

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

Gloria L. Marshall, individually and :
as Executor of the Estate of Alvin :
Harris, :

Plaintiff, :

v. :

Actavis, Plc.; :
Actavis Pharma, Inc. f/k/a Watson :
Pharmaceuticals, Inc.; :
Watson Laboratories, Inc.; and :
Anda, Inc., :

Defendants. :

COMPLAINT AND DEMAND
FOR JURY TRIAL

Case No. _____

COMPLAINT

Plaintiff, Gloria L. Marshall, individually and in a representative capacity on behalf of the Estate of Alvin Harris and his surviving heirs, (“Plaintiff”) by and through the undersigned counsel, hereby sues Defendants Actavis, Plc., Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Anda, Inc. (“Defendants”) and alleges as follows:

INTRODUCTION

1. This case involves the prescription drug Androderm®, which is a patch manufactured, sold, distributed and promoted by Defendants as a testosterone replacement therapy.

2. Defendants failed to conduct adequate pre- and post-market safety testing and research to ensure that Androderm® was safe for its intended use and failed to adequately warn physicians about each of the risks associated with Androderm® and the monitoring regimen required to ensure patient safety

3. Defendants misrepresented, concealed, and omitted material facts regarding the safety and efficacy of Androderm® in for hypogonadism and a condition they refer to as "low testosterone."

4. Androderm® causes serious injury and bodily harm. For example, Androderm® causes the hematocrit level to increase, thereby thickening the blood. This effect, if not monitored regularly and controlled properly, can lead to life threatening heart attacks, strokes and thrombotic events.

5. Defendants engaged in aggressive direct-to-consumer and physician marketing and advertising campaigns to grow the market for Androderm®. For example, Defendants' Androderm® website indicates that it is "For men with low testosterone," a condition which the Androderm® website claims is largely caused by the aging process. The Androderm® website also represents that Androderm® is "highly effective" and that its design ensures proper dosing and minimized risks.

6. As a result of Defendants' aggressive and misleading marketing campaign, taken together with the marketing campaigns of other testosterone supplement manufacturers, medical diagnoses of "Low T" have increased exponentially. It is estimated that between 2001 and 2011, testosterone prescriptions tripled among men older than 40. Walk-in-clinics have sprung up across the country and sales are expected to more-than triple from \$1.6 million to \$5 billion by 2017. Yet the New England Journal of Medicine has warned that only 2 percent of men older than 40 should actually be receiving testosterone replacement therapy.

7. As recent safety studies demonstrate, consumers of Androderm® were misled as to the drug's safety and efficacy. In fact, a study released in November 2013 of more than 8,000

men treated in the Veterans Health Administration found testosterone therapy increased the risk of heart attack, stroke, and death by almost 30 percent.

8. As a result of Defendants' misconduct, thousands of men, including Plaintiff, have suffered severe injuries, including but not limited to life-threatening cardiac events, strokes, and thrombolytic events.

PARTIES

9. Plaintiff Alvin Harris, deceased, was a natural person and a citizen of the State of Virginia and used the prescription Androderm® as prescribed and directed by his physician.

10. Defendant Actavis, Plc is a foreign corporation organized and existing under the laws of Ireland with its global headquarters located at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Actavis, Plc also has administrative headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all relevant times herein, Actavis, Plc was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm® in the State of Utah and is therefore subject to the jurisdiction and venue of the State of Utah. Actavis, Plc has conducted business and derived substantial revenue from within the state of Utah.

11. Defendant Actavis Pharma, Inc., formerly known as Watson Pharmaceuticals, Inc., is a domestic corporation organized and existing under the laws of the state of Nevada and maintains its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. By way of background, Watson Pharmaceuticals, Inc. acquired Actavis Group in 2012 and announced shortly thereafter that, as of January 2013, it would change its name to Actavis Pharma, Inc. Watson Pharmaceuticals, Inc. acquired the original manufacturer of Androderm®, TheraTech, Inc., in 1999. At all relevant times herein, Actavis

Pharma, Inc. f/k/a Watson was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm® in the State of Utah and is therefore subject to the jurisdiction and venue of the State of Utah. The current registered agent is C T Corporation System located at 1108 E. South Union Ave, Midvale, UT 84047. Actavis Pharma, Inc. f/k/a Watson Pharmaceuticals, Inc. has conducted business and derived substantial revenue from within this state and Plaintiff's resident state of Virginia.

12. Defendant Watson Laboratories, Inc., is a domestic corporation organized and existing under the laws of the state of Delaware and previously operated at 577 Chipeta Way, Salt Lake City, UT 84108. They currently maintain its current principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all relevant times herein, Defendant Watson Laboratories, Inc., a subsidiary of Actavis, Inc, was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm® in the State of Utah and is therefore subject to the jurisdiction and venue of the State of Utah. The current registered agent is C T Corporation System located at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. Watson Laboratories, Inc. has conducted business and derived substantial revenue from within this state and Plaintiff's resident state of Virginia.

13. Defendant Anda, Inc. is a domestic corporation organized and existing under the laws of the state of Florida and maintains its principal place of business at 2915 Weston Road, Weston, Florida, 33331. At all relevant times herein, Defendant Anda, Inc., a subsidiary of Actavis, Plc, was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Androderm® in the State of Utah and is therefore subject to the jurisdiction and venue of the State of Utah. The current registered agent

is C T Corportation System located at 1200 South Pine Island Rd, Plantation, FL 33324. Anda, Inc. has conducted business and derived substantial revenue from within this state and Plaintiff's resident state of Virginia.

JURISDICTION AND VENUE

14. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds \$75,000, exclusive of interest and cost, and because, among other reasons, Defendant has significant contacts with this district by virtue of doing business within this judicial district.

15. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(1) because certain Defendants resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

GENERAL ALLEGATIONS

16. This action is for damages brought on behalf of Plaintiff who was prescribed and supplied with, received and who took and applied the prescription drug Androderm®, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief for the injuries caused by this drug to Plaintiff.

17. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's damages and resulting death.

18. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Androderm® for the use and application by men, including, but not limited to, Plaintiff.

19. At all times herein mentioned, Defendants were authorized to do business within this state and Plaintiff's resident state of Virginia..

20. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries including the untimely death suffered by Plaintiff herein.

21. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when Plaintiff's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to

misrepresent to the public and to the medical profession that the drug Androderm® is safe and free from serious side effects. In fact, Defendants' are still actively promoting Androderm® as safe and effective to treat low testosterone to this day. Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

OVERVIEW

22. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the diminished production or nonproduction of testosterone.

23. In 1994, when Theratech, Inc., the original manufacturer of Androderm®, asked for FDA approval of Androderm®, hypogonadism was considered to be a relatively uncommon condition among American men.

24. However, after Androderm® was approved by the FDA in 1995, Defendants and other testosterone supplement manufacturers engaged in media campaigns to convince men who were experiencing the typical effects of the aging process that they were suffering from low testosterone, which could be treated with testosterone supplements, including Androderm®. The marketing campaign consisted of advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Androderm® users, and online media including Defendants' website for Androderm®: www.myandroderm.com.

25. Myandroderm.com asserts that 4 to 5 million otherwise healthy men experience low testosterone and encourages male visitors to get "a simple blood test" to determine whether they have low T or testosterone. The site also identifies a number of "symptoms" that it associates with low testosterone which are symptoms that are more commonly associated with aging, weight gain, and lifestyle.

26. Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed and that conditions associated with normal aging could be caused by low testosterone levels.

27. As part of their marketing campaign, Defendants promoted Androderm® as an easy to apply patch for testosterone replacement therapy. Defendants contrast their product's at-home patch with other topical testosterone supplements in that the patch protects against the transfer of testosterone to others and assures proper dosing. *See* Androderm Patches, *available at* http://www.myandroderm.com/androderm_patches.aspx#HighlyEffective (last visited March 26, 2014).

28. Defendants' marketing campaign encouraged men to discuss testosterone replacement therapy with their doctors and consumers and their physicians relied on Defendants' promises of safety, effectiveness, and ease of use. Although prescription testosterone replacement therapy has been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

29. As a direct result of this marketing campaign, sales of replacement therapies have more than doubled since 2006 and are expected to triple to \$5 billion by 2017 according to forecasts by Global Industry Analysts. *See* Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, *Bloomberg Business Week*, *available at*: <http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra>.

30. However, a study published in the *Journal of the American Medical Association* ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 – 2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue

and one quarter of men had not had their testosterone levels tested before being prescribed with testosterone replacement therapy.

31. The marketing campaign was successful in creating the belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of Androderm® is safe for human use, even though Defendants knew or should have known this to be false, and even though Defendants had no reasonable grounds to believe them to be true.

32. What consumers received, however, were not safe drugs, but a product which causes life-threatening injuries, including heart attacks, stroke, and thrombotic events.

33. There have been a number of studies suggesting that testosterone in men increases the risk of heart attacks and strokes.

34. In 2010, a New England Journal of Medicine Study entitled “Adverse Events Associated with Testosterone Administration” was discontinued after an exceedingly high number of men in the testosterone group had suffered adverse events.

35. In November of 2013, a JAMA study was released entitled “Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels” which indicated that testosterone therapy raised the risk of death, heart attack and stroke by approximately 30%.

36. On January 29, 2014, a study was released in PLOS ONE entitled “Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men” which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease.

FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

37. The U.S. Food and Drug Administration approved Androderm® on September 29, 1995 for the treatment of adult males who have low or no testosterone. Since receiving FDA approval, the Defendants, their subsidiaries, and their predecessors advertised and marketed Androderm® as safe and effective to treat low testosterone in men.

38. Androderm® is a patch gel containing 2, 2.5, 4, or 5 mg of testosterone, applied to the stomach, arms, back or thighs and enters the body through transdermal absorption.

39. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

40. In men, testosterone levels normally begin a gradual decline after the age of thirty.

41. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood (ng/dl). However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

42. Androderm® may produce undesirable side effects to patients who use the drug, including but not limited to, death, cardiovascular events, stroke, and thrombotic events.

43. In addition to the above, Androderm® has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users. Patients taking Androderm® may experience enlarged prostates and increased serum prostate-specific antigen levels.

44. Secondary exposure to Androderm® can cause side effects in others, including women and children. For example, testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into contact with Androderm®.

45. Defendants' marketing strategy has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

46. Defendants' advertising campaign sought to create the image and belief by consumers and their physicians that the use of Androderm® was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

47. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Androderm®. Defendants deceived potential Androderm® users by relaying positive information through the press, including testimonials, to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

48. Defendants concealed material relevant information from potential Androderm® users and minimized user and prescriber concern regarding the safety of Androderm®,

49. In particular, in the warnings Defendants give in their advertisements, Defendants fail to mention any potential cardiac events, stroke, pulmonary embolisms, or other dangerous side effects and falsely represent that Defendants adequately tested Androderm® for all likely

side effects. The Defendants also failed to provide adequate warnings and instructions regarding the importance of adequate monitoring of hematocrit levels.

50. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Androderm®. If Plaintiff in this action had known the risks and dangers associated with Androderm®, Plaintiff would not have taken Androderm® and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

51. Plaintiff, Alvin Harris, deceased, was prescribed Androderm® and used it as directed from approximately October 2005 to February 2008. Plaintiff resumed using Androderm® July 2008 until May 2012.

52. Plaintiff was 64 (sixty-four) years of age when he was prescribed and used testosterone for symptoms he attributed to low testosterone.

53. Plaintiff had no history of clotting events or stroke prior to taking testosterone. In keeping with his proactive lifestyle, Plaintiff agreed to initiate testosterone treatment.

54. Plaintiff was diagnosed with Deep Vein Thrombosis (DVT) on or about October 14, 2011. Plaintiff experienced symptoms and was diagnosed with a stroke on or about June 21, 2012. Plaintiff experienced a second stroke on or about July 24, 2012, which contributed to his untimely death on August 3, 2012.

55. Had Defendants properly disclosed the risks associated with testosterone, Plaintiff would have avoided the risk of DVT and Stroke by either not using testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

56. Plaintiff files this lawsuit within two (2) years of first suspecting that the Androderm® was the cause of appreciable harm sustained by Plaintiff, within two (2) years of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering their injuries and the wrongful conduct that cause such injuries. Plaintiff could not by the exercise of reasonable diligence have discovered any wrongdoing, nor could Plaintiff have discovered the causes of his injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when Plaintiff's injuries were discovered, their causes were not immediately known.

57. Plaintiff did not suspect, nor did he have reason to suspect, that wrongdoing had caused his injuries, nor did Plaintiff have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the defects in the Androderm® and the wrongful conduct of the Defendant as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of Defendant. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant herein misrepresented and continue to misrepresent to the public, to the medical profession and to Plaintiff that the Androderm® is safe and free from serious defects and side effects and Defendant has fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

58. As alleged herein, as a direct, proximate, and legal result of Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to DVT and Stroke. Plaintiff has endured pain and suffering, has

suffered economic loss, including incurring significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

59. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

60. The Androderm® manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks. The Androderm® manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Androderm®, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

61. As a direct and proximate result of Plaintiff's reasonably anticipated use of Androderm® as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE

62. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though set forth herein.

63. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Androderm.

64. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Androderm® and failed to adequately test and warn of the risks and dangers of Androderm®.

65. Despite the fact that Defendants knew or should have known that Androderm® caused unreasonable, dangerous side effects, Defendants continued to market Androderm® to consumers including Plaintiff, when there were safer alternative methods of treating loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions Androderm®'s advertising claims are caused by low testosterone.

66. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

67. Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

THIRD CAUSE OF ACTION
FOR BREACH OF IMPLIED WARRANTY

68. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

69. Prior to the time that the aforementioned products were used by Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Androderm® was of merchantable quality and safe and fit for the use for which it was intended.

70. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Androderm®.

71. Androderm® was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Androderm® has dangerous propensities when used as intended and will cause severe injuries to users.

72. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
FOR BREACH OF EXPRESS WARRANTY

73. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth here.

74. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that

Androderm® is safe, effective, fit and proper for its intended use. Plaintiff purchased Androderm® relying upon these warranties.

75. In utilizing Androderm®, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that Androderm is unsafe and unfit for its intended uses.

76. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
FRAUD

77. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

78. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Androderm®, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Androderm®, which the Defendants had a duty to disclose.

79. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Androderm® and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Androderm®. Defendants knew of the foregoing, that Androderm® is not safe, fit and effective for human consumption, that using Androderm® is hazardous to health, and that Androderm® has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

80. Defendants concealed and suppressed the true facts concerning Androderm® with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not

prescribe Androderm®, and Plaintiff would not have used Androderm®, if they were aware of the true facts concerning its dangers.

81. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

82. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

83. From the time Androderm® was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Androderm® was safe, fit and effective for human consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Androderm® and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

84. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

85. The representations by the Defendants were in fact false, in that Androderm is not safe, fit and effective for human consumption, using Androderm® is hazardous to health, and Androderm® has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

86. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance on the prescription, purchase and use of Androderm®.

87. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Androderm®. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Androderm. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

88. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION
WRONGFUL DEATH

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

90. Plaintiff is the surviving significant other, successor-in-interest, and heir to the Decedent, who used Defendants' Androderm® and was injured and died as a result. Decedent was prescribed, supplied with, and consumed Androderm as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactures, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold, or otherwise placed in the stream of interstate commerce by Defendants.

91. The injuries and damages of Plaintiff and Decedent were caused by the wrongful, acts, omissions, and fraudulent misrepresentations of Defendants' Androderm®, the Decedent suffered catastrophic and ultimately fatal injuries.

92. As a result of the death of Decedent, Plaintiff was deprived of love, companionship, affection, society, solace, and moral support of the Decedent.

93. Plaintiff is entitled to recover economic and non-economic damages against all

Defendants for the wrongful death directly and legally caused by the defects in Defendants' Androderm® and by the Defendants' conduct as described herein.

94. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of her husband's companionship and society, and accordingly, the Plaintiff has been caused great harm and mental anguish.

EIGHT CAUSE OF ACTION
SURVIVAL ACTION

95. Plaintiffs hereby incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

96. As a direct and proximate result of the Defendants' conduct, and failure to comply with applicable standards, as outlined above, the Injured Party suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to the Injured Party's death.

97. The representative/administrator/successor-in-interest of the Injured Party's estate brings this claim on behalf of the Injured Party's estate and the Injured Party's beneficiaries for damages.

98. The representative/administrator/successor-in-interest of the Injured Party's estate further pleads all survival damages allowed by statute and law in the state or states in which the causes of action accrued.

PUNITIVE DAMAGES ALLEGATIONS

99. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

100. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Androderm® users and for the primary purpose of

increasing Defendants' profits from the sale and distribution of Androderm®. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

101. Prior to the manufacturing, sale, and distribution of Androderm®, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Androderm®.

102. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Androderm® and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Androderm®. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Androderm® knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

103. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants jointly and severally as follows:

- (a) For general damages in a sum in excess of the jurisdictional minimum of this Court;
- (b) For medical, incidental, and hospital expenses according to proof;
- (c) For pre-judgment and post-judgment interest as provided by law;
- (d) For full refund of all purchase costs Plaintiff paid for testosterone;
- (e) For compensatory damages in excess of the jurisdictional minimum of this Court;
- (f) For consequential damages in excess of the jurisdictional minimum of this Court;
- (g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
- (h) For attorneys' fees, expenses, and costs of this action; and
- (i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: August 1, 2014

Respectfully submitted,



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JS 44 (Rev. 3/13)

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 NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Gloria L. Marshall, individually and as Executor of the Estate of Alvin Harris

DEFENDANTS

Actavis, Plc.; Actavis Pharma, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; and Anda, Inc.

(b) County of Residence of First Listed Plaintiff Fairfax Cty, Virginia
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Morris Cty, NJ
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Robert J Debyr & Associates
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915

2014 AUG - 1

3:43

DISTRICT OF UTAH

BY: DEPUTY CLERK

IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

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

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

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

	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	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities Employment <input type="checkbox"/> 446 Amer. w/Disabilities Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition) <input type="checkbox"/> 465 Other Immigration Actions	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

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

VI. CAUSE OF ACTION (Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 USC Sec 1332 - This action involves a pharmaceutical claim arising out of the use of Androderm.

VII. Previous Bankruptcy Matters (For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

VIII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

IX. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

X. This case (check one box) Is not a refiling of a previously dismissed action is a refiling of case number previously dismissed by Judge

DATE 8/1/14

Case: 2:14cv00567
Assigned To : Pead, Dustin B.
Assign. Date : 8/1/2014
Description: Marshall v Actavis et al

