UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

[redacted] On Behalf of Itself and All Others Similarly Situated, Plaintiff, vs. SANOFI-AVENTIS, JEAN-FRANÇOIS DEHECQ, GÉRARD LE FUR, HANSPETER SPEK, MARC CLUZEL and JEAN-PIERRE LEHNER, Defendants.	Civil Action No. CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Sanofi-Aventis ("Sanofi" or the "Company") publicly traded stock or American Depository Receipts ("ADRs") between February 17, 2006 and June 13, 2007 (the "Class Period"), who were damaged thereby.

JURISDICTION AND VENUE

2. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act") and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Sanofi conducts business in this district and its ADRs trade on the New York Stock Exchange ("NYSE"), which is located in this district.

THE PARTIES

3. Plaintiff [redacted] purchased Company stock during the Class Period as set forth in the attached certification and was damaged thereby.

4. Defendant Sanofi's U.S. headquarters is in Bridgewater, New Jersey. Sanofi's ADRs are traded on the NYSE, which is an efficient market. The Company's stock trades on the Euronext exchange, which is also an efficient market.

5. Defendant Jean-François Dehecq ("Dehecq") was CEO of Sanofi up until December 2006 and served as Chairman of the Company thereafter.

6. Defendant Gérard Le Fur ("Le Fur") became the CEO of Sanofi in December 2006.

7. Defendant Hanspeter Spek ("Spek") was the Executive Vice President of Pharmaceutical Operations of Sanofi at all relevant times.

8. Defendant Marc Cluzel ("Cluzel") was the Senior Vice President of Scientific and Medical Affairs at all relevant times.

9. Defendant Jean-Pierre Lehner ("Lehner") was Senior Vice President of Medical and Regulatory Affairs at all relevant times.

SCIENTER ALLEGATIONS

10. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Sanofi stock and ADRs during the Class Period.

PRE-CLASS PERIOD EVENTS AND STATEMENTS

11. Sanofi is the third largest pharmaceutical company in the world. In 2002, Sanofi began testing a new drug, rimonabant (Zimulti in the U.S./Acomplia in Europe), which is a CB1 cannabinoid receptor antagonist, designed to fight obesity by reducing appetite. As the first drug of its class, Zimulti was projected to become extremely profitable for Sanofi. Not only did Zimulti show promise for treating obesity, but also for treating other conditions associated with type 2 diabetes and heart disease. Sanofi set out to conduct a set of four worldwide phase III clinical trials, called RIO (Rimonabant In Obesity) to study the drug in approximately 6,600 obese or overweight patients. The first of the four studies, RIO-Europe, was published in *The Lancet* on April 16, 2005. The article stated the following:

> Weight loss at 1 year was significantly greater in patients treated with rimonabant 5 mg . . . and 20 mg . . . compared with placebo . . . . Significantly more patients treated with rimonabant 20 mg than placebo achieved weight loss of 5% or greater ($p<0.001$) and 10% or greater ($p<0.001$). Rimonabant 20 mg produced significantly greater improvements than placebo in waist circumference, HDL-cholesterol, triglycerides, and insulin resistance, and prevalence of the metabolic syndrome. . . . Rimonabant was generally well tolerated with mild and transient side effects.

The article stated the following concerning safety: "Similar frequencies of serious adverse events were reported in all groups: except for psychiatric disorders." And further, "[t]he most common adverse events leading to study discontinuation were depressed mood disorders in all treatment groups." The article concluded: "Treatment with rimonabant was associated with clinically meaningful weight loss and additional improvements in waist circumference, lipid concentrations, and insulin resistance, and had a favourable safety profile."

12. Sanofi submitted its New Drug Application ("NDA") for Zimulti in April 2005 and on June 23, 2005, the Company announced that the Food and Drug Administration ("FDA") had accepted it for filing. In its press release, the Company stated that Zimulti was "thought to represent a new approach for the comprehensive management of cardiovascular risk factors."

13. On November 16, 2005, Sanofi issued a press release announcing the publication of the second study, RIO-Lipids, in *The New England Journal of Medicine*.[1] The release stated that patients on rimonabant "experienced a significant improvement in a range of cardiometabolic risk factors that may contribute to type 2 diabetes and heart disease." The release also noted findings from the study that patients taking rimonabant experienced a reduction in triglyceride levels and increases in HDL-cholesterol (good cholesterol), as well as "reductions in waist circumference and body weight, improved glucose tolerance, and decreased blood pressure." The release stated that "the most frequent side effects leading to discontinuation in placebo, rimonabant 5 mg and 20 mg groups included depression (0.6% vs. 1.7% and 2.9%)."

14. On February 14, 2006, Sanofi announced the publication of the RIO-North America study in the *Journal of the American Medical Association*, stating in its heading, "Study Shows

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[1] The results of this study were first revealed at the American College of Cardiology meeting in March 2004.

Rimonabant Maintains Improvements in Multiple Cardiometabolic Risk Factors For Up to Two Years."[2] The article contains a quote from the Principal Investigator of the study stating that

> "[r]imonabant 20 mg once daily produced sustained clinically meaningful weight loss and improvements in associated risk factors during two years of treatment. . . . The sustained improvements we see in several risk factors were beyond what was expected from the observed weight loss and suggests that rimonabant represents an exciting breakthrough in our quest to improve the multiple cardiometabolic risk factors contributing to increased risk for diabetes and heart disease in patients who have abdominal obesity."

Concerning safety, the press release stated: "In the first year, rimonabant 20 mg once daily was generally well-tolerated and adverse events were mostly mild to moderate." The release listed "depressed mood disorder" as one of "[t]he most common adverse events leading to discontinuation." The release stated that in the second year of the study, adverse events and discontinuations decreased, with "no significant differences" between rimonabant and placebo.

15. In addition to the four RIO studies, Sanofi also conducted a program of three clinical trials called STRATUS (Studies with Rimonabant And Tobacco Use) to study Zimulti for smoking cessation and subsequent prevention of weight gain. STRATUS-US was the first of the studies, the results of which were announced along with the RIO-Lipids study at the American College of Cardiology's annual meeting in March 2004. The study showed that Zimulti was effective for smoking cessation and researchers reported no differences between the drug and placebo groups with regard to depression and anxiety. The results for the remaining two studies, STRATUS-WW and STRATUS-EU, have not been disclosed.

16. It became evident through these large studies that Zimulti was very promising and had the potential to become a blockbuster drug with multiple indications. Each study published

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[2] The results of this study were first revealed at the American Heart Association's meeting in November 2004.

showed that the drug was effective yet had only minor side effects and produced a low occurrence of only mild to moderate adverse events. Before February 17, 2006, it appeared as though Zimulti would have no problem gaining FDA approval.

CLASS PERIOD EVENTS AND STATEMENTS

17. On February 17, 2006, upon reviewing Sanofi's NDA, the FDA responded by issuing an approvable letter for Zimulti's obesity indication.

18. Sanofi filed its response to the FDA approvable letter on October 26, 2006. This response contained additional information that the FDA requested regarding the completed Zimulti studies. At this time, Sanofi had data from at least four large studies, RIO-Europe, RIO-Lipids, RIO-North America and RIO-Diabetes.

19. On October 27, 2006, Sanofi issued a press release announcing the publication of the RIO-Diabetes study in *The Lancet*. The release stated that:

> The one year trial showed that rimonabant 20 mg once daily significantly improved several cardiometabolic risk factors including weight, HbA1c (a measure of blood sugar control), HDL-cholesterol (good cholesterol), and triglycerides (fats in the blood), systolic blood pressure as well as waist circumference in overweight/obese patients with type 2 diabetes . . . .

The release also stated: "The most frequent adverse events leading to discontinuation were depressed mood disorders, nausea and dizziness."

20. On October 31, 2006, during a conference call, defendant Spek, the Executive Vice President of Pharmaceutical Operations, stated: "[W]e will not speculate at all what the FDA now has to do or will do and within which timeline."

21. On December 5, 2006, Sanofi issued a press release concerning the results of the SERENADE (Study Evaluating Rimonabant Efficacy in Drug-NAïve DiabEtic Patients) trial, with the headline "New Data Shows Acomplia (Rimonabant) Benefited Patients with Type 2 Diabetes by

Improving Blood Sugar Control, Reducing Weight and Acting on Other Cardiometabolic Risk Factors." Sanofi stated that the study

> showed that patients with type 2 diabetes not currently treated with anti-diabetic medications experienced significant improvements in blood sugar control and weight as well as other risk factors such as HDL-cholesterol (good cholesterol) and triglycerides when compared to placebo.

The release also stated that "SERENADE is the second study demonstrating that rimonabant significantly improved blood sugar levels in people with type 2 diabetes." As for the drug's safety, the release listed the most common side effects, which included among other things, "depressed mood (0.7% [placebo] vs. 5.8% [rimonabant 20 mg])."

22. The same day that the SERENADE results were announced, Sanofi's stock rose $1.13 (2.6%) to $45.09.

23. On December 8, 2006, Sanofi announced that its October 26, 2006 resubmission was considered by the FDA to be a "complete, class 2 response," meaning that the FDA would review it and act within six months.

24. On February 12, 2007, Sanofi issued a press release announcing its submission of the SERENADE study report to the FDA.

25. On March 26, 2007, Sanofi issued a press release announcing that the FDA EMDAC Meeting would be held on June 13, 2007. The release stated: "The Committee will discuss the efficacy and safety of rimonabant in obesity. Sanofi-Aventis is pleased to have the opportunity to present its data on rimonabant and to exchange with experts."

26. On May 3, 2007, Sanofi held its first quarter "Sales and Earnings Analyst/Investor Presentation." The presentation highlighted the strong performance of Zimulti and portrayed the extremely large population of potential patients who could benefit by taking the drug.

27. On May 10, 2007, Sanofi submitted its "Briefing Information" for the FDA Committee's meeting, including all of the updated data for all completed and ongoing clinical trials of Zimulti.

28. Defendants' statements set forth above were materially false and misleading when made because defendants concealed data concerning Zimulti's propensity to cause depression.

29. On June 13, 2007, the committee met and made a unanimous decision (14-0) that Zimulti could not be recommended for approval. After the FDA's decision on June 13, 2007, Sanofi's securities declined $1.87, or 4.16%, closing at $43.07 on heavy trading volume (8.9 million shares). The following day, the stock dropped to $41.33 on even heavier trading volume (12.2 million shares).

POST-CLASS PERIOD EVENTS

30. On June 29, 2007, Sanofi decided to completely withdraw its NDA for Zimulti, which means that the FDA panel will not meet to consider approving the drug.

LOSS CAUSATION/ECONOMIC LOSS

31. During the Class Period, as detailed herein, defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated Sanofi's stock price and operated as a fraud or deceit on Class Period purchasers of Sanofi stock by misrepresenting the Company's business. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, Sanofi's stock and ADR prices fell precipitously, as the prior artificial inflation came out of the prices over time. As a result of their purchases of Sanofi stock and/or ADRs during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

32. Sanofi's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

33. The defendants are also liable for any false FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false and the FLS was authorized and/or approved by an executive officer of Sanofi who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

34. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's stock and ADRs traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock and ADRs; and

(e) Plaintiff and other members of the Class purchased Sanofi stock and/or ADRs between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

35. At all relevant times, the markets for Sanofi stock and ADRs were efficient for the following reasons, among others:

(a) As a regulated issuer, Sanofi filed periodic public reports with the SEC;

(b) Sanofi regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services; and

(c) Sanofi ADRs were actively traded in an efficient market, namely the NYSE, under the symbol SNY. Its stock traded on the Euronext exchange, which is also an efficient market.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

36. Plaintiff incorporates ¶¶1-35 by reference.

37. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

38. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Sanofi stock and ADRs during the Class Period.

39. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Sanofi stock and ADRs. Plaintiff and the Class would not have purchased Sanofi stock and/or ADRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

40. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Sanofi stock and ADRs during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

41. Plaintiff incorporates ¶¶1-40 by reference.

42. The Individual Defendants acted as controlling persons of Sanofi within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about Sanofi, the Individual Defendants had the power and ability to control the actions of Sanofi and its employees. Sanofi controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

CLASS ACTION ALLEGATIONS

43. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Sanofi stock or ADRs during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of Sanofi and their families and affiliates.

44. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Sanofi had more than 2.7 billion shares of stock outstanding, owned by thousands of persons.

45. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the 1934 Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the prices of Sanofi stock and ADRs were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

46. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

47. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

48. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding plaintiff and the members of the Class damages and interest;

C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: November 13, 2007