICALS LLC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

7. Defendant TAKEDA PHARMACEUTICALS INTERNATIONAL INC. is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. As part of its business TAKEDA PHARMACEUTICALS INTERNATIONAL INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

8. Defendant TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC. is an Illinois corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. As part of its business TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

9. Defendant TAKEDA SAN DIEGO INC. is a California corporation, having a principal place of business at 10410 Science Center Drive, San Diego, CA 92121. As part of its business TAKEDA SAN DIEGO INC. is involved in the research, development, sales and marketing of pharmaceutical products including Actos and pioglitazone hydrochloride.

10. Upon information and belief, at relevant times, Defendants were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of New York, either directly or indirectly through third parties or related entities, its products, including Actos and pioglitazone hydrochloride.

11. At relevant times, Defendants conducted regular and sustained business and engaged in substantial commerce and business activity in the State of New York, which included but was not limited to selling, marketing and distributing its products including Actos and pioglitazone hydrochloride in New York.

12. Upon information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America including the State of New York, and Defendants derived and derive substantial revenue from interstate commerce.

13. Upon information and belief, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a company domiciled in Japan and is the parent/holding company of Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL INC., TAKEDA PHARMACEUTICALS NORTH AMERICA INC., TAKEDA PHARMACEUTICALS LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC., TAKEDA SAN DIEGO INC.

14. Upon information and belief, at all relevant times, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED exercised and exercises dominion and control over Defendants TAKEDA PHARMACEUTICALS INTERNATIONAL INC., TAKEDA PHARMACEUTICALS NORTH AMERICA INC., TAKEDA PHARMACEUTICALS LLC., TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER INC., TAKEDA SAN DIEGO INC..

15. Upon information and belief, at all relevant times, Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED expected or should have expected that its acts would have consequences within the United States of America and the State of New York, derived and derive substantial revenue from interstate commerce.

16. Upon information and belief, at all relevant times, Defendants, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED have transacted and conducted business in the State of New York. and/or contracted to supply goods and services

within the State of New York and these causes of action have arisen from same.

17. Upon information and belief, at all relevant times, Defendants, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED committed a tortuous act without the State of New York causing injury within the State of New York out of which act(s) these causes of action arise.

18. Upon information and belief, at all relevant times, Defendants, including Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED committed tortuous act(s) within the State of New York out of which act(s) these causes of action arise.

FACTUAL BACKGROUND

19. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, Actos and pioglitazone hydrochloride for treatment of Type 2 Diabetes Mellitus.

20. Actos received FDA approval in 1999 to treat Type 2 Diabetes Mellitus.

21. Prior to applying for and obtaining approval for Actos, Defendants knew or should have known that Actos use in humans was associated with and/or would cause the induction of bladder cancer and Defendants possessed pre-clinical scientific studies including animal evidence, which evidence Defendants knew or should have known was a signal that bladder cancer risk needed to be further tested and studied before placing Actos on the market.

22. Despite bladder cancer findings in animal model carcinogenicity studies and other pre-clinical evidence, Defendants failed to adequately conduct complete and proper testing of Actos prior to filing its New Drug Application of Actos.

23. It is now known that additional bladder cancer evidence from human clinical trials also became known to Defendants in the early 2000's.

24. From the date of approval to market Actos, Defendants made, distributed, marketed and sold Actos without adequate warning to Plaintiff's prescribing physicians or plaintiff that Actos was associated with and/or could cause bladder cancer and presented a risk of bladder cancer in patients who used it and without adequate warning that Defendants had not adequately conducted complete and proper testing and studies of Actos with regard to carcinogenicity.

25. For over 10 years and to date, Defendants concealed and failed to completely disclose its knowledge that Actos was associated with or could cause bladder cancer or its knowledge that it had failed to fully study and test regarding that risk.

26. Defendants' failure to disclose information that they possessed regarding the failure to adequately study and test Actos for bladder cancer risk further rendered warnings for this medication inadequate.

27. Upon information and belief, Defendants ignored the association between the use of Actos and pioglitazone hydrochloride and the risk of developing bladder cancer.

28. On June 7, 2011, the Caisse nationale de l'assurance maladie, at the request of the French regulatory agency, published a report concluding that there is a statistically significant association between exposure to pioglitazone (Actos) and bladder cancer and that the risk increased with exposure longer than one year.

29. On June 9, 2011, the European Medicine Agency suspended the use of Actos in light of the French Marketing Authorization Committee and the French National Pharmacovigilance Committee's findings regarding the increased risk of bladder cancer.

30. On June 10, 2011, Germany's Federal Institute for Drugs and Medical Devices suspended the use of Actos.

31. On June 15, 2011, the FDA informed the public that use of the diabetes medication Actos for more than one year may be associated with an increased risk of bladder cancer. The Actos label was then changed to reflect this information in the Warnings and Precautions section as well as the patient Medication Guide to include information regarding the risk of bladder cancer.

32. FDA further recommended on June 15, 2011 that healthcare physicians discontinue pioglitazone use in patients with active bladder cancer.

33. On June 17, 2011, Health Canada Press Release indicated that in light of studies suggesting an increased risk of bladder cancer with the diabetes drug pioglitazone, as well as actions taken by other regulatory agencies, Health Canada informed healthcare professionals and Canadians that it is undertaking a review of the drug's status.

34. As a proximate result of Defendants' conduct, Plaintiff Terrence Allen's physician prescribed Actos to said Plaintiff and said Plaintiff used Actos from approximately 2004 through approximately May 2011.

35. As result of using Defendants' Actos, Plaintiff Terrence Allen was caused to suffer bodily injury in January 2011 including cancerous tumor(s) in his bladder and was thus caused to sustain severe and permanent personal injuries, pain, suffering, and mental anguish.

36. The injuries and damages sustained by Plaintiff were caused or substantially contributed to by Defendants' Actos and the Defendants' wrongful conduct.

37. The product warnings for Actos in effect during the time period Plaintiff used Actos were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians as well as Plaintiff of the bladder cancer risk associated with this drug.

38. The Defendants did not provide adequate warnings to Plaintiff's doctors, Plaintiff, the health care community and the general public about the increased risk of serious adverse events that are described herein.

39. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' Actos, Plaintiff would not have purchased or taken Actos and would have chosen to request other treatments or prescription medications.

40. By reason of the foregoing, Plaintiff has developed serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

41. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

42. Defendants had a duty to Plaintiffs to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Actos and pioglitazone hydrochloride into the stream of commerce, including a duty to assure that Actos and pioglitazone hydrochloride would not cause users to suffer unreasonable, dangerous side effects such as cancer.

43. Defendants failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Actos into interstate commerce in that Defendants knew or should have known that using Actos caused a risk of unreasonable, dangerous side effects, including bladder cancer.

44. Despite the fact that Defendants knew or should have known that Actos was associated with and/or caused bladder cancer, Defendants continued to market, manufacture, distribute and/or sell Actos to consumers, including the Plaintiff.

45. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

46. Defendants' negligence and/or recklessness was the proximate cause of Plaintiff's injuries, harm and economic loss which he suffered and/or will continue to suffer.

47. As a result Defendants' negligence and/or recklessness the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

48. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed, believes, and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

49. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

50. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

SECOND CAUSE OF ACTION
AS AGAINST DEFENDANTS
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

51. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

52. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Actos into the stream of commerce, and in the course of same, directly advertised or marketed Actos and pioglitazone hydrochloride to consumers or persons responsible for consumers, and therefore, had a duty to both the Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of the Product.

53. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of Actos and pioglitazone hydrochloride and/or are associated with the use of Actos and pioglitazone hydrochloride.

54. The Actos and pioglitazone hydrochloride manufactured and/or supplied by the Defendants was defective due to inadequate post-marketing warnings and/or instructions

because, after the Defendants knew or should have known of the risks of bladder cancer from Actos use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physicians, and continued to aggressively promote Actos.

55. Due to the inadequate warning regarding bladder cancer, Actos was in a defective condition and unreasonably dangerous at the time that it left the control of the Defendants.

56. Defendants failed to adequately warn Plaintiff and Plaintiff's prescribing physicians of human and animal results in preclinical studies pertaining to bladder cancer and Actos.

57. Defendants' failure to adequately warn Plaintiff and Plaintiff's prescribing physicians of a bladder cancer risk prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of Actos and pioglitazone hydrochloride.

58. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' Actos and pioglitazone hydrochloride, Plaintiff would not have purchased or taken Actos and could have chosen to request other treatments or prescription medications.

59. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the potential life-threatening side effects of the Defendants' Actos and pioglitazone hydrochloride, Plaintiff's prescribing physicians would have discussed the risks of bladder cancer and Actos with the Plaintiff and/or would not have prescribed it.

60. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

61. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and

punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

62. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

63. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

64. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

65. At all times relevant, Actos was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

66. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Actos.

67. Actos and pioglitazone hydrochloride as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation, because when it left the hands of Defendants' manufacturers

and suppliers it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

68. At all times herein mentioned, Actos and pioglitazone hydrochloride was in a defective condition and was unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when Actos was used in a form and manner instructed and provided by Defendants.

69. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

70. At the time of Plaintiff's use of Actos, it was being used for its intended purpose, and in a manner normally intended, namely for the treatment of Type 2 Diabetes Mellitus.

71. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an unreasonable risk to the health of consumers, and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

72. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Actos. This was demonstrated by the existence of other Type 2 Diabetes Mellitus medications which had a more established safety profile and a considerably lower risk profile.

73. Plaintiff could not, by the reasonable exercise of care, have discovered Actos's defects and perceived its danger.

74. The defects in Defendants' product were substantial and contributing factors in causing Plaintiff's injuries.

75. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the aforementioned injuries and damages.

76. Due to the unreasonably dangerous condition of Actos, Defendants are strictly liable to Plaintiff

77. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

78. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

79. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

80. Defendants expressly warranted that Actos was safe for its intended use and as otherwise described in this complaint. Actos did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient and animal studies, the representation that it was safe, and the representation that it did not have high and/or unacceptable levels of life-threatening side effects like bladder cancer, that it would improve health, maintain health, and potentially prolong life.

81. The express warranties represented by the Defendants were a part of the basis for Plaintiff's use of Actos and Plaintiff relied on these warranties in deciding to use Actos.

82. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which the Actos and pioglitazone hydrochloride was to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

83. Actos does not conform to these express representations because Actos is not safe or effective and may produce serious side effects, including among other things bladder cancer, degrading Plaintiff's health, and shrinking his life expectancy.

84. As a result of the foregoing breach of express warranty the Plaintiff was caused to suffer bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

85. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to his use of Defendants' Actos drug.

86. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

87. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

88. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTY
FOR A PARTICULAR PURPOSE)

89. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

90. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

91. The Defendants impliedly represented and warranted to the users of Actos that Actos was safe and fit for the particular purpose for which said product was to be used, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

92. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff's health and shortened his life expectancy.

93. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

94. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Actos was safe and fit for its intended use.

95. Actos and pioglitazone hydrochloride were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

96. Defendants breached the aforesaid implied warranty, as their drug Actos was not

fit for its intended purposes and uses.

97. As a result of the foregoing breach of warranty, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

98. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

99. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

100. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

101. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

102. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Actos and pioglitazone hydrochloride, to treat Type 2 Diabetes Mellitus.

103. Defendants marketed, sold and distributed Actos and knew and promoted the use for which Actos was being used by Plaintiff and impliedly warranted to Plaintiff that Actos was of merchantable quality and fit for the ordinary purpose for which it was intended, namely treating diabetes, improving health, maintaining health, and potentially prolonging life.

104. These representations and warranties aforementioned were false, misleading, and inaccurate in that Actos and pioglitazone hydrochloride were unsafe, degraded Plaintiff's health and shortened his life expectancy.

105. Plaintiff reasonably relied on the skill, expertise and judgment of the Defendants and its representations as to the fact that Actos was of merchantable quality.

106. The Actos and pioglitazone hydrochloride manufactured and supplied by the Defendants was not of merchantable quality, as warranted by the Defendants in that the drug had dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

107. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

108. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including bladder cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future cancer(s), reasonable fear of future cancer, any and all life complications caused by Plaintiff's bladder cancer, as well as the need for lifelong

medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

109. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

110. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

111. By reason of the foregoing, Plaintiff is entitled to compensatory and punitive damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

112. The limitations on liability set forth in CPLR § 1601 do not apply to this action by reason of one or more of the exceptions set forth in CPLR § 1602.

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (VIOLATION OF THE NEW YORK GENERAL BUSINESS LAW SECTION 349)

113. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

114. Defendants have intentionally and wrongfully represented deceptive, inaccurate, false and misleading material information as to the safety of Actos to Plaintiff's physicians, Plaintiff, and other consumers.

115. Defendants knew or reasonably should have known that Actos and pioglitazone hydrochloride carried the risk of serious adverse effects, including but not limited to bladder cancer, to its intended users, including Plaintiff.

116. Defendants failed to disclose material facts in the conduct of trade or commerce in that they did not disclose the risk of serious adverse effects to the intended users of Actos.

117. Reasonable consumers, including Plaintiff, were injured by Defendants' unfair and deceptive acts.

118. By reason of the foregoing, Plaintiffs were caused bodily injury, pain, suffering and economic loss.

119. As a direct and proximate result of Defendants' conduct, Plaintiffs have suffered actual damages and requests an award of damages against Defendants, as authorized by New York General Business Law § 349, et seq. Plaintiffs are entitled to statutory damages, costs and reasonable attorney's fees, plus disgorgement of any profits Defendants earned as a result of their violation of the law.

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (LOSS OF CONSORTIUM)

120. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this complaint as if fully restated here.

121. Plaintiff Susan Allen was and is the lawful spouse of Plaintiff Terrence Allen, and

as such, was and is entitled to the comfort, enjoyment, society and services.

122. As a direct and proximate result of the foregoing, Plaintiff Susan Allen was deprived of the comfort and enjoyment of the services and society of her spouse and has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiff Susan Allen's injuries and damages are permanent and will continue into the future. The Plaintiffs seek compensatory and punitive damages from the Defendant as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiffs attorney's fees;

4. Awarding Plaintiffs the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

Dated: July 29, 2011

By: _____
Paul J. Pennock (PJP 3315)

WEITZ & LUXENBERG, P.C.
Attorneys for Plaintiff
700 Broadway
New York, New York 10003
Phone: (212) 558-5500
Facsimile: (212) 363-2721

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Terrence Allen and Susan Allen

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

(c) Attorney's (Firm Name, Address, and Telephone Number)
Weitz & Luxenberg, P.C.
700 Broadway
New York, New York 10003

DEFENDANTS

Takeda Pharmaceuticals North America Inc.

County of Residence of First Listed Defendant Lake County, IL
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

Unknown

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

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

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

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

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal injury; 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 7/29/10

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

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

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

UNITED STATES DISTRICT COURT

for the

Western District of New York

Terrence Allen and Susan Allen

Plaintiff

v.

Takeda Pharmaceuticals North American, et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* See attached rider.

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:

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

Defendants' Rider

Takeda Pharmaceuticals North America Inc.
One Takeda Parkway
Deerfield, Illinois 60015

Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome
Chuoku, Osaka, Japan

Takeda Pharmaceuticals LLC
One Takeda Parkway
Deerfield, Illinois 60015

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

Takeda Global Research & Development Center Inc.
One Takeda Parkway
Deerfield, IL 60015

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