

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

**Janet Makinen, Judith Renee Lasswell,
Christina Brothers, & Kathleen M. Callahan,
on behalf of themselves and others similarly
situated**

CASE NUMBER: 06CV1762

Plaintiff,

-against-

**Sanofi-Aventis U.S. LLC and Corporate Does 1-3
Being the US predecessors of Sanofi-Aventis U.S.
LLC;**

Jury Trial Demanded

**SUMMONS IN A CIVIL
ACTION**

Defendants.

To the above named Defendants:

YOU ARE HEREBY SUMMONED and required to file with the Clerk of this Court and serve upon the Plaintiff's Attorney *Susan Chana Lask, Esq.* Attorney for Plaintiff, 244 Fifth Avenue, Suite 2369 New York, NY 10001 (212) 358-5762 , an answer to the complaint which is herewith served upon you, within twenty (20) days after the service of this summons, exclusive of the day of service, where service is made by delivery upon you personally within New York State. If you fail to do so, judgment will be taken against you by default for the relief demanded in the complaint.

CLERK

DATE

BY DEPUTY CLERK

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

**Janet Makinen, Judith Renee Lasswell,
Christina Brothers, & Kathleen M. Callahan,
on behalf of themselves and others similarly
situated,**

Plaintiffs,

-against-

**Sanofi-Aventis U.S. LLC and Corporate Does 1-3
Being the US predecessors of Sanofi-Aventis U.S.
LLC;**

Defendants.

Case No. 06CV1762

Originally Filed 3/6/06

**FIRST AMENDED
CIVIL COMPLAINT UNDER FRCP 15(a)
CLASS-ACTION**

Jury Trial Demanded

JURISDICTION & VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §1332. The Class Action Fairness Act of 2005, Pub. L. 109-2, 119 Stat. 4, wherein the class (1) has 100 or more class members; (2) seeks damages in excess of \$5 million in aggregate stakes; and (3) has at least one defendant who is a citizen of a different state than at least one member of the proposed class.
2. Venue is proper in this District pursuant to 28 U.S.C. §1391 as Defendant's Investor's Relations Office is located at 90 Park Avenue, New York, NY 10016, Defendants advertised in this District, received substantial compensation and profits from sales of the drug in this District, and made material omissions and misrepresentations and breached warranties in this District and there are numerous consumers in this venue damaged by Defendants' conduct as well as Defendants' promotional and sales activities are transacted here.
3. At all relevant times Defendants used the ports of New York or the roads and other means of transportation in the State of New York to transport their products, including Ambien®, into the State of New York where they sold and/or distributed their products to New York residents or entities in New York.

PARTIES

4. Plaintiff, Janet Makinen, is a resident of the State of Florida, County of Pasco.
5. Plaintiff, Christina Brothers, is a resident of the State of Texas, City of Cedar Park.
6. Plaintiff, Lieutenant 03 Judith Renee Lasswell, is a resident of the State of Florida, Tampa, County of Hillsborough.
7. Plaintiff, Kathleen M. Callahan, is a resident of the State of New York, City of Shokan, Ulster

County.

8. Since filing the Complaint and filing this Amended Complaint, some 400 persons nationwide have contacted Plaintiff's counsel via telephone, letters and e-mail complaining about Defendants' product causing adverse side effects covered by this action and some 200 persons have forwarded signed consent forms to include them in this class-action.

9. Defendant Sanofi-Aventis U.S. LLC ("Sanofi") is registered in the State of Delaware and is a global health care company, which among its many core therapeutic areas are included diseases of the central nervous system and they manufacture and promote Ambien® is a drug that Defendants .

10. Upon information and belief, Defendant Sanofi is listed on the New York Stock Exchange (NYSE: SNY) as described on their website and in a March 20, 2006 "Statement responding to recent media reports regarding appropriate use of Ambien® (zolpidem tartrate) CIV in the U.S." Distributed on their website at <http://www.sanofi-aventis.us>.

11. Defendant Sanofi maintains a commercial investor relations office at 90 Park Avenue, New York, New York 10016 and corporate headquarters at 300 Somerset Corporate Blvd. Bridgewater, New Jersey.

12. Defendants are subject to the consumer laws of New Jersey as they maintain their corporate offices in New Jersey.

13. Defendants Corporate Does 1-3 are the US predecessors of Defendant Sanofi that have been involved in the manufacture, sales, distribution and research and development of Ambien® at various points of time relevant to this action.

Defendants' Nationwide Activities Regarding Ambien®

14. Defendants are a foreign corporation, company or other business entity which have been and/or is now engaged in the business of manufacturing, selling, distributing and engaging in promotional activities via television, radio and print media nationwide for the drug Ambien®.

15. At all relevant times Defendants were and are in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand name prescription drug Ambien®.

16. At all relevant times Defendants directly marketed Ambien® to putative class members in all states and territories of the United States.

17. Defendant Sanofi maintains 14 geographical sites throughout the country to promote Ambien®. About 8,000 of those sites are field sales and medical affairs representatives, making Defendant's sales force the second largest in the U.S. pharmaceutical industry.

18. Defendant Sanofi has four U.S. based research and development ("R&D") sites employing approximately 2,300 scientists, physicians and support staff. There are Bridgewater, NJ and Great Valley, PA sites covering all aspects of R&D, a Tucson Center specializing in Combinatorial Chemistry and a Cambridge, MA site handling Genomics Research.

SUBSTANTIVE ALLEGATIONS

19. The side effects pertinent to this action are amnesic nocturnal eating behavior and/or Sleep-Related Nocturnal Eating Disorder (NS- RED) (excessive eating while asleep) (both referred to sometimes herein as “sleep-eating”) and somnambulism (sleepwalking) and the activities engaged in while sleepwalking.

Plaintiff Makinen

20. Plaintiff Janet Makinen is a housewife and was first prescribed Ambien® in about 1998 at 10 mg at before bedtime for her insomnia. She took it until about June, 2005. Plaintiff was a migraine sufferer who occasionally took Imitrex.

21. Approximately two weeks after taking Ambien® as prescribed, Plaintiff experienced adverse effects .

22. After being asleep for about an hour to two hours, she multiple times experienced the side effect of somnambulism and amnesic nocturnal eating behavior, walked to her kitchen and ate hundreds of calories of food, including raw eggs, uncooked yellow rice, cans of vegetables, loaves of bread, bags of chips and bags of candy.

23. Plaintiff would wake up about an hour later vomiting from the amnesic nocturnal eating .

24. Plaintiff became irate when her husband tried to stop her eating while sleeping.

25. Plaintiff experienced a substantial weight gain as a result of the Ambien® side effects.

Plaintiff suffers from GERD, a food regurgitation, and other stomach problems, including an ulcer, as a result of the Ambien® side effects.

26. Plaintiff never experienced the side effects of somnambulism and amnesic nocturnal eating behavior once she stopped taking Ambien® in 2005.

Plaintiff Lieutenant 03 Lasswell

27. Plaintiff is a Lieutenant 03 in the US Navy stationed at USCENTCOM, Tampa, Florida.

28. Plaintiff was prescribed 10 mg Ambien® in February, 2005 for insomnia and took it as prescribed.

29. In February, 2005 ,after taking Ambien® for about a few days, Plaintiff took Ambien® one night at about 7 p.m., went to sleep and at about 9 p.m. entered into somnambulism.

30. Plaintiff dressed herself and walked to the intelligence center where she worked in a stumbling almost drunken state and talking nonsense with her coworkers. The coworkers walked her back to her barracks and put her back to bed and told her about the incident the next day. Plaintiff has no memory of this incident.

31. The week of August 26, 2005 Plaintiff lost gaps of memory as a result of taking Ambien®.

32. Plaintiff has no memory of those events as a result of Ambien®.

33. On September 3, 2005 at 6 a.m Plaintiff ingested her Ambien® in bed to go to sleep for the rest of that day, which was a Saturday.

34. Plaintiff entered into somnambulism at about 9 a.m. and took another Ambien® while in that state. Plaintiff never fell asleep but instead went to the Post Office and mailed packages, went to the Base library and returned overdue books and checked out two DVDs, then believes she went to the dry cleaners, then went to the Base Exchange with a DVD to return to the store for a refund and while there wandered around the store aimlessly.

35. Plaintiff does not recall these events and only remembers pieces of what happened that day.

36. On September 3, 2005 Plaintiff was arrested by her Base Police for shoplifting where she apparently drove to a Marshalls and other stores in the area and for taking a printer cartridge at the Base exchange.

37. Plaintiff faces larceny charges and her top secret security clearance at the US Navy was revoked over this incident with DVDs. She also faces a possible dishonorable discharge from the Navy after 17 years and severance pay of over \$110,000 before taxes and a substantial pension.

Plaintiff Brothers

38. Plaintiff Brothers worked as a financial analyst and presently studies for her CPA.

39. She was prescribed 10mg of Ambien® for transient insomnia in early May of 2005

40. On the third day of taking her prescription she took her prescribed dosage at around 1:57 a.m. after retiring to bed. She entered somnambulism and the next thing she recalls is waking up on the concrete floor of a jail cell.

41. She discovered later from the police report that she got out of bed about 6 am, left her house, drove her mother's car into a two parked vehicles and left the scene. She returned home as if nothing happened, had a conversation with her mother and was arrested in her bedroom that morning.

42. Plaintiff has no memory of the events that night and into the morning and leading to her Arrest.

43. Plaintiff was severely bruised and injured and faces criminal charges for the occurrence while she was under the influence of Ambien®.

Plaintiff Callahan

44. Plaintiff is a lab technician in hematology in a New York State office.

45. She was first prescribed Ambien® at 10 mg for insomnia in about 2003

46. Plaintiff took Ambien® intermittently from about 2003 through about January, 2005.

47. Plaintiff was taking daily during that period Xenical, a fat blocker and Selexa, an antidepressant.

48. Plaintiff always took the Ambien® and went right to bed.

49. Plaintiff experienced both amnesic nocturnal eating behavior (excessive eating while asleep) and somnambulism (sleepwalking) as side effects of Ambien®.

50. There were times when she found her refrigerator door open, crumbs on the floor and her

hands had chocolate icing on them and a ring of chocolate around her mouth. Another time she woke up in bed with her hand in a box potato chip box. Plaintiff would find the next morning dishes in her sink showing evidence of her eating. Another time she woke up with her telephone in her hand which was a result of a phone conversation she had with her doctor that she has no recollection of, which is one of multiple unrecalled phone conversations she had under the influence of Ambien®.

51. The most egregious event that occurred was in or about September, 2004 when Plaintiff took her prescribed dose, was knocked out quickly and fell asleep in her chair in front of the television. Plaintiff has no memory of anything past that.

52. What occurred that night was Plaintiff entered somnambulism and opened her door for a neighbor who sexually assaulted her.

53. The next most egregious event occurred January, 2005. After working a night shift, Plaintiff some time during the day took her prescribed dose, went to bed and fell asleep. Plaintiff has no memory of anything except that she woke up some 10 hours later and discovered she was nude, had cuts and scrapes on her knees and bruises on her body. Her arms hurt and she was sore. She woke up confused, with five memories only. The memories were (1) being driven in her car by her neighbor, it was dark and she wanted to sleep, (2) the neighbor was pushing food at Plaintiff while she was in her chair, (3) being pulled backwards and trying to pull herself away, (4) trying to cover herself with her lab coat (5) her neighbor coming out of her bathroom.

54. Plaintiff discovered she was sexually assaulted again by the same neighbor who found her in her car. The matter is now in the hands of the District Attorney as a sexual assault.

55. After that incident, Plaintiff never took Ambien® again.

RESEARCH CONFIRMING ADVERSE SIDE EFFECTS OF AMBIEN® AS EXPERIENCED BY PLAINTIFFS

56. Ambien®, its chemical name being Zolpidem, has been linked by scientific studies with sleepwalking and sleep-eating, to wit: Mendelson WB. "Sleepwalking associated with zolpidem" (letter). J Clin Psychopharmacol 1994;14:150.; Harazin J, Berigan TR. "Zolpidem tartrate and somnambulism". Mil Med 1999;164:669-70.; Sauvanet JP, Maarek L, Roger M, Renaudin J, Louvel E, Orofiamma B. "Open longterm trials with zolpidem in insomnia." In: Sauvanet JP, Langer SZ, Morselli PL, eds. "Imidazopyridines in sleep disorders." New York: Raven Press, 1988:339- 49. Ganzoni E, Santoni JP, Chevillard V, Sebille M, Mathy B. "Zolpidem in insomnia: a 3-year post-marketing surveillance study in Switzerland." J Int Med Res 1995;23:61-73. Iruela LM. "Zolpidem and sleepwalking (letter)". J Clin Psychopharmacol 1995;15:223. In the T.I. Morgenthaler, M.H. Silber , "Amnestic sleep-related eating disorder associated with zolpidem", Sleep Medicine 3 (2002) 323–327. Additionally, The National Sleep Foundation Meeting Minutes of June 22, 2005 relates zolpidem as a cause of sleep-eating.

CLASS ACTION ALLEGATIONS

57. The class of plaintiffs consists of and includes all persons in the United States that have purchased and ingested Ambien® from 2000 to date and experienced the side effects of amnesic nocturnal eating behavior and/or Sleep-Related Nocturnal Eating Disorder (NS-RED) (excessive eating while asleep) and somnambulism (sleepwalking) in which they were injured or damaged as a result of these side effects, as more fully described herein below.

58. The class does not include the defendants and/or their agents, subsidiaries or employees. Defendants caused or will cause, and all class members have suffered or will suffer, financial damage and/or personal injury as a result of the acts or omissions of Defendant.

59. The class is sufficiently numerous that joinder of all members is impracticable. Upon information and belief, more than 1000 persons have suffered injury or damage as a direct and proximate result of ingesting Ambien® during this class period.

60. Plaintiffs will fairly and adequately protect the interests of the class. The interests of the class representatives are coincident with, and not antagonistic to, those of the other class members and Plaintiffs are represented by experienced and able counsel who has previously litigated class actions and similar types of cases. Plaintiffs have diligently worked closely with Counsel Susan Chana Lask, and as a team together they have organized research, experts and proofs substantiating the adverse side effects and damages as alleged herein.

61. Susan Chana Lask, Esq. is an experienced litigator who handled nationwide class actions, including multi-million dollar complex Federal Hazardous Waste and Products Liability Litigation because of her chemistry background. She was involved with numerous government agencies involving Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Superfund and the EPA starting with her work in 1986 with the preeminent national firm of Rivkin, Radler, Dunne and Bayh (working with New York's then Senators and partners Senators Dunne and Bayh). She was involved in the class-action case of the chemical warfare Agent Orange against Morton Thikol, the chemical creosote pollution case against James Graham Brown Foundation in Kentucky, Alabama and Florida, and class-action cases regarding the existence of PCB pollutants in the Hudson River. In 1994 she worked in Los Angeles with class action counsel against Taco Bell for laborers' wages, which was a success. Her successful work with attorney generals nationwide and other government agencies in 2002 helped effectuate a successful settlement of the class action RICO consumer fraud suit against Miss Cleo and the end of her \$8 Million Dollar Corporation that defrauded consumers nationwide. In 2003 she commenced and settled a class action for New York City drivers wherein the City of New York changed traffic violation laws upon Ms. Lask demonstrating class members were being ticketed under a law that did not exist. In 2006 she discovered a class of detainees in two New Jersey Counties that were illegally strip searched and her amended complaint to class action was granted based on her discoveries. Since 1995 she has been an expert in television, print and

radio media on various legal issues, and in 1995 represented one of the most widely publicized international white collar criminal cases involving complicated air traffic laws leading the news media to follow Ms. Lask's work worldwide since then. Finally, she was counsel to a Lloyd's of London agent in New York investigating and litigating worldwide multi-million dollar complex litigation freight losses. Her record has been stellar and she has not had as much as a sanction in any of the thousands of cases she has represented since 1989. She has already garnered expert opinions on this particular case and scientific research and data supporting the allegations in this case. Her mission is to adequately protect the class, to obtain a fair settlement for each member and a fair warning for future consumers of the product at issue in this case.

62. There are questions of law and fact common to the class. Common questions of law include the liability Defendants for manufacturing, producing, selling, advertising and/or distributing Ambien®. Common questions of fact include, but are not limited to, (a) the available scientific and technical knowledge of amnesic nocturnal eating behavior and somnambulism when Ambien® was manufactured and sold; (b) Defendants' knowledge or reason to know of the health hazards or adverse side effects of Ambien®; (c) Defendants' failures to test or adequately test Ambien® while marketing the drug; (d) Defendants' failures to test or adequately test Ambien® post-marketing the drug after receiving FDA approval and pursuant to their obligations under 21 CFR §§ 314.80-81; (e) Defendant's failure to warn consumers of the adverse side effects and hazards that are the subject of this action; (f) whether Defendants' conduct constitutes a false or misleading practice in violation of New Jersey law; (g) whether Defendants concealed or suppressed material information concerning the safety and efficacy of Ambien®; (h) whether Defendants engaged in deceptive or misleading promotional campaigns designed to induce doctors to prescribe the drug to consumers who purchased it for a good night's sleep yet they did not get a full nights sleep from the product due to adverse side effects; and (i) whether consumers were damaged as a result of Defendants' misrepresentations and omissions and, if so, the amount of damages.

63. Plaintiffs' claims are typical of the class members' claims and derive from a common nucleus of operative facts in that the Defendants' Ambien® was purchased, prescribed, ingested and caused harm to the Plaintiffs by causing them to enter a hypnotic state where they functioned to their detriment by entering into an "auto-pilot" trance-like state and operating dangerous machinery, vehicles, binge eating and engaging in activities they have no memory of, resulting in damage to themselves, their careers, reputations and to others.

64. Plaintiffs and all similarly situated class members have suffered and will continue to suffer injury and damage as a result of Defendants' actions.

65. Upon information and belief, the named Plaintiffs not only represent a large number of class members who have been harmed, but also, due to Defendants' failure to adequately warn of the

potential dangers of Ambien®, Plaintiffs represent an even larger number of class members who have yet to discover that they have been or will be injured as for the most part the side effect of Ambien® is amnesia when amnestic nocturnal eating behavior and somnambulism occur . For these reasons, a class action is especially appropriate to promote judicial efficiency and to protect class members' interests and rights.

66. Each class member has been or will be similarly injured by Defendant's acts and omissions in manufacturing, marketing, selling, designing, and/or supplying Ambien®.

67. Class treatment is a superior method for the fair and efficient adjudication of the issues in dispute because it permits a large number of injured parties, joinder of whom is impracticable, to prosecute their common claims in a single forum simultaneously. In addition, it does not infringe upon the rights of those class members who wish to opt-out and litigate their claims separately.

68. The class action provides an efficient method whereby the relative rights of the class members and Defendant can be fairly managed.

ACTS AND OMISSIONS OF DEFENDANTS

69. Upon information and belief, Defendants obtained the patent to Ambien® under patent No. 4,382,938 in about 2000, and said patent expires October 21, 2006.

70. Upon information and belief, as reported by various media, Defendants' Ambien® generated revenues of \$1.99 billion and 26.2 million prescriptions in 2005.

71. Defendants designed, manufactured, marketed, sold, marketed and/or placed into the stream of commerce Ambien® knowing that it had side effects of amnestic nocturnal eating behavior, sleep eating and somnambulism.

72. Defendants suppressed, concealed, misrepresented and/or obscured data regarding the adverse side effects of Ambien®.

73. Defendants were aware or should have been aware of studies and data linking Ambien® and its side effects of sleep walking and sleep eating, but nevertheless continued to design, produce, manufacture, market, distribute and/or sell it without any warnings as to potential detrimental side effects of sleep-eating and somnambulism associated with it.

74. Despite their actual knowledge of the detrimental side effects, Defendants failed to warn or adequately and sufficiently warn the Plaintiffs and other class members, the public, governmental bodies and the Medical Community of the harmful and detrimental side effects.

75. Defendants failed to test or adequately test Ambien® prior to manufacturing, marketing, distributing and/or selling it.

76. Defendants published false and/or misleading information about the safety and potential adverse side effects of Ambien®.

77. Since March, 2006, Defendant Sanofi continued its deceptions to the public by making multiple false and misleading public statements in the media by its agents and representatives in

response to the consumer complaints of amnesic nocturnal eating behavior and/or Sleep-Related Nocturnal Eating Disorder (NS- RED) (excessive eating while asleep), stating somnambulism (sleepwalking) is listed in the Ambien® contraindications and that specific side-effect covers sleep-eating.

78. Specifically, at Defendant Sanofi's website to the public at <http://www.sanofi-aventis.us/> in its March 20, 2006 "Statement responding to recent media reports regarding appropriate use of AMBIEN® (zolpidem tartrate) CIV in the U.S.", Defendant Sanofi states:

"Recent anecdotal reports in the media have focused on rare occurrences of sleepwalking and sleep-related eating in patients who may also be taking AMBIEN. The safety profile of AMBIEN is well established and reported in the AMBIEN Prescribing Information approved by the US Food and Drug Administration (FDA). After recently conducting a thorough analysis sanofi-aventis has not observed any significant change in that safety profile of AMBIEN. The information currently contained in the US Prescribing Information remains accurate: somnambulism is a possible rare adverse event.

79. Defendant Sanofi's statement purposely minces words to misrepresent to the public and deflect public attention from the dangerous adverse side effect of sleep eating by claiming sleep walking and sleep eating are one and the same adverse side effect when they are actually very different events.

80. Defendant Sanofi also fails to admit that upon information and belief its contraindications only recently list somnambulism as an adverse side effect and it was not listed during the years 2000 to 2005.

COUNT I: NEGLIGENCE

81. Plaintiffs hereby incorporate by reference each paragraph of this Complaint, as if fully set forth herein.

82. At all times material hereto, Defendants designed, developed, manufactured, marketed, delivered and/or sold Ambien®.

83. At all times material hereto, Defendants knew or should have known that Ambien® would be used by Plaintiffs and class members who would suffer the adverse side effects of amnesic nocturnal eating behavior (excessive eating while asleep) and somnambulism (sleepwalking).

84. At all times material hereto, Defendants designed, developed, manufactured, marketed, distributed and/or sold Ambien® knowing, or through the exercise of reasonable care, should have known that it was defective and would damage the Plaintiffs and class members.

85. Defendants failed to warn, or adequately or sufficiently warn, either directly or indirectly, the foreseeable users of the potential hazards and costs associated with the use of Ambien®.

86. Defendants failed to test or adequately test Ambien®.

Defendants systematically failed to represent accurately to the Plaintiffs and class members, either directly or indirectly, that Ambien® can pose a health hazard and injure persons by its adverse side-effects or that Ambien® was defective.

87. Defendants systematically failed to monitor and investigate reported instances of sleep eating and somnambulism (sleepwalking) resulting from the use of Ambien®.
88. Defendants systematically failed to train, warn or educate, or inadequately trained, warned or educated Plaintiffs, class members or their Doctors of the signs and symptoms of adverse reactions of amnesic nocturnal eating behavior (excessive eating while asleep) and somnambulism (sleepwalking) to the use of Ambien® or that users of Ambien® should be carefully observed for signs or symptoms of adverse side effects, even though it had a duty to do so.
89. Defendants systematically failed to acknowledge responsibility for adverse side effects caused by Ambien®, thereby contributing to the false impression cultivated by Defendants that Ambien® is safe.
90. Defendants failed to represent accurately to Plaintiffs and class members, either directly or indirectly, that Ambien®, used for its ordinary and intended purpose, can pose a health hazard and/or injure users as a result of its adverse side effects, whereby class members were induced to purchase and utilize Ambien® and continue to purchase and utilize the product without knowledge that it caused adverse side effects of sleep eating.
91. Defendants at all times failed and continue to fail to perform their duties to warn.
92. Defendants' actions, as alleged, constitute violations of statutory and regulatory provisions.
93. Defendants' acts and omissions complained of in this count were committed by them with indifference to the rights of the Plaintiffs and other class members and were carried out to maximize the sale and use of Ambien®.
94. As a direct and proximate result of Defendant's conduct, Plaintiffs and class members have suffered and will continue to suffer damage.

COUNT II: STRICT LIABILITY

95. Plaintiffs hereby incorporate by reference each paragraph of this Complaint, as if fully set forth herein.
96. Defendants have been and are engaged in the business of designing, manufacturing, marketing, distributing and/or selling Ambien®.
97. Ambien®, as used by Plaintiffs and class members was defective and unreasonably dangerous, unfit for its intended use because of the deleterious and highly harmful effects it causes to Plaintiffs and other class members.
98. Defendants reasonably expected Ambien® to be used by Plaintiffs and other class members.
99. Plaintiffs and other class members used Ambien® in the manner in which was intended and expected by Defendants.
100. At the time of such use, Ambien® had not been changed from the time it was designed, manufactured, marketed, distributed or sold by Defendants.
101. As a direct and proximate cause of Plaintiffs and class members using Defendants'

defective and unreasonably dangerous product, Plaintiffs and other class members have suffered and will continue to suffer damages.

COUNT III: BREACH OF IMPLIED WARRANTIES

102. Plaintiffs hereby incorporate by reference each paragraph in this Complaint, as if fully set forth herein.

103. Defendants failed to represent accurately to class members, either directly or indirectly, that Ambien® is unfit and unsafe to some consumers with insomnia and other sleep related disorders.

104. Defendants intended Ambien® to be used on persons suffering from insomnia, and impliedly warranted through the sale, advertising, and/or marketing of Ambien® that it was fit for these normal and foreseeable uses.

105. Plaintiffs and class members, as foreseeable and intended users of Defendant's product, relied upon Defendant's representations, skill, expertise and judgment in assuming that Ambien® would not only perform its basic functions to keep them asleep as warranted, but was safe, and would not have adverse side effects of sleep walking, memory loss and sleep eating.

106. Defendants breached these implied warranties in that Ambien® as designed, manufactured, marketed, distributed or sold is deleterious and highly harmful, and can and does injure persons and others as a result of their entering into a hypnotic state to sleep walk and sleep eat where they suffer consequences of bodily harm and personal injury such as falling down stairs, burning themselves while cooking while sleep eating and eating inedible items and raw foods that led to stomach problems..

107. As a direct and proximate result of Defendants' breach of implied warranties of good and merchantable quality and fitness for a particular purpose and for their intended use, Plaintiffs and other class members have suffered and will continue to suffer direct and material harm and injury.

COUNT IV: FRAUD

108. Plaintiffs hereby incorporate by reference each paragraph in this Complaint, as if fully set forth herein.

109. Upon information and belief, Defendants at all times in designing, manufacturing, marketing, distributing and selling Ambien® knew that this product was and is hazardous and/or potentially hazardous to consumers, and knew that it caused sleep walking and sleep eating.

110. At all times relevant in marketing their Ambien®, Defendants falsely and fraudulently represented expressly or impliedly to Plaintiffs, class members, the public and the market that Ambien® was safe. Defendants suppressed and concealed facts that Ambien® could be harmful, dangerous and deleterious to consumers.

111. Upon information and belief, Defendants knew of these dangerous propensities when it

designed, acquired the patent, manufactured, marketed, distributed and sold Ambien®.

112. Defendants at all times had a continuing duty to disclose the dangerous propensities of their product to Plaintiffs, class members, the public, and the market, and the suppression of these facts constituted misleading and fraudulent misrepresentations because Defendants published and disseminated information such as publications and televised commercials representing Ambien® would put a person to sleep and was well-suited, safe and highly effective for its intended use, and which were likely to mislead for want of communication of suppressed facts, including the hazardous nature and dangerous propensities of Ambien®'s side effects.

113. The misrepresentations, suppressions, and failures to disclose information were made by Defendants with the intent to induce Plaintiffs, class members, the public and the market to purchase and use Ambien®.

114. Plaintiffs and class members relied on Defendants misrepresentations as well as the absence of adverse information in purchasing and using Ambien®.

115. Defendants continued at all times relevant to falsely and fraudulently misrepresent, suppress, and fail to disclose the dangerous propensities of Ambien®, including the fact that Ambien® causes sleep walking, memory loss and sleep eating.

116. Plaintiffs and class members, at the times these failures to disclose and suppressions of fact occurred, and at the time of purchase and use of the product, were ignorant of the existence of the facts that Defendants misrepresented, suppressed and failed to disclose.

117. Plaintiffs and class members had been aware of the existence of the facts misrepresented or not disclosed by Defendants, Plaintiffs and class members would not have purchased or used Ambien® or continued to purchase and use the product once the side effects occurred, and would have not suffered the damages and injuries alleged herein.

118. As a direct and proximate result of Defendants suppression of facts and failure to disclose, and the continued manufacture, sale and marketing of Ambien®, Plaintiffs and class members were or will be directly and materially harmed and injured.

119. All Defendants acts and omissions complained of in this count were committed by them with indifference to the rights of Plaintiffs and other class members and were intentionally carried out to maximize the sale and use of Ambien®.

COUNT V: UNFAIR TRADE PRACTICES

120. Plaintiffs hereby incorporate by reference each paragraph in this Complaint, as if fully set forth herein.

121. Defendants engaged in unlawful and deceptive trade practices that have injured Plaintiffs as described herein and upon information and belief, these unlawful and deceptive trade practices were committed willfully and knowingly by Defendants.

122. Defendants engaged, or have had the potential to engage in similar unlawful and deceptive trade practices that either have or potentially could have injured other persons or entities.

123. Defendants unlawful and deceptive trade practices committed during the operation of their business as described in this Count violated statutory law.

124. The unlawful and deceptive trade practices of Defendants impact the public interest in that they are capable of repetition, and upon information and belief, have been repeated against other persons or entities as alleged in this Complaint.

125. Because of the unlawful and deceptive trade practices of Defendants, Plaintiffs and class members have suffered and continue to suffer damages.

126. Defendants' willful and knowing commission of multiple unlawful unfair and deceptive acts in designing, manufacturing, marketing, distributing and/or selling Ambien®, have caused injury to Plaintiffs and class members.

COUNT VI: EXPRESS WARRANTY

127. The Plaintiffs hereby incorporate by reference each paragraph in this Complaint, as if fully set forth herein.

128. At all times relevant, Defendants, in order to induce the Plaintiff and class members to purchase and use Ambien®, warranted and represented that its product was safe for its intended use for insomnia to get a good nights sleep.

129. Plaintiffs and other class members purchased and used Ambien® in reliance on the Defendant's above- mentioned warranties and representations.

130. The Ambien® distributed, sold and/or delivered by Plaintiffs and class members were not of a character as stated by the Defendant, but on the contrary, were defective and deficient as it did not put Plaintiffs and class members to sleep but placed them into a hypnotic "auto-pilot" state causing them to sleep walk and/or sleep-eat without any memory.

131. Upon information and belief, Defendants received due and proper notice from Plaintiffs and other class members about the defective and deficient character in Ambien®, and Plaintiffs herein provide Defendants with additional notice of the same.

132. As a result of the defective and deficient nature of Ambien®, which is contrary to the warranties and representations of Defendants, the Plaintiff and class members have suffered and continue to suffer damage.

COUNT VII: CONSUMER FRAUD VIOLATIONS

132. The Plaintiffs hereby incorporate by reference each paragraph in this Complaint, as if fully set forth herein.

133. Defendant Sanofi maintains their corporate home in New Jersey.

134. Ambien® was primarily marketed and developed in New Jersey at all relevant times alleged herein.

135. Scientific research, studies, and presentations relating to the safety of Ambien® and its clinical studies were conducted in New Jersey.

136. Upon information and belief the ultimate decision making power regarding marketing and development of Ambien®, was exercised in New Jersey.

137. Upon information and belief, the fraud allegedly was conceived of and executed from New Jersey.

138. Upon information and belief, Defendants' senior level committee in charge of overseeing the development of Ambien®, and executing plans and activities related to Ambien® met in New Jersey and are connected to deliberate suppression and/or misrepresentation of damaging information concerning Ambien®.

139. Upon information and belief, the misrepresentations and omissions in the marketing and advertising of the drug all emanated mainly from New Jersey.

140. Plaintiffs and the class member received less than what was promised as they did not receive a medication that would put them to sleep but it actually had them enter into a half sleep-half awake mode where they ultimately would sleep eat or engage in other activities that endangered themselves and others.

141. Plaintiffs suffered a loss in value by continuing to purchase and use Ambien® not knowing that Ambien® caused their sleep eating and other bizarre behaviors because Defendant failed to include those adverse side effects in its contraindications and advertising.

142. Upon information and belief, Defendants engaged in a longterm, widespread, uniform pattern of deception to cover up these known adverse side effects of Ambien® in order to gain a profit as a result of consumer marketing and resulting purchases.

143. Upon information and belief, in order for Defendants to continue profiting, Defendants avoided studies revealing the negative side effects of Ambien®.

144. During all relevant times, the New Jersey Consumer Fraud Act ("CFA") was in effect.

145. The CFA prohibits consumer fraud in connection with the sale and/or advertisement of merchandise.

146. Ambien® is "merchandise" as defined by N.J.S.A. 56:81(c).

147. Defendant's actions, as alleged herein, constitute a "sale" or "advertisement" as defined by N.J.S.A. 56:81(e).

148. At all relevant times material hereto, defendant conducted trade and commerce within the meaning of the CFA,

149. Plaintiffs, the putative class members, and defendant are "persons" within the meaning of N.J.S.A. 56:81.

150. Section 56:82 of the New Jersey CFA provides that unconscionable and deceptive conduct in connection with the sale or marketing of a product is unlawful, e.g.:

"The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of

any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice..."

151. Defendants violated the CFA, N.J.S.A. 56:81, et seq., by the act, use or employment of an unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, and the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of Ambien®.

152. Defendant's deceptive representations and material omissions to Plaintiffs and the members of the Class were, and are unfair and deceptive acts and practices.

153. As a direct and proximate result of the above violations of the CFA, Plaintiff and Class members suffered an ascertainable loss and other damages by purchasing Ambien®

154. Plaintiffs and the putative class would not have purchased and ingested Ambien® nor continued had they known the true and complete risks of sleep walking and sleep eating side effects.

155. Plaintiff and the members of the Class have sustained, and continue to sustain, significant monetary damages as a result of purchasing Ambien®

156. Plaintiffs hereby demand a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class of others similarly situated, request that this Honorable Court grant the following relief:

- A. An order certifying the cause of action as a class action pursuant to Fed. R.Civ.P. 23 with Plaintiffs as Class Representatives and an award of attorney's fees and costs.
- B. Judgment against Defendants, jointly and severally, awarding Compensatory Damages to Plaintiffs and each member of the proposed Class in an amount to be determined by a Jury and/or the Court on a class wide basis.
- C. Judgment against Defendants in an undetermined amount upon the claims of fraud, unfair trade practices and other causes of action including damages, exemplary and/or punitive damages, and costs of suit, including attorney's fees;
- D. Judgment against Defendants for appropriate equitable relief and costs of suit, including attorney's fees;
- E. A judgment pursuant to New Jersey Consumer Fraud Act, N.J.S.A. 56:81, et seq., including treble damages, attorney fees and costs

- F. For such other damages, equitable relief, or other relief that the Court may deem just and proper, including pre and post judgment interest.

Dated: New York, NY
April 21, 2006

/s

BY: Susan Chana Lask, Esq./1744

Attorneys for Plaintiffs
Law Offices of Susan Chana Lask
244 Fifth Avenue, Suite 2369
New York, NY 10001
(212) 358-5762

Case No. 06CV1762

Year 2006

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

Janet Makenen, Judith Renee Lasswell,
Christina Brothers, & Kathleen M. Callahan,
on behalf of themselves and others similarly
situated,

Plaintiffs,

-against-

Sanofi-Aventis U.S. LLC and Corporate Does 1-3
Being the US predecessors of Sanofi-Aventis U.S.
LLC;

Defendants.

FIRST AMENDED CIVIL COMPLAINT

Attorneys for Plaintiffs
Law Offices of Susan Chana Lask
244 Fifth Avenue, Suite 2369
New York, NY 10001
(212) 358-5762
