

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

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**Janet Makinen, on behalf of herself  
and all others similarly situated,**

**Case No. 06CV1762  
Originally Filed 3/6/06**

**Plaintiffs,**

**-against-**

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

**Defendants.**

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**PLAINTIFF'S FIRST  
SET OF INTERROGATORIES  
and REQUEST FOR PRODUCTION  
OF DOCUMENTS**

**Definitions**

The term "the product" as used hereinafter in these interrogatories shall mean the product which caused injury or damage to the plaintiff as alleged in the plaintiff's pleadings .

The terms "defendant" or "defendants" are used interchangeably to mean any and all defendants named herein.

**Manufacturing**

1. Please give the name, title, and address of the persons who have custody of any records relating to the manufacture and distribution of the product since its initial marketing in the United States by defendant, any agent or assignor of the product to defendant.

2. If any changes were made in the qualitative or quantitative formula of the product after it was first manufactured by the defendant, any agent of defendant or any assignor of the formula/product to the defendant, please set forth, in full detail:

- (a) what the changes were,
- (b) when they were made,
- (c) why they were made.

3. On the date the product was first manufactured and/or introduced for sale into the United States, please list:

- (a) the indications of the product,
- (b) the contraindications of the product,
- (c) any precautions or warnings and recommendations by you given to patient consumers.

4. Please explain any and all changes made in any indications, contraindication and/or warnings noted in the answer to the preceding interrogatory from the time of the first manufacture date to this date.

### **Tests and Inspections**

5. Please describe in detail all premarket testing done with the product by the defendants and/or their predecessor owners and manufacturers of the product, including:

- (a) the place of each such test,
- (b) the person responsible for each such test,
- (c) the purpose of each such test,
- (d) the number of people or animals involved in each such test,
- (e) the results of each such test,
- (f) the name and address of each person who has custody of any records relating to each such test, and state when and where counsel for plaintiff may examine such documents or attach copies of such records to the answers to these interrogatories if you will do so without a motion to produce.

6. With regard to each adverse side effect discovered through the testing described in response to the preceding interrogatory, please state, as to each such side effect:

- (a) a complete description of the side effect,
- (b) the chance or magnitude of risk of a user suffering the side effect,
- (c) all action taken by the defendant to minimize or eliminate the side effect,
- (d) the name, address, and position of the person responsible for the decision to manufacture the product and similar product despite the side effect.

7. If on any occasion has the Food and Drug Administration required the addition of a warning or contraindication to the labeling of the product and similar products, then please state as to each such occasion:

- (a) the date,
- (b) the nature of the addition required,
- (c) the reason the addition was required.

8. If on any occasion the defendant or anyone else or any entity ever tested the product and similar products to ascertain their uses and possible adverse side effects following the marketing of the product and similar products to the public, then state as to each such test:

- (a) the dates between which it was conducted,
- (b) the name, title, and address of the person in charge of it,
- (c) whether the product was tested on humans or on animals,
- (d) a full and complete description of the test,
- (e) the results of the test, and
- (f) the dates of issue and identification by article title of any publication that carried such information.

9. With respect to each illness, disease, condition, or complaint for which the defendant has recommended the use of the product and similar products, please state who in the defendant's employ for the past ten years has the final responsibility for approving the product for marketing and use by the medical profession generally.

### **F.D.A.**

10. Did you ever file an I.D.A. or an N.D.A. with the U.S. Food and Drug Administration regarding the product and similar products and if so then please list:

- (a) the dates of each such filing,
- (b) the dates of any supplementary filings,
- (c) all documents that were submitted with each such filing, and
- (d) the name, title, and last known address of the person or persons responsible for the submission of each such

application or document and the names of those who have custody of said documents to date.

11. If an FDA Summary Basis of Approval at the premarket stage or any stage of this product was issued to defendant and or its predecessors then please summarize and attach all such documents.

### **Consulting Opinions**

12. Please state the names, titles, and addresses of all persons known to the defendant who have expressed their opinions or beliefs that:

(a) the product was not adequately tested and evaluated prior to its marketing by the defendant and/or its predecessors,

(b) the labeling and advertising and promotional literature for the product was inadequate, inaccurate, or incomplete.

13. With respect to the expressions referred to in the preceding interrogatory, please state as to each such expression of opinion or belief:

(a) the date it was made,

(b) the circumstances under which it was made,

(c) the identity of the person who made it,

(d) a complete account of its substance,

(e) whether it was made in writing or has been reduced thereto, and the names, titles, and addresses of the persons who have custody of each such writing.

14. Please state the names, titles, and addresses of all persons known to the defendant who have expressed their opinions or beliefs that the risks of harmful and serious side effects outweigh the potential benefits of the product and similar products and with respect to the expressions of opinion or belief referred herein, please state as to each such expression:

(a) the date it was made,

(b) the identity of the person who made it,

(c) a complete account of its substance,

(d) whether it was made in writing or reduced thereto, and if so, the names, titles, and addresses of the persons who have custody of each such writing.

### **Similar Products**

15. If the defendant manufactures similar products today, such as Ambien CR, please describe in complete detail all differences in qualitative or quantitative formula, components, manufacturing process, or testing process between similar products presently produced and similar products produced both on or about the date the product was produced and on the date of the occurrence. Include in the answer for each change:

(a) the date of each such change,

(b) the reasons for each such change,

(c) the name, address, and position of the person responsible for each such change,

(d) the name and address of each person with custody of any records related to each such change.

### **Advertising**

16. Please describe in complete detail the campaigns by which the product and similar products were advertised or promoted during the past five years, including, for each such campaign:

- (a) the various media and forms of communication through which the product and similar products were advertised,
- (b) the nature and verbatim content of text, copy, pictures, animations, films, tapes, and other written and broadcast statements and documents relating to the product and similar products,
- (c) the amount of money and other resources involved in such promotion or advertising,
- (d) the name, address, and position of the person responsible for approving the wording of the representations made in each advertisement,
- (e) the name, address, and position of the person who actually formulated the wording of the representations made in each advertisement,
- (f) the name and address of the advertising agency, if any, employed by the defendant to formulate or develop each advertisement,
- (g) the geographical areas in which such promotion or advertising took place,
- (h) the name and address of each television or radio station or network which ran an advertisement during the campaign, and the dates on which each advertisement was run by each such station or network,
- (i) the name, page number, and issue date of each publication which ran an advertisement during the campaign,
- (j) the dates between which each piece of copy or advertising was run, printed, broadcast, or distributed.

17. For every occasion that the defendant prepared and distributed a pamphlet or brochure designed to be distributed to users of the product and similar products either directly or through their pharmacist or physician, please:

- (a) give the date of release of each such pamphlet or brochure,
- (b) give the purpose of each such pamphlet or brochure,
- (c) give the name, title, and address of the person responsible for the preparation of each such pamphlet or brochure,
- (d) attach copies of each such pamphlet or brochure to the answers to these interrogatories.

#### **Warnings**

18. If the defendant or any agent or employee of the defendant affixed, attached, or caused to be affixed or attached to the product and similar products or to the packaging of the product and similar products any label, tag, warning, directions, or instructions, please state for each such writing:

- (a) its purpose,
- (b) its complete and verbatim contents and dates each such warning was first posted,
- (c) the name and address of each person who has custody of any records relating to the formulation and composition of the writing on each such label or tag, etc.,
- (d) when and where counsel for the plaintiff may examine all such records and labels or tags, etc.

19. Please describe in full and complete detail each of the activities the defendant has undertaken with the intention of warning the medical profession and the public of the risks inherent in the use of the product and similar products, and give the inclusive dates of each such activity, including the dates and contents of all "dear doctor" letters.

20. If a pharmacy or retail store sold the product, was there at any time a warning apparent to and understandable by the user without consulting a physician or other specialist that would warn specifically of sleep walking, sleep eating and/or sleep driving? Please attach a copy of any such specific warning accompanying the product hereto.

21. If the defendant has ever changed the wording of any warning to members of the medical profession, users of the product or similar products, or the general public concerning the use of the product or similar products, please give:

- (a) a complete account of each such change,
- (b) the date of each such change,
- (c) the reasons for each such change,
- (d) the name, address, and position of the person responsible for each such change,
- (e) the name and address of each person with custody of any records or other documents pertaining to each such change.

### **Complaints**

22. Please list in chronological order the names and addresses of all persons who have received a claim or claim to have received injuries resulting, or suspected by them or their physicians to have resulted, from the use of the rproduct, and with respect to each such person, please state:

- (a) the nature of the injury claimed,
- (b) the date the defendant first received notice of the injury,
- (c) the name and address of the attending physician involved,
- (d) the defendant's response to the notice of injury,
- (e) the name and address of each person who has custody of any documents related to, and including copies of, the notice of injury, and the defendant's response to such notice.

23. If any lawsuits have been filed against the defendant for injury or death from the use of the product or similar products, please state with regard to each such lawsuit:

- (a) its nature,
- (b) the day it was filed,
- (c) the place it was filed,
- (d) the court in which it was filed and its docket number and caption,
- (e) the judgment or settlement reached, or present status if pending,
- (f) the name, title, and address of each employee or agent of the defendant who testified at the trial or gave a deposition,
- (g) the name, title, and address of each expert witness who testified on behalf of the defendant,
- (h) the name, title, and address of each expert witness who testified on behalf of the plaintiff.

24. Please state when and in what manner the defendant communicated to the medical profession, the public generally, or the Food and Drug Administration, regarding any claimed injuries resulting from the use of the drug.

### **Contentions of Defendant**

25. If it is the contention of the defendant that the alleged occurrence was caused in whole or in part by some person or persons other than the defendant, please state fully:

- (a) the identity of each such person, firm, or corporation,
- (b) how such other person caused or contributed to cause the alleged occurrence.

26. If it is the contention of the defendant that the alleged occurrence was caused or contributed to by some act or omission by the plaintiff, please describe in detail each act or omission of the plaintiff.

27. If it is the contention of the defendant that liability for the alleged occurrence was assumed by the plaintiff, please state and describe in complete detail all acts or omissions of the plaintiff or any other person or party by which the defendant claims or contends to be relieved of liability.

### **Standards**

28. Please completely identify any state or federal statutes or company or trade standards which cover the components, production, testing or health risks of the product and similar products, and fully state the substance of each.

### **Marketing**

29. If the defendant markets the product and similar products through salespersons or retailers, please state the names, addresses and phone numbers of the salesperson or sales managers throughout the United States that promote this and similar products.

30. If the defendant uses or has used salespersons or retailers in connection with the marketing of the product and similar products, please give a complete account of all instructions given to each such salesperson or retailer with respect to the uses, safety, and side effects of the product and similar products.

31. Please list each newsletter, report, or other material, if any, that has been sent to the salespeople or retailers who market the product and similar products for the defendant, and as to each such newsletter, report, or other material, state the date it was issued.

### **Labels**

32. Provide the name(s), title(s), and address(es) of the person(s) in charge of labeling and advertising of the product and similar products since it has been sold in the United States?

### **Awareness of Defective Condition**

33. If the defendant was ever aware of any danger or hazard, including sleep walking, sleep eating and/or sleep driving, in the use of the product prior to the time of the Plaintiff's Complaint then please state:

- (a) when defendant became aware of such defect or hazard in the use or operation of the product,
- (b) what was the nature of such defect or hazardous condition,
- (c) whether the defendant at any time informed the public, FDA or any other entity of such condition described in subsection (b).

### **Request for Production of Documents and Things Pursuant to Rule 34 by the Plaintiff**

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, the defendant is hereby requested to produce or make available to plaintiff's representatives for inspection and copying the discovery documents described herein which are in the possession or control of, or available to the defendant, or its officers, agents, employees, or representatives, or to the officers, officials, executives, agents, employees, or representatives of persons, companies, or entities affiliated with, or connected with, or controlled by, the defendant or its subsidiaries.

"Discovery documents," referred to herein, shall be understood to include all written matter of any nature whatsoever, relating or referring to the subject matter of the requests to produce, including all correspondence, letters, telegrams, memoranda, lists, summaries, statistics, tables, forms, investigation reports, engineering reports or other reports, and notes, regardless of origin or source, and shall include notes or records of conversations, including conversations or communications between or among the officers, officials, executives, agents, employees, or representatives of defendant, and between any other person or persons, and the officers, officials, executives, agents, employees, or representatives of defendant.

Whenever a request is made for specific discovery documents, such request does not limit the generality of any other request but represents an endeavor to pinpoint for the convenience of defendant certain specific documents which plaintiff knows or presumes to exist.

(A) Documents Which Have Been Destroyed

If any document sought by these requests has been destroyed, and no copy exists within the Defendant's possession, custody, or control, identify the document, the date of its destruction, the reason for its destruction, and the person responsible for ordering its destruction as well as produce any policy that called for the destruction thereof.

(B) Privileged Documents

Documents requested to be produced that the Defendant believes may be withheld on the grounds of other privilege or work product should be listed with a brief description of each document, and a statement of the basis for withholding the document.

(C) Drug Products

These requests relate to the defendant's drug products, especially the drug product which allegedly caused the injuries and damage to the plaintiff as alleged in the instant matter.

(D) Broad Interpretation of "Document"

The term "document" should be construed as broadly as is permissible under the Federal Rules of Civil Procedure. The term is intended to encompass the following: Any medium by which information is recorded, stored, communicated, or utilized, including papers (of any kind, type or character) and any method or medium by which information may be communicated, recorded, or retrieved by people or by computers. The term includes, without limitation, photographs, photostats, xrays, motion pictures, audio tape, video tape recordings, computer generated material, computer disks, CDROMs and any other form or type of computer stored or computer retrievable data, microfilm and microfiche, or any other process by which information is reduced for storage or use.

If the document or information is in a computer readable form, please specify the software (including the exact version and release) used to create the information. Also specify any other software, hardware, or information such as passwords or usersupplied files that are required or desirable on the disks. Specify the exact configuration of the hardware on which the information was created, including the memory size (and graphics control board in the event the information contains or requires graphics). Please give the exact name, release, and version of the operating system used on the hardware.

(E) Instructions

These Requests for Production of Documents are deemed continuing until trial. If any information sought by these Requests for Production of Documents is learned of or obtained after they have been answered, or if the answers for any reason shall later become incorrect or incomplete, there shall be a continuing duty to the time of trial on the party answering these Requests for Production of Documents to formally supplement any answers previously submitted pursuant to Fed. R. Civ. P. 26(e) and other federal case law construing the duty to supplement under these rules.

Defendant is hereby notified that the defendant's duty to respond includes the duty to provide answers concerning records, documents, and things not in the defendant's physical possession, but which can be obtained from sources under the defendant's control.

Any reference to defendant includes all agents, subsidiaries and documents transferred to the defendant from the predecessor licensors/assignors of the product as part of the sale of the product to the defendant. All documents are requested for the past 10 years, and anything relevant to premarketing that may be before 10 years ago must also be produced.

(F) Requests for Production of Documents

Please produce for copying and inspection.

1 Each written, printed or graphic representation, statement, document, advertisement, catalogue, circular, and brochure uttered or propounded by or on behalf of the defendant which relates to the virtues, qualities, characteristics, capabilities, or capacity of the product or the dangers, limitations, or propensities of the product.

2. Each written or printed document and statement and each illustration (by way of illustration) which accompanied the product when it was purchased or was attached to or enclosed in the product container or packaging and each pamphlet, set of directions or instructions, leaflet, and booklet of any kind.

3. Each letter or communication since the introduction of the product in the United States whereby the defendant was notified by anyone, including medical professionals, of a person experiencing somnambulism and sleep-eating occurrences when taking Ambien or Ambien CR.

4. Each piece or item of correspondence between the complaining person and the defendant.

5. All the pleadings including deposition transcripts filed by all parties in every other lawsuit which have arisen out of the occurrence of somnambulism and/or sleep-eating related to the product of AmbienCR.

6. Each investigation report relating to the occurrence of somnambulism and/or sleep-eating or to the product prepared by any agency, bureau, or commission of the federal government or any state, local, or municipal government.

7. Each written, printed, or graphic representation, statement, document, catalogue, report, or memorandum which relates to the testing or inspection of the product.

8. Each written, printed, or graphic representation, statement, document, catalogue, report, or memorandum which relates to the marketing, advertising, distribution, or promotion of the product.

9. Any and all notes or memoranda reflecting any conversation which took place between the defendant, or any agent, or employee of the defendant and persons complaining of somnambulism and/or sleep-eating.

10. New Drug Application (NDA), including all supplements and correspondence.

11. Package insert (or detail card) direct mailing, brochures, labeling, cartons, copy for Physicians Desk Reference, and all other labeling and promotional data.

12. Reference, and all other labeling and promotional data.

13. Instructions to detail men.

14. Basic or raw data relating to early investigation of drug, with animals and otherwise, together with summaries and reports made therein.

15. Reports of clinical investigators stating good and bad drug effects, not limited to those performed up until the drug went on the market.

16. Side effects and adverse reports of all types from all sources, together with defendant's evaluations thereof and followup correspondence, if any.

17. Interoffice management memoranda dealing with drug side effects, and the giving of warnings to physicians about side effects.

18. Instructions to salesmen to blame side effects that their product was causing on the drugs that the patient was taking.

19. Instructions to salesmen to push a drug over a physician's resistance, so as to increase their bonuses.

20. Interoffice memoranda recognizing the need to warn about side effects, but deciding not to do so because of the possible averse effect on sales.

21. Memorandum about physician who was conducting research with the drug demanded a grant that amounted to blackmail (which the company paid).

22. Memorandum indicating that a physician who was conducting research on the drug received continuing financial support to continue investigation in order to delay his or her publication of negative data.

23. List of lay publications in which the company would seek to "plant" favorable articles about its ethical drug.

24. Evidence that defendant wrote letter and articles for physicians to submit to medical journals under their own name.

25. Memoranda containing admissions that data had been withheld from the FDA.

26. Report prepared for FDA but not sent; cover note on it stating that when it was sent later, the FDA should be told this was just a copy of one that had been previously sent.

27. A photocopy of all medical and any other records pertaining to the plaintiff and maintained by various physicians, hospitals, or other institutions in possession of the defendant.

28. A photocopy of all package inserts contained in the prescription drug package dispensed by the pharmacist to the client.

29. All documents that defendant generated or acquired at the request of or in compliance with any requirement of the Federal Drug Administration.

30. All documents reflecting any statements of policy or corporate code of ethics or statements of principle to which the defendant ascribes or has in the past subscribed.

31. All documents that identify the name, address, and qualifications of any and all expert witnesses with whom defendant has consulted concerning the instant drug product litigation.

32. All documents pertaining to any experts that defendant expects to testify at any trial involved in the instant drug product. This item should be construed to include documents pertaining to the following topics:

(a) the name, address, and qualifications of the expert,

(b) any and all correspondence or communications by and between the defendant or anyone acting on the defendant's behalf with the expert,

(c) any and all documents provided to or made available to the expert,

(d) documents that identify the nature and scope of the work that the expert was asked to or is expected to conduct,

- (e) all documents that pertain to or reflect the opinions of any such expert,
- (f) all documents that form the basis of the expert's opinion,
- (g) all documents pertaining to the compensation that any such expert has received or may receive,
- (h) all documents that pertain to any other legal action or disputed issue in which the expert has rendered an opinion or given testimony on any issue at any time in the past, and
- (i) all documents that reflect or relate to the expert's relationship with the defendant, any physician or health care provider that at any time participated in the instant drug product, and
- (j) all documents that reflect or relate to the expert's relationship with any agency of the federal government, any state government, or any foreign government.

The plaintiff requests that the documents and things herein requested be produced at the office of the plaintiff's attorney, *Law Offices of Susan Chana Lask, Esq., 244 Fifth Avenue, Suite 2369, New York, NY 10001*, on the 30th day after service of this request.

The defendant may comply with this request by forwarding a copy of each document and thing requested to the plaintiff's attorney if such copies are postmarked prior to the date for which production has been designated in the preceding paragraph. The defendant is also requested to appropriately designate each document and thing produced so as to indicate the paragraph above pursuant to which each document and thing is produced. If a document or thing is produced pursuant to more than one paragraph, the designation should so indicate.

Dated: August 14, 2006

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