

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA**

LISA TUYES

Plaintiff

V.

Civil Action No. _____

Section: _____

SANOFI-AVENTIS U.S., INC,
SANOFI S.A., AVENTIS PHARMA S.A.,
AND SANOFI-AVENTIS U.S. LLC, separately,
and doing business as WINTHROP U.S.

Defendants

COMPLAINT AND JURY DEMAND

Plaintiff, Lisa Tuyes, by and through her attorneys, respectfully submits the following Complaint and Jury Demand against Defendants Sanofi-Aventis U.S. , Inc; Sanofi S.A.; Aventis Pharma S.A.; and Sanofi- Aventis U.S. LLC, separately, and doing business as Winthrop U.S. (Defendants"), and alleges the following:

NATURE OF THE ACTION

1. This action seeks to recover damages for injuries sustained by Plaintiff as the direct and proximate result of the wrongful conduct of Defendants, Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S. LLC, and Sanofi-Aventis U.S., Inc., in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of TAXOTERE®, a prescription medication used in the treatment of breast cancer.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds \$75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of Louisiana. As set forth more fully below, all Defendants are entities organized in states other than the State of Louisiana, all Defendants have their principal place of business in a state other than the State of Louisiana, and none of the Defendants is a citizen or resident of the State of Louisiana.
3. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in the State of Louisiana, including, but not limited to, the marketing, advertising, selling, and distributing of drugs, including TAXOTERE®, to the residents in this State.
4. As alleged *infra*, Plaintiff's injuries complained of in the instant civil action "arise out of or "relate to" the Defendants' contacts with the State of Louisiana.
5. Here, Defendants have sufficient "minimum contacts" with the State of Louisiana, such that the imposition of jurisdiction would not violate "traditional notions of fair play and substantial justice."
6. At all times relevant hereto, Defendants Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S. , Inc., have been "doing business" and have committed tortious acts, in whole or in part, within the State of Louisiana.
7. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., have or had employees in the State of Louisiana.

8. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S. , Inc., actively marketed TAXOTERE® within the State of Louisiana by providing marketing information about the drug to medical doctors and providers of medical treatment throughout the State of Louisiana.
9. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S. , Inc., solicited purchases of TAXOTERE® within the State of Louisiana by soliciting purchases of TAXOTERE® from medical doctors and providers of medical treatment throughout the State of Louisiana.
10. Upon information and belief, at all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., provided product information about TAXOTERE® to medical doctors and providers of medical treatment throughout the State of Louisiana.
11. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., sold TAXOTERE® within the State of Louisiana by selling the drug to medical doctors and providers of medical treatment throughout the State of Louisiana.
12. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., shipped TAXOTERE® to the State of Louisiana by shipping the drug to medical doctors and providers of medical treatment throughout the State of Louisiana.
13. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., expected that TAXOTERE® would be sold, purchased, and used in the State of Louisiana.
14. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., purposefully directed its activities towards the State of Louisiana.
15. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis

- U.S., Inc., exercised the privilege of conducting business in the State of Louisiana.
16. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., enjoyed the benefits and protections of the laws of the State of Louisiana.
 17. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.'s activities in the State of Louisiana were neither irregular nor casual; rather, those activities were systematic and continuous.
 18. Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., had fair warning that it might be subject to personal jurisdiction in the State of Louisiana and that it might be hauled into court in the State of Louisiana with respect to its systematic and continuous activities involved with the marketing, advertising, solicitation of purchases, and sales of TAXOTERE® in the State of Louisiana.
 19. Specific personal jurisdiction over Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., in the State of Louisiana is reasonable.
 20. There is no burden on Defendant Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., in litigating the instant case in Louisiana as Defendant Sanofi-Aventis U.S. LLC, regularly, systematically and continuously solicits and conducts business in the State of Louisiana, and already enjoys the benefits and protections of the laws of the State of Louisiana.
 21. Plaintiff has a substantial interest in obtaining convenient and effective relief in the State of Louisiana — the place where Defendants purposeful activities ultimately resulted in her injuries. On the other hand, if personal jurisdiction does not lie in Louisiana, Plaintiff will be forced to litigate her case(s) in New Jersey and/or France.
 22. At all times relevant hereto, as set forth more fully *infra*, Defendant Sanofi-Aventis U.S.

LLC and Sanofi-Aventis U.S., Inc., are wholly-owned subsidiaries of Defendant Sanofi S.A. — 100% owned and controlled by Defendant Sanofi S.A.

23. At all times relevant hereto, as set forth more fully *infra*, Defendant Aventis-Pharma S.A. is a wholly-owned subsidiary of Defendant Sanofi S.A.
24. At all times relevant hereto, as set forth more fully *infra*, Defendant Aventis-Pharma S.A., a wholly-owned subsidiary of Defendant Sanofi S.A., was the patent-holder of TAXOTERE®. Indeed, Defendant Aventis-Pharma S.A., along with Defendant Sanofi-Aventis U.S. LLC, prosecutes patent infringement lawsuits with respect to docetaxel (TAXOTERE®) in the United States. *See, e.g., Aventis Pharma S.A. and Sanofi-Aventis US LLC v. Haspira. Inc.*, 743 F. Supp. 2d 305, 322 (D. Del. 2010) *affd*; 675 F.3d 1324 (Fed. Cir. 2012).
25. At all times relevant hereto, Defendant Sanofi-Aventis US LLC and Sanofi-Aventis U.S. , Inc., were the agents of Defendant Sanofi S.A. and its wholly-owned subsidiary Defendant Aventis-Pharma S.A. — the patent-holder of TAXOTERE® for purposes of marketing, advertising, soliciting purchases, and selling TAXOTERE® in the State of Louisiana.
26. At all times relevant hereto, Defendant Sanofi-Aventis US LLC LLC and Sanofi-Aventis U.S. , Inc., were the alter ego of Defendant Sanofi S.A. and its wholly-owned subsidiary Defendant Aventis-Pharma S.A. — the patent-holder of TAXOTERE® for purposes of marketing, advertising, soliciting purchases, and selling TAXOTERE® in the State of Louisiana.
27. Plaintiffs use of, and ultimately injury by, TAXOTERE® in the State of Louisiana was not an isolated occurrence, but arose from the purposeful efforts of Defendant Sanofi

S.A. and Defendant Aventis-Pharma S.A., through Defendant Sanofi S.A.'s and Defendant Aventis-Pharma S.A.'s agent, Defendant Sanofi-Aventis US LLC, and Sanofi-Aventis U.S. , Inc., to create and serve the market for TAXOTERE® in the State of Louisiana by the marketing, advertising, soliciting purchases, and selling of TAXOTERE® in the State of Louisiana.

28. Defendant Sanofi S.A. and Defendant Aventis-Pharma S.A. placed TAXOTERE® into the stream of commerce with the intent that it would be marketed, advertised, and sold by their agent and/or alter ego Defendant Sanofi-Aventis US LLC and Sanofi-Aventis U.S., Inc., in the State of Louisiana.
29. At all times relevant hereto, the activities of Defendant Sanofi-Aventis US LLC and Sanofi-Aventis U.S. , Inc., were of such character as to amount to doing the business of Defendant Sanofi S.A. and Defendant Aventis-Pharma S.A. — the patent-holder of TAXOTERE® — in the State of Louisiana.
30. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants marketed, advertised, and distributed the dangerous product in this District; Plaintiff resides in this District; Plaintiff's harms, losses, and damages occurred in this District; Defendants do substantial business in the State of Louisiana and within this District; and at all times relevant hereto, Defendants developed, manufactured, promoted, marketed, distributed, warranted, and sold TAXOTERE® in interstate commerce.

PARTIES

31. Plaintiff is and was at all relevant times a citizen and adult resident of the State of Louisiana and domiciled in Jefferson Parish. Plaintiff was prescribed and administered TAXOTERE®, which was developed, manufactured, promoted, marketed, distributed,

and sold by Defendants. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

32. Defendant Sanofi S.A. is a corporation or Societe Anonyme organized and existing under the laws of France, having its principal place of business at 54 rue La Soetie, 75008 Paris, France.
33. Defendant Aventis Pharma S.A. is a corporation or Societe Anonyme organized and existing under the laws of France, having its principal place of business at 20 Avenue Raymond Aron, 92160 Antony, France.
34. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. LLC is a subsidiary of Defendant Sanofi S.A. Defendant Sanofi S.A. is the only member and owns 100% of the membership interest (both financial and voting) of Defendant Sanofi-Aventis U.S. LLC. Defendant Sanofi-Aventis U.S. LLC does not have any members that are citizens, residents, or domiciliaries of the State of Louisiana. Defendant Sanofi-Aventis U.S. LLC sometimes operates, promotes, markets, sells, distributes pharmaceutical products, and does business under the name of Winthrop U.S., which is not a separately existing legal entity but rather is a business unit or division operating within and part of Sanofi-Aventis U.S. LLC.
35. Sanofi-Aventis U.S., Inc, is a Delaware limited liability company, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. Inc., is a subsidiary of Defendant Sanofi S.A. Defendant Sanofi S.A. is the only member and owns 100% of the membership interest (both financial and voting) of Defendant Sanofi-Aventis U.S., Inc. Defendant Sanofi-Aventis U.S., Inc., does

not have any members that are citizens, residents, or domiciliaries of the State of Louisiana.

DEFENDANTS' OWNERSHIP AND UNITY OF INTEREST

36. Sanofi S.A. is a French multinational pharmaceutical parent company that operates worldwide through a complex, consolidated, and intermingled web of more than 400 wholly-owned subsidiaries, including Aventis Pharma S.A., Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC. As of 2013, Sanofi S.A. was the world's fifth-largest pharmaceutical company by sales.
37. At all times relevant, Sanofi S.A. was engaged in the business of researching, analyzing, licensing, designing, formulating, compounding, patenting, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug TAXOTERE® through its numerous wholly-owned subsidiaries in the United States and throughout the world, including Defendants Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC.
38. The predecessor to the entity now known as Sanofi S.A. was founded in 1973 as a subsidiary of Elf Aquitaine, a French oil company subsequently acquired by Total, when Elf Aquitaine took control of the Labaz group pharmaceutical company. In 1993, Sanofi entered the U.S. pharmaceutical market by first partnering with and then later acquiring Sterling Winthrop and its prescription pharmaceutical business in 1994. Sanofi was incorporated under the laws of France in 1994 as a *societe anonyme*.
39. Aventis was formed in 1999 when the French company Rhone-Poulenc S.A. merged with the German corporation Hoechst Marion Roussel, which itself was formed from the 1995 merger of Hoechst AG with Cassella, Roussel Uclaf, and Marion Merrell Dow. The

merged company was based in Schiltigheim, near Strasbourg, France.

40. Sanofi-Aventis S.A. was formed in 2004 with the merger of Aventis and Sanofi-Synthelabo, each of which had previously been formed through mergers. Sanofi-Aventis changed its name to Sanofi S.A. on May 6, 2011, after receiving approval at its annual general meeting.
41. Sanofi S.A.'s shares are listed on the New York Stock Exchange and the NASDAQ Global Market. Sanofi S.A. is required by law to register its securities in the United States under section 12(g) of the Securities Exchange Act of 1934 on Form 20-F and to file its annual reports on Form 20-F.
42. According to Sanofi S.A.'s Form 20-F filed with the U.S. Securities and Exchange Commission for the fiscal year ended December 31, 2014, Sanofi S.A. owns 100% of the membership and voting interest of Sanofi-Aventis U.S. LLC. and Sanofi-Aventis U.S., Inc. Therefore, Sanofi S.A. controls and directs the operations of Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.
43. Sanofi-Aventis U.S. LLC, according to Sanofi S.A.'s Form 20-F, was formed on June 28, 2000 as a Delaware limited liability company whose principal activity was identified as "Pharmaceuticals." Sanofi-Aventis U.S., Inc., is a foreign corporation having a principal place of business in Delaware, and effective December 31, 2005, the operations of Aventis Pharmaceuticals, Inc., and Sanofi Syntholab, Inc., were merged into Sanofi-Aventis U.S., Inc.
44. Upon information and belief, Aventis Pharma S.A. was formed as a successor in interest to Rhone-Poulenc Rorer, S.A.
45. At all times material to this lawsuit, Defendants Sanofi S.A., Aventis Pharma S.A., and

Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., were engaged in the business of, and/or were successors in interest to, entities engaged in the business of researching, analyzing, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug TAXOTERE® to the general public, including Plaintiff.

46. At all times material to this lawsuit, Defendants were authorized to do business within the State of Louisiana; did in fact transact and conduct business in the State of Louisiana; derived substantial revenue from goods and products used in the State of Louisiana; and supplied TAXOTERE® within the State of Louisiana.
47. At all relevant times, and as more fully set forth below, Defendants acted in conjunction with other affiliated, related, jointly owned and/or controlled entities or subsidiaries, including each other, in the development, marketing, production, labeling, promoting, packaging, advertising, and/or selling of TAXOTERE® to the general public, including Plaintiff. Defendants acted jointly and/or as each other's agents, within the course and scope of the agency, with respect to the conduct alleged in this Complaint, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another and are jointly liable for their misconduct and wrongful acts as alleged herein.
48. As the corporate parent of these wholly-owned subsidiaries, Sanofi S.A. directs and controls the operations of Aventis Pharma S.A. Sanofi-Aventis U.S. LLC, and Sanofi-Aventis U.S., Inc. Accordingly, there exists, and at all relevant times herein existed, a unity of interest, ownership, and conduct between Sanofi S.A., Aventis Pharma S.A., and

Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc. with regard to the manufacture, distribution, development, testing, and labeling of the TAXOTERE® in question and with regard to other related conduct, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another.

49. Sanofi S.A., through its complicated web of various affiliates, wholly-owned subsidiaries, and predecessor companies, including Aventis Phatina S.A... Sanofi-Aventis U.S. LLC, and Sanofi-Aventis U.S., Inc. have been directly involved in and has overseen the invention, development, clinical trials, and strategy for marketing, distributing, selling, and promoting TAXOTERE® (docetaxel) throughout the world and in the United States. Sanofi S.A. markets TAXOTERE® (docetaxel) worldwide in over 100 different countries. When press releases are issued announcing the introduction, marketing, and distribution of TAXOTERE® (docetaxel) in a new country, the press releases are issued by Sanofi S.A., or before 2011 when Sanofi S.A. changed its name, by Sanofi- Aventis.

DEFENDANTS' INVOLVEMENT IN THE DEVELOPMENT, PATENTING, TESTING MARKETING. AND SALE OF TAXOTERE® (DOCETAXEL)

50. TAXOTERE® is a drug used in the treatment of various forms of cancer, including, but not limited to, breast cancer. Docetaxel (TAXOTERE®) is a part of a family of drugs commonly referred to as Taxanes.
51. Taxanes are diterpenes produced by the plants of the genus Taxus (yews) featuring a taxadiene core. Taxanes are widely used as chemotherapy agents. Taxane agents include paclitaxel (TAXOL®) and docetaxel (TAXOTERE®). Taxane agents also exist as cabazitaxel and in generic forms as well.
52. Paclitaxel (TAXOL®), which was developed, manufactured, and distributed by Bristol-

Myers Squibb and is the main competitor drug to TAXOTERE®, was first approved by the U.S. Food and Drug Administration (FDA) in December 1992.

53. The drug and chemical compound that would become known as TAXOTERE® was invented and developed by Michel Colin, Daniel Guenard, Françoise Gueritte—Voegelien, and Pierre Potier of Rhone-Poulence Sante. TAXOTERE® was designed as an increased potency Taxane.
54. The initial patent disclosing the formulation and computation of docetaxel (TAXOTERE®) was issued to Rhone-Poulence Sante and subsequently assigned to Defendant Aventis Pharma S.A. in March 1989. Sanofi S.A. owns 100% of the shares or financial interest of Aventis Pharma S.A., and Sanofi S.A. therefore directs and controls the operations and activities of Aventis Pharma S.A. Since March 1989, Sanofi S.A., through its wholly-owned subsidiary, Aventis Pharma S.A., has controlled the development and been the owner, holder, or assignee of the patents related to TAXOTERE®.
55. In 1989, Sanofi issued the prior art publication F. Lavelle, *Experimental Properties of RP 56976*, a taxol derivative. RP 56976 was the number that Rhone-Polunec, Aventis Pharma S.A.'s predecessor, assigned to docetaxel.
56. Sanofi began enrolling patients in Phase I clinical testing trials on June 21, 1990. The study reporting on these trials was called the "TAX 001" study, which continued until May 13, 1992. The results from the TAX 001 study were reported on May 24, 1994. Accordingly, Sanofi was not only involved in the patenting and assignment of the compound TAXOTERE®, but Sanofi was also directly involved in the clinical trials and testing of the compound TAXOTERE®. Accordingly, Sanofi S.A. and Aventis

Pharma S.A. have direct and personal knowledge of the results of those tests and Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC's decisions to withhold information and data from those tests from physicians, healthcare providers, patients, and Plaintiff in the United States.

57. Rhone-Poulenc Rorer S.A., before it was acquired by or merged into Aventis Pharma S.A., initially sought FDA approval for TAXOTERE® in December 1994. The FDA's Oncologic Drugs Advisory Committee panel unanimously recommended the rejection of Rhone-Poulenc Rorer S.A.'s request for the approval of TAXOTERE®, because TAXOTERE® was more toxic than its competing drug TAXOL®, which had already received FDA approval, and because more studies of docetaxel's side effects were needed.
58. TAXOTERE® was ultimately approved by the FDA on May 14, 1996. According to its product labeling, TAXOTERE® was "indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy."
59. After the initial FDA approval, Defendants sought and were granted FDA approval for additional indications for TAXOTERE®. Based on self-sponsored clinical trials, Defendants claimed superiority over other chemotherapy products approved to treat breast cancer. Defendants' marketing claims included claims of superior efficacy over the lower potency Taxane product paclitaxel (TAXOL®), which was the primary competitor product to TAXOTERE®.
60. Contrary to Defendants' claims of superior efficacy, post market surveillance has shown that the more potent and more toxic TAXOTERE® does not in fact offer increased efficacy or benefits over other Taxanes, as Defendants have claimed and advertised.

Defendants concealed the existence of studies from the FDA, physicians, and patients that refuted Defendants' claims.

61. A study of available clinical studies concerning the relative efficacy of Taxanes in the treatment of breast cancer, published in the August 2007 journal *Cancer Treatment Review*, concluded that no significant differences were found in the efficacy and outcomes obtained with TAXOTERE® (docetaxel) or TAXOL® (paclitaxel).
62. A study published in 2008 in the New England Journal of Medicine, titled *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*, concluded that TAXOL® (paclitaxel) was more effective than TAXOTERE® for patients undergoing standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.
63. Despite the publication of these studies, Defendants continued to make false and misleading statements promoting the "superior efficacy" of TAXOTERE® over the competing product paclitaxel (TAXOL®). In June 2008, Sanofi-Aventis utilized marketing and promotional materials for TAXOTERE® at the annual meeting for the American Society of Clinical Oncology, comparing the efficacy of TAXOTERE® versus paclitaxel (TAXOL®). Specifically, Sanofi-Aventis utilized a "reprint carrier," citing a clinical study published in the August 2005 edition of the Journal of Clinical Oncology ("JCO"). The 2005 JCO study concluded that "docetaxel (TAXOTERE®) demonstrated superior efficacy compared with paclitaxel (TAXOL®), providing significant clinical benefit in terms of survival and time to disease progression, with a numerically higher response rate and manageable toxicities."
64. Whatever the merits of the 2005 JCO study may have been, Defendants' statements in the "reprint carrier" marketing the conclusions of the 2005 JCO study were false and/or

misleading in light of the 2007 and 2008 studies finding that docetaxel (TAXOTERE®) was not more effective than paclitaxel (TAXOL®) in the treatment of breast cancer.

65. As a result of these false and misleading statements, in 2009, the FDA issued a warning letter to Sanofi-Aventis (the same company as Defendant Sanofi S.A. before Sanofi-Aventis changed its name in 2011) citing these unsubstantiated claims of superiority over paclitaxel stating:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a professional reprint carrier [US.DOC.07.04.078] for Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion (Taxotere) submitted under cover of Form FDA 2253 by Sanofi-Aventis (SA) and obtained at the American Society of Clinical Oncology annual meeting in June 2008. The reprint carrier includes a reprint¹ from the Journal of Clinical Oncology, which describes the TAX 311 study. This reprint carrier is false or misleading because it presents unsubstantiated superiority claims and overstates the efficacy of Taxotere. Therefore, this material misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a) and 321(n). *Cf.* 21 CFR 202.1(e)(6)(i), (ii) & (e)(7)(ii).²

66. A Qui Tam lawsuit was also filed against Sanofi-Aventis and its affiliates in the United States District Court for the Eastern District of Pennsylvania by a former employee accusing Sanofi-Aventis and its affiliates of engaging in a fraudulent marketing scheme, paying kickbacks, and providing other unlawful incentives to entice physicians to use docetaxel (TAXOTERE®). *See U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, Civil Action No. 02-2964 (E.D. Pa. 2015).

67. Beginning in 1996, Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S., Inc. and

¹ Jones SE, Erban J, Overmoyer B, et al. Randomized phase III study of docetaxel compared with paclitaxel in metastatic breast cancer. *J Clin Oncol.* 2005;23(24):5542-51.

² Correspondence signed by Keith Olin, Pharm.D., Regulatory Review Officer in the FDA's Division of Drug Marketing, Advertising and Communications to MaryRose Salvacion, Director of US Regulatory Affairs Marketed Products at Sanofi-Aventis.

Sanofi-Aventis U.S. LLC and their predecessors and affiliates designed, directed, and/or engaged in a marketing scheme that promoted TAXOTERE® for off-label uses not approved by the FDA. The scheme took two forms: first, Defendants trained and directed their employees to misrepresent the safety and effectiveness of the off-label use of TAXOTERE® to expand the market for TAXOTERE® in unapproved settings; and second, Defendants paid healthcare providers illegal kickbacks in the form of sham grants, speaking fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free reimbursement assistance to incentivize healthcare providers to prescribe TAXOTERE® for off-label uses. As a direct result of Defendants' fraudulent marketing scheme, Defendants dramatically increased revenue on sales of TAXOTERE® from \$424 million in 2000 to \$1.4 billion in 2004. *U.S. ex rel. Gohil v. Sanofi-Aventis US, Inc.*, 96 F. Supp. 3d 504, 508 (E.D. Pa. 2015).

68. As a direct result of their wrongful conduct and illegal kickback schemes, Defendants directly caused thousands of individuals to be exposed to TAXOTERE®'s increased toxicity as compared to other available less toxic products.
69. As a direct result of their aforementioned conduct, Defendants caused thousands of individuals to be exposed to increased frequency and more severe side effects, including, but not limited to, disfiguring permanent alopecia (hair loss).

**DEFENDANTS' COVER UP IN THE UNITED STATES
REGARDING THE CAUSAL RELATIONSHIP BETWEEN DOCETAXEL
TAXOTERE AND PERMANENT DISFIGURING HAIR LOSS**

70. Although alopecia, or hair loss, is a common side effect related to chemotherapy drugs, permanent alopecia is not. Defendants, through their publications and marketing materials, misled Plaintiff, the public, and the medical community to believe that, as with

other chemotherapy drugs that cause alopecia, patients' hair would grow back.

71. Defendants knew or should have known that the rate of permanent alopecia related to TAXOTERE® was far greater than with other products available to treat the same condition as Defendants' product.
72. Permanent baldness (permanent alopecia) is a disfiguring condition, especially for women. Women who experienced disfiguring permanent alopecia as a result of the use of TAXOTERE® suffer great mental anguish as well as economic damages, including, but not limited to, loss of work or inability to work due to significant psychological damage.
73. Although women might accept the possibility of permanent baldness as a result of the use of TAXOTERE® if no other product were available to treat their cancer, this was not the case. Before Defendants' wrongful conduct resulted in thousands of women being exposed to the side effects of TAXOTERE®, there were already similar products on the market that were at least as effective as TAXOTERE® and did not subject female users to the same risk of disfiguring permanent alopecia as does TAXOTERE®.
74. Beginning in the late 1990's, Sanofi S.A. and Aventis Pharma S.A. sponsored and/or were aware of a study titled the GEICAM 9805 study. In 2005, Sanofi S.A. and Aventis Pharma S.A. knew that the GEICAM 9805 study demonstrated that 9.2% of patients who took TAXOTERE® had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer, after taking TAXOTERE®. Sanofi S.A. and Aventis Pharma S.A. knowingly, intentionally, and wrongfully withheld these results contained in the GEICAM 9805 study from physicians, healthcare providers, patients, and Plaintiff in the United States.
75. In 2006, Defendants knew or should have known that a Denver-based oncologist in the

United States had observed that an increased percentage (6.3%) of his patients who had taken TAXOTERE® suffered from permanent disfiguring hair loss for years after the patients had stop taking TAXOTERE®.

76. Despite Defendants' knowledge of the relevant findings from the GEICAM 9805 study, as well as reports from patients who had taken TAXOTERE® and suffered from permanent disfiguring hair loss, Defendants have failed, to date, to provide accurate information and proper warnings to physicians, healthcare providers, and patients in the United States, including Plaintiff, that patients who take TAXOTERE® are at a significantly increased risk of suffering from permanent disfiguring hair loss.
77. Defendants have chosen to withhold this information in the United States despite advising physicians, patients, and regulatory agencies in other countries, including the European Union and Canada, that TAXOTERE® causes an increased risk of permanent disfiguring hair loss. Defendants instead continued to warn or advise physicians, healthcare providers, patients, and Plaintiff in the United States only with the generic, vague, and insufficient warning that "hair generally grows back" after taking TAXOTERE®.
78. Users of TAXOTERE® were not presented with the opportunity to make an informed choice as to whether the benefits of TAXOTERE® were worth its associated risks. Defendants engaged in a pattern of deception by overstating the benefits of TAXOTERE® as compared to other alternatives while simultaneously failing to warn of the risk of disfiguring permanent alopecia.
79. Although Defendants publish information in other countries to individual patients as well as regulatory agencies related to TAXOTERE® and the risk of permanent alopecia, and

despite numerous U.S. label changes and safety warnings issued by Defendants since 1995, the words permanent alopecia or permanent hair loss did not appear in any information published by Defendants in the United States until, at the earliest, December 2015.

80. As a direct result of Defendants' wrongful and deceptive acts, thousands of cancer victims were exposed to the risk of disfiguring permanent alopecia without any warning and without any additional benefit.
81. As a direct result of Defendants' failure to warn patients of the risk of disfiguring permanent alopecia in the United States, thousands of cancer victims, including Plaintiff, as well as their health care providers, were deprived of the opportunity to make an informed decision as to whether the benefits of using TAXOTERE® over other comparable products was justified.
82. Defendants preyed on one of the most vulnerable groups of individuals at the most difficult time in their lives. Defendants obtained billions of dollars in increased revenues at the expense of unwary cancer victims simply hoping to survive their condition and return to a normal life.
83. TAXOTERE® was defective in its design. TAXOTERE® was designed as an increased potency Taxane. This increased potency resulted in increased toxicity, which can be directly related to increased adverse events. The most likely reason Defendants designed the increased potency Taxane was to enable them to obtain a patent (and the concurrent market advantage) on a product that in fact was not novel but instead only more dangerous.
84. Plaintiff as well as numerous other cancer victims, was an innocent victim of

Defendants' greed, recklessness, and willful and wanton conduct.

**PLAINTIFF'S DIAGNOSIS, TREATMENT, AND
RESULTING DISFIGURING PERMANENT ALOPECIA**

85. In October 2007, Plaintiff was diagnosed with stage 3 breast cancer.
86. On or around January 2008 to approximately May 2008, Plaintiff was administered TAXOTERE® in Jefferson Parish. Neither Plaintiff nor her treating healthcare providers were aware of or informed by Defendants that disfiguring permanent alopecia can occur following treatment with TAXOTERE®. Accordingly, Plaintiff did not know or suspect until on or around August 2016 that she was suffering from continuing hair loss as a result of taking TAXOTERE®. As a result of Defendants' wrongful conduct, Plaintiff has continued to suffer and will suffer in the future from disfiguring permanent alopecia as a result of receiving chemotherapy with TAXOTERE®.

NATURE OF THE CLAIMS

87. Despite the fact that Defendants disclosed risks associated with TAXOTERE® and permanent alopecia to patients and regulatory agencies in other countries, Defendants failed to either alert Plaintiff, the public, and the scientific community in the United States or performing further investigation into the safety of TAXOTERE® regarding the side effect of disfiguring permanent alopecia. Defendants failed to update the warnings for TAXOTERE®, and they failed to disclose the results of additional studies as Defendants learned new facts regarding the defects and risks of their product.
88. In particular, Defendants:
- (a) failed to disclose their investigation and research from 2005, including, but not limited to, the results of the GEICAM 9805 study, and failed to further

investigate, research, study, and define fully and adequately the safety profile of TAXOTERE® in response to these studies;

- (b) failed to provide adequate warnings about the true safety risks associated with the use of TAXOTERE®
- (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of TAXOTERE® and its effects on the degree or severity of side effects related to permanent alopecia;
- (d) failed to disclose in the "Warnings" Section that permanent alopecia is a frequent side effect associated with the use of TAXOTERE®;
- (e) failed to advise prescribing physicians, such as Plaintiff's physicians, to
- (f) instruct patients that permanent alopecia was a side effect, much less a frequent side effect, linked to TAXOTERE®;
- (g) failed to provide adequate instructions on how to intervene and/or reduced
- (h) the risk of permanent alopecia related to the use of TAXOTERE®;
- (i) failed to provide adequate warnings and information related to the increased risks of permanent alopecia;
- (j) failed to provide adequate warnings regarding the increased risk of permanent alopecia with the use of TAXOTERE® as compared to other products designed to treat the same conditions as TAXOTERE®; and
- (k) failed to include a "**BOXED WARNING**" related to permanent or persistent alopecia.

89. During the years since first marketing TAXOTERE® in the U.S., Defendants modified the U.S. labeling and prescribing information for TAXOTERE® on multiple occasions.

Defendants failed, however, to include any warning whatsoever related to permanent alopecia despite Defendants' awareness of the frequency and severity of this side effect until at the earliest, December 2015.

90. Before applying for and obtaining approval of TAXOTERE®, Defendants knew or should have known that consumption of TAXOTERE® was associated with and/or would cause disfiguring side effects including disfiguring permanent alopecia.
91. Despite knowing that TAXOTERE® was likely to result in increased rates of alopecia and disfiguring permanent alopecia, Defendants produced, marketed, and distributed TAXOTERE® in the United States.
92. Defendants failed to adequately conduct complete and proper testing of TAXOTERE® prior to filing their New Drug Application for TAXOTERE®.
93. From the date Defendants received FDA approval to market TAXOTERE®, Defendants made, distributed, marketed, and sold TAXOTERE® without adequate warning to Plaintiff or Plaintiff's prescribing physicians that TAXOTERE® was associated with disfiguring permanent alopecia.
94. Defendants ignored the association between the use of TAXOTERE® and the risk of disfiguring permanent alopecia.
95. Despite issuing numerous other label changes and safety warnings, Defendants failed to disclose information that they possessed regarding their failure to adequately test and study TAXOTERE® related to the side effect of disfiguring permanent alopecia. Plaintiff and her healthcare providers could not have discovered Defendants' false representations and failures to disclose information through the exercise of reasonable diligence.

96. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

**ESTOPPEL FROM PLEADING PRESCRIPTIVE STATUTES
OR STATUTES OF LIMITATION OR REPOSE**

97. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.
98. Plaintiff is within the applicable statutes of limitations for the claims presented herein because Plaintiff did not discover the defects and unreasonably dangerous condition of Defendants' TAXOTERE® and the risks associated with its use in the form of disfiguring permanent alopecia, and could not reasonably have discovered the defects and unreasonably dangerous condition of Defendants' TAXOTERE® and the risks associated with its use, due to the Defendants' failure to warn, suppression of important information about the risks of the drug, including, but not limited to, the true risk benefit profile, and the risk of disfiguring permanent alopecia and damages known by Defendants to result from the use of TAXOTERE®, and other acts and omissions.
99. In addition, Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, affirmative misrepresentations

and omissions, which include Defendants' intentional concealment from Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public that Defendants' TAXOTERE® was defective, unreasonably dangerous and carried with it the serious risk of developing the injuries Plaintiff has suffered while aggressively and continually marketing and promoting TAXOTERE® as safe and effective. This includes, but is not limited to, Defendants' failure to disclose and warn of the risk of disfiguring permanent alopecia and injuries known by Defendants to result from use of TAXOTERE®, for example, and not by way of limitation, internal concern about reports and studies finding an increased risk of disfiguring permanent alopecia; suppression of information about these risks and injuries from physicians and patients, including Plaintiff; use of sales and marketing documents and information that contained information contrary to the internally held knowledge regarding the aforesaid risks and injuries; and overstatement of the efficacy and safety of TAXOTERE®.

100. Defendants had a duty to disclose that TAXOTERE® was defective, unreasonably dangerous and that the use of Defendants' TAXOTERE® carried with it the serious risk of developing disfiguring permanent alopecia as the Plaintiff has suffered. Defendants breached that duty.
101. Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public, had no knowledge of, and no reasonable way of discovering, the defects found in Defendants' TAXOTERE® or the true risks associated with the use of Defendants' TAXOTERE® at the time the product was purchased and used by Plaintiff.
102. Defendants did not notify, inform, or disclose to Plaintiff, Plaintiff's prescribing health care professionals or the general consuming public that Defendants' TAXOTERE® was

defective and that its use carried with it the serious risk of developing the injuries Plaintiff has suffered and complained of herein until a safety labeling change issued in December 2015, although this change is inadequate as it fails to warn of the true risks related to permanent alopecia.

103. Because Defendants failed in their duty to notify Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public that their TAXOTERE® was defective and, further, actively attempted to conceal this fact, Defendants should be estopped from asserting defenses based on statutes of limitation or repose. The doctrine of *contra non valentem agere nulla currit praescriptio* prevents the running of liberative prescription when the cause of action is not known or reasonably knowable by the plaintiff. There are four instances recognized by the Louisiana Supreme Court where *contra non valentem* is applied to prevent the running of prescription: (1) where there is some legal cause which prevented the courts or their officials from taking cognizance of or acting on the plaintiff's action; (2) where there was some condition coupled with the contract or connected with the proceedings which prevented the creditor from suing or acting; (3) where the debtor himself has done some act effectually to prevent the creditor from availing himself of his cause of action; or (4) where the cause of action is neither known nor reasonably knowable by the plaintiff even though this ignorance is not induced by the defendant. Plaintiff asserts that the third category of *contra non valentem* applies in this case due to the misrepresentations and omissions by defendants, described *supra*. The third category of *contra non valentem* applies when the defendant has done some act effectually to lull the victim into inaction and prevent him or her from availing himself of their cause of action. When, as here, the defendants engaged in concealment,

misrepresentation, fraud, and ill practices, prescription is suspended until plaintiff was made aware of the link between the use of Talc and cancer. In the alternative, Plaintiff asserts that the fourth category of contra non valentum applies in this case due to the fact that there was no information available to the Plaintiff that would put a reasonable Plaintiff on notice of the link between Talc and cancer.

104. Accordingly, Plaintiff files this lawsuit within the applicable statutes of limitations, Plaintiff could not by exercise of reasonable diligence have discovered any wrongdoing, nor could have discovered the causes of her injuries at an earlier time, and when Plaintiffs injuries were discovered, their causes were not immediately known or knowable based on the lack of necessary information, which was suppressed by the Defendants. Further, the relationship of Plaintiff's injuries to TAXOTERE® exposure through the Defendants' drug was inherently difficult to discover, in part due to the Defendants' knowing suppression of important safety information. Consequently, the discovery rule should be applied to toll the running of the prescriptive/statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence should have discovered, that Plaintiff may have a basis for an actionable claim.

LIABILITY UNDER THE LOUISIANA PRODUCTS LIABILITY ACT

105. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint inclusive, with the same force and effect as if fully set forth herein.
106. Under the Louisiana Products Liability Act, Plaintiff shows that the serious risk of developing disfiguring permanent alopecia and other injuries are the direct and proximate result of breaches of obligations owed by Defendants to Plaintiff, including defects in design, marketing, manufacture, distribution, instructions and warnings by

Defendants, which breaches and defects are listed more particularly, but not exclusively, as follows:

- (a) Failure to instruct and/or warn of the serious risk of developing disfiguring permanent alopecia and other injuries;
- (b) Failure to adequately instruct and/or warn healthcare providers, including those healthcare providers who administered TAXOTERE® to Plaintiff, of the serious risk of developing disfiguring permanent alopecia and other injuries;
- (c) Manufacturing, producing, promotion, formulating, creating, and/or designing TAXOTERE® without adequately testing it;
- (d) Failing to provide adequate warning of the dangers associated with TAXOTERE®;
- (e) The defects in designing, formulating, researching, developing, manufacturing, marketing, promoting and selling a medication when it knew or reasonably should have known of the propensity to cause disfiguring permanent alopecia and other injuries;
- (f) Defendants' liability under the Louisiana Products Liability Act as a result of its design, development, manufacture, marketing, and sale of a medication which is defective and unreasonably dangerous for the risk of developing disfiguring permanent alopecia and other injuries;
- (g) The continued production and sale of docetaxel (TAXOTERE®) given the propensity of the medication to cause disfiguring permanent alopecia and other injuries;
- (h) Providing inaccurate labeling and inadequate warnings and instructions;

- (i) Utilizing testing methods which were not accurate, sensitive, specific, and/or reproducible;
- (j) Other breaches and defects which may be shown through discovery or at trial; and
- (k) Generally, the failure of Defendants to act with the required degree of care commensurate with the existing situation.

FIRST CLAIM FOR RELIEF
(Design Defect under LSA-RS 9:2800.56)

- 107. Plaintiff repeats, reiterates, and re-alleges **all** paragraphs of this Complaint, with the same force and effect as if fully set forth herein.
- 108. At **all** times relevant, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed TAXOTERE® as hereinabove described that was used by Plaintiff.
- 109. TAXOTERE® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.
- 110. At those times, TAXOTERE® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.
- 111. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of TAXOTERE®.
- 112. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or

formulation, in that, when it left the hands of Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and it was more dangerous and posed risk greater than an ordinary consumer would expect.

113. At all times relevant, TAXOTERE® was in a defective condition and unsafe, and Defendants knew or had reason to know that TAXOTERE® was defective and unsafe, especially when used in the form and manner as provided by Defendants.
114. Defendants knew, or should have known, that at all times relevant, TAXOTERE® was in a defective condition and was and is inherently dangerous and unsafe.
115. At the time of Plaintiff's use of TAXOTERE®, the TAXOTERE® was being used for the purposes and in a manner normally intended, namely for the treatment of breast cancer.
116. Defendants with this knowledge voluntarily designed TAXOTERE® in a dangerous condition for use by the public, and in particular, Plaintiff.
117. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.
118. In creating TAXOTERE®, Defendants created a product that was and is unreasonably dangerous for its normal, intended use, and a safer alternative design existed.
119. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was manufactured defectively and was unreasonably dangerous to its intended users.
120. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants reached the intended users in

the same defective and unreasonably dangerous condition in which Defendants' TAXOTERE® was manufactured.

121. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers and to Plaintiff in particular; and Defendants are therefore liable for the injuries sustained by Plaintiff in accordance with Louisiana Products Liability Act.
122. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of TAXOTERE®. This was demonstrated by the existence of other breast cancer medications which had a more established safety profile and a considerably lower risk profile, namely paclitaxel (TAXOL®).
123. Plaintiff and Plaintiff's physicians could not, by the exercise of reasonable care, have discovered TAXOTERE®'s defects mentioned herein and perceived its danger.
124. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the product created a risk of serious and dangerous side effects, including disfigurement as well as other severe and personal injuries that are permanent and lasting in nature, and Defendants failed to adequately warn of these risks.
125. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

126. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including disfigurement and/or permanent disfiguring alopecia, as well as other severe and permanent health consequences from TAXOTERE®, they failed to provide adequate warnings to users or consumers of the product, and they continued to improperly advertise, market, and/or promote TAXOTERE®.
127. By reason of the foregoing, Defendants are liable to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of TAXOTERE®, a defective product.
128. Defendants' defective design, manufacturing defect, and inadequate warnings of TAXOTERE® were acts that amount to willful, wanton, and/or reckless conduct by Defendants.
129. The defects in Defendants' drug TAXOTERE® were a substantial and contributing factor in causing Plaintiff's injuries.
130. Due to the unreasonably dangerous conditions of TAXOTERE®, Defendants are liable to Plaintiff.
131. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; future psychological counseling and therapy expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent

alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

SECOND CLAIM FOR RELIEF
(Inadequate Warning Under LSA-RS 9:2800.57)

132. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.
133. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced TAXOTERE® into the stream of commerce, and in the course of same, directly advertised or marketed TAXOTERE® to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and her physicians to warn of risks associated with the use of the product, including, but not limited to, permanent disfiguring alopecia.
134. Defendants had/have a duty to warn of adverse drug reactions, including, but not limited to, permanent disfiguring alopecia, which they knew or should have known can be caused by the use of TAXOTERE® and/or are associated with the use of TAXOTERE®.
135. The TAXOTERE® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects, including, but not limited to, permanent disfiguring alopecia, associated with the use of TAXOTERE . The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in

particular, the risks of disfiguring permanent alopecia.

136. Defendants failed to provide adequate warnings to physicians and users, including Plaintiff's physicians and Plaintiff, of the increased risk of disfiguring permanent alopecia associated with TAXOTERE®, although Defendants aggressively and fraudulently promoted the product to physicians.
137. Due to the inadequate warning regarding the serious risk for disfiguring permanent alopecia, TAXOTERE® was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.
138. Defendants' failure to adequately warn Plaintiff and her prescribing physicians of the serious risk of disfiguring permanent alopecia prevented Plaintiff's prescribing physicians and Plaintiff herself from correctly and fully evaluating the risks and benefits of TAXOTERE®.
139. Had Plaintiff been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Plaintiff would not have taken TAXOTERE®.
140. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Plaintiff's physicians would have discussed the risks of disfiguring permanent alopecia with Plaintiff and/or would not have prescribed it.
141. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of TAXOTERE®, Plaintiff suffered disfiguring permanent alopecia.
142. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses,

including, but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

THIRD CLAIM FOR RELIEF
(Breach of Express Warranty Under LSA-RS 9:2800.58)

143. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.
144. Defendants expressly warranted that TAXOTERE® was safe and well accepted by users.
145. TAXOTERE® does not conform to these express representations, because TAXOTERE® is not safe and has numerous serious side effects, including, but not limited to, permanent and disfiguring alopecia, many of which were not accurately warned about by Defendants.
146. As a direct and proximate result of the breach of these warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, disfigurement, losses, and damages.
147. Plaintiff and Plaintiff's physicians relied on Defendants' express warranties. Furthermore, the express warranties represented by Defendants were a part of the basis for Plaintiffs and Plaintiff's physicians use of TAXOTERE® and Plaintiff relied upon these warranties in deciding to use TAXOTERE®.

148. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendants for use of TAXOTERE® in recommending, prescribing, and/or dispensing TAXOTERE®. Defendants breached the aforesaid express warranties, as their drug TAXOTERE® was and is defective and causes harm and injury as discussed herein.
149. At the time of the making of express warranties, Defendants had knowledge of the purpose for which TAXOTERE® was to be used, and warranted same to be in all respects safe, effective, and proper for such use.
150. Defendants expressly represented to Plaintiff, Plaintiff's physicians, and/or healthcare providers that TAXOTERE® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.
151. Defendants knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue in that TAXOTERE® was not safe and fit for the use intended, and, in fact, TAXOTERE® produced serious injuries to the users that were not accurately identified and represented by Defendants.
152. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future psychological counseling and therapy expenses; past and future loss of earnings; past and future loss

and impairment of earning capacity; permanent disfigurement, including permanent alopecia; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

FOURTH CLAIM FOR RELIEF
(Breach of Warranty in Redhibition)

153. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.
154. TAXOTERE® contains a vice or defect which renders it useless or its use so inconvenient that consumers would not have purchased it had they known about the vice or defect.
155. Pursuant to Louisiana Civil code article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. TAXOTERE®, which was sold and promoted by Defendants, possesses a redhibitory defect because it is unreasonably dangerous, as described above, which renders TAXOTERE® useless or so inconvenient that it must be presumed that had Plaintiff known of the defects, Plaintiff herein would not have bought TAXOTERE®
156. Defendants were aware of the substantial risks of disfiguring permanent alopecia associated with TAXOTERE® but failed to fully disclose those risks to Plaintiff.
157. In accordance with Louisiana Civil Code article 2545, Defendants, as the manufacturers, distributors and sellers of TAXOTERE®, are deemed to be aware of its redhibitory defects.
158. Had Plaintiff been made aware of the defects contained in TAXOTERE®, he would not

have purchased TAXOTERE®. This characteristic rendered TAXOTERE® unfit for its intended purposes.

159. Defendants are liable to Plaintiffs under the theory of redhibition as a consequence of the sale to Plaintiff a product unfit for its intended use.
160. Plaintiff is entitled to the return of purchase price paid for TAXOTERE®, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys' fees and costs, pecuniary and non-pecuniary damages, as well as any other legal and equitable relief to which Plaintiffs may be entitled.
161. As a result of the aforementioned breach of obligation by Defendants, Plaintiff suffered and continues to suffer from the following items of damage, all past, present, and future, for which Plaintiff is entitled to be compensated by Defendants, *in solido*, in an amount which is just and reasonable:
 - (a) Medical and related expenses;
 - (b) Physical injury and disability;
 - (c) Physical pain and suffering;
 - (d) Mental anguish and distress;
 - (e) Loss of earnings;
 - (f) Impairment to earning capacity;
 - (g) Loss of enjoyment of life; and
 - (h) Other items of damage which may be shown through discovery or at trial.
162. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of \$75,000.00, together with interest, costs of suit, and all such other and further relief as

the Court deems proper.

FIFTH CLAIM FOR RELIEF
(Fraud)

163. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein. Fraud is a misrepresentation or a suppression of the truth made with the intention either to obtain an unjust advantage for one party or to cause a loss or inconvenience to the other. Fraud may also result from silence or inaction. - La. C.C. art.1953. Defendants are liable to plaintiff for all damages arising from defendants' fraudulent misrepresentations and suppressions.

SIXTH CLAIM FOR RELIEF
(Unfair Trade and Deceptive Practices)

164. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein. The Louisiana Unfair Trade Practices Act, codified in Louisiana Revised Statutes 51:1401 et seq., makes "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce" unlawful. Section 1409, entitled "Private Actions," specifically creates a private cause of action under LUTPA, which is available to any person "who suffers any ascertainable loss of money or movable property ... as a result of the use or employment by another person of an unfair or deceptive method, act, or practice ...", La. R.S. 51:1409.
165. Acts which constitute unfair or deceptive practices are not specifically defined in the statute and are instead determined by courts on a case-by-case basis. Ferrara v. City of Shreveport, 29,845 (La.App. 2 Cir. 9/24/97), 702 So.2d 723, 726, writ denied,97-2679

(La.1/9/98), 705 So.2d 1109. In order to prevail in an action under LUTPA, a plaintiff must prove that the defendant's underlying conduct offends public policy, is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. *Camp, Dresser & McKee, Inc. v. Steimle and Associates, Inc.*, 94–547 (La.App. 5 Cir. 2/15/95), 652 So.2d 44. For conduct to be “unfair” under LUTPA, it must offend established public policy. *NOLA 180 v. Treasure Chest Casino*, 11–853 (La.App. 5 Cir. 3/27/12), 91 So.3d 446, 449. Under LUTPA, “Trade” or “commerce” is defined as “the advertising, offering for sale, sale, or distribution of any services and any property, corporeal or incorporeal, immovable or movable, and any other article, commodity, or thing of value wherever situated, and includes any trade or commerce directly or indirectly affecting the people of the state.” La. R.S. 51:1402(9).

166. Here, Defendants’ actions violate the LUTPA and subject the Defendants to damages, including attorneys, fees, per statute.

PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

WHEREFORE, Plaintiff demands trial of this matter by jury and further demands judgment against Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi-Aventis U.S. , Inc., and Sanofi-Aventis U.S. LLC, separately and doing business as Winthrop U.S. in an amount to be determined at trial by the trier of fact for her injuries, harms, damages, and losses as set forth above, special damages, treble damages. costs, expert witness fees, attorneys' fees, filing fees, pre- and post-judgment interest, all other injuries and damages as shall be proven at trial, and such other further relief as the Court may deem appropriate, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Morris Bart

Morris Bart (LA Bar # 002788)

Betsy J. Barnes (LA Bar # 19473)

Richard L. Root (LA Bar #19988)

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COUNSEL FOR PLAINTIFFS

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

LISA TUYES

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

(c) Attorneys (Firm Name, Address, and Telephone Number)
Morris Bart, LLC, 631 Poydras St., 24th Floor, New Orleans, La. 70130
(504) 525-8000 Attorneys: Morris Bart, Richard L. Root, and Betsy J. Barnes

DEFENDANTS

SANOFI-AVENTIS U.S., INC., SANOFI S.A., AVENTIS PHARMA S.A., AND SANOFI-AVENTIS U.S. LLC, separately, and doing business as WINTHROP U.S.

County of Residence of First Listed Defendant Middlesex, New Jersey
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

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

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

- | | | | | | |
|---|---------------------------------------|---------------------------------------|---|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 119 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes

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

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from Another District (specify)
- 6 Multidistrict Litigation - Transfer
- 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 usc 1332

Brief description of cause:

Personal injury/Products Liability against Drug Manufacturer

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$ 1,000,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Chief Judge Kurt D. Engelhardt

DOCKET NUMBER MDL-2740

DATE 10/12/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Morris Bart

FOR OFFICE USE ONLY

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT
for the
Eastern District of Louisiana

LISA TUYES

Plaintiff(s)

v.

SANOFI S.A., ET AL

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Aventis Pharma S.A.
20 Avenue Raymond Aron
92160 Antony
France

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney,

whose name and address are: Morris Bart
Betsy Barnes
Richard Root
Morris Bart, LLC
601 Poydras St., 24th Floor
New Orleans, La. 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT
for the
Eastern District of Louisiana

LISA TUYES

Plaintiff(s)

v.

SANOFI S.A., ET AL

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Sanofi-Aventis U.S., LLC
c/o Corporation Service Company
2711 Centerville Road Suite 400
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney,

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AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

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_____, a person of suitable age and discretion who resides there,
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Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: