



2. This Court has federal 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.

3. Defendants have significant contacts in the vicinage of Plaintiff's residence such that they are subject to the personal jurisdiction of the court in that vicinage.

4. A substantial part of the events and omissions giving rise to Plaintiff's causes of actions occurred in the vicinage of Plaintiff's residence, as well as in the district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in both districts.

5. Venue for this case is appropriate in the United States District Court, Eastern District of Louisiana. The Order permitting direct filing into the Eastern District of Louisiana is MDL No. 2740, Pretrial Order No. 5, dated December 13, 2016. Plaintiff would have originally filed in this, the United States District Court, Eastern District of Louisiana.

### **PARTIES**

6. Plaintiff is and was at all relevant times a citizen and adult resident of Jefferson Parish in the State of Louisiana and was prescribed and administered TAXOTERE®, which was developed, manufactured, promoted, marketed, distributed, and sold by Defendants, within this District. Specifically, Plaintiff was treated with TAXOTERE® at University Medical Center located at 2000 Canal St., New Orleans, LA 70112. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

7. Defendant Sanofi S.A. is a corporation or *Société Anonyme* organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

8. Defendant Aventis Pharma S.A. is a corporation or *Société Anonyme* organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

9. 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.

10. 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.

**DEFENDANTS' OWNERSHIP AND  
UNITY OF INTEREST**

11. 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. and Sanofi-Aventis U.S. LLC. As of 2013, Sanofi S.A. was the world's fifth-largest pharmaceutical company by sales.

12. 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.

13. 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 *société anonyme*.

14. Aventis was formed in 1999 when the French company Rhône-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.

15. Sanofi-Aventis S.A. was formed in 2004 with the merger of Aventis and Sanofi-Synthélabo, 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.

16. 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.

17. 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. Therefore, Sanofi S.A. controls and directs the operations of Sanofi-Aventis U.S. LLC.

18. 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.”

19. Upon information and belief, Aventis Pharma S.A. was formed as a successor in interest to Rhone-Poulenc Rorer, S.A.

20. At all times material to this lawsuit, Defendants Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC 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.

21. At all times material to this lawsuit, Defendants were authorized to do business within the United States; did in fact transact and conduct business in the United States; derived substantial revenue from goods and products used in the United States; and supplied TAXOTERE® within the United States.

22. 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.

23. As the corporate parent of these wholly-owned subsidiaries, Sanofi S.A. directs and

controls the operations of Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC. 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 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.

24. Sanofi S.A., through its complicated web of various affiliates, wholly-owned subsidiaries, and predecessor companies, including Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC, has 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)**

25. 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.

26. 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.

27. 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.

28. The drug and chemical compound that would become known as TAXOTERE® was invented and developed by Michel Colin, Daniel Guenard, Françoise Gueritte–Voegelé, and Pierre Potier of Rhone-Poulenc Santé. TAXOTERE® was designed as an increased potency Taxane.

29. The initial patent disclosing the formulation and computation of docetaxel (TAXOTERE®) was issued to Rhone-Poulenc Santé 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®.

30. 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.

31. 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.

32. Rhône-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 Rhône-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.

33. 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."

34. 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®.

35. 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.

36. 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).

37. 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.

38. 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.”

39. 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.

40. 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 reprint<sup>1</sup> 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).<sup>2</sup>

41. 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).

42. Beginning in 1996, Sanofi S.A., Aventis Pharma S.A., and 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®

---

<sup>1</sup> 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.

<sup>2</sup> 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.

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 U.S. Inc.*, 96 F. Supp. 3d 504, 508, (E.D. Pa. 2015).

43. 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.

44. 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**

45. 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.

46. 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.

47. 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.

48. 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®.

49. 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.

50. 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®.

51. 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.

52. 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®.

53. 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.

54. 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.

55. As a direct result of Defendants’ wrongful and deceptive acts, thousands of women were exposed to the risk of disfiguring permanent alopecia without any warning and without any additional benefit.

56. As a direct result of Defendants’ failure to warn patients of the risk of disfiguring

permanent alopecia in the United States, thousands of women, 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.

57. 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.

58. 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.

59. Plaintiff, as well as numerous other women, were the innocent victims of Defendants' greed, recklessness, and willful and wanton conduct.

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

60. After being diagnosed with breast cancer, Plaintiff met with her oncologist to discuss further treatment and decided to move forward with chemotherapy treatment. She was administered TAXOTERE® from approximately July 2009 through approximately October 2009. Plaintiff was treated with TAXOTERE® at University Medical Center located at 2000 Canal St., New Orleans, LA 70112. Neither Plaintiff nor her treating healthcare providers were aware of or informed by Defendants that disfiguring permanent alopecia can occur following treatment with 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**

61. 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 perform 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.

62. 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 instruct patients that permanent alopecia was a side effect, much less a frequent side effect, linked to TAXOTERE®;
- (f) failed to provide adequate instructions on how to intervene and/or reduced the risk of permanent alopecia related to the use of TAXOTERE®;
- (g) failed to provide adequate warnings and information related to the increased

risks of permanent alopecia;

- (h) 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
- (i) failed to include a **“BOXED WARNING”** related to permanent or persistent alopecia.

63. 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.

64. 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.

65. 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.

66. Defendants failed to adequately conduct complete and proper testing of TAXOTERE® prior to filing their New Drug Application for TAXOTERE®.

67. 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.

68. Defendants ignored the association between the use of TAXOTERE® and the risk

of disfiguring permanent alopecia.

69. 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.

70. 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 STATUTES OF LIMITATIONS OR REPOSE**

71. Plaintiff incorporates by reference the averments of the preceding paragraphs of the Complaint as if fully set forth at length herein.

72. 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.

73. 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®.

74. 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.

75. 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 her use at the time she purchased and used Defendants' TAXOTERE®.

76. 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.

77. 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.

78. 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 Plaintiff's 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 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 STATE PRODUCTS LIABILITY ACT**

79. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint

inclusive, with the same force and effect as if fully set forth herein.

80. Under the law of the Plaintiff's resident state, 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, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State, 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)**

81. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

82. At all times relevant, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed TAXOTERE® as hereinabove described that was used by Plaintiff.

83. 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.

84. At those times, TAXOTERE® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.

85. 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®.

86. 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.

87. 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.

88. 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.

89. 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.

90. Defendants with this knowledge voluntarily designed TAXOTERE® in a dangerous condition for use by the public, and in particular, Plaintiff.

91. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

92. In creating TAXOTERE®, Defendants created a product that was and is unreasonably dangerous for its normal, intended use, and a safer alternative design existed.

93. 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.

94. 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.

95. 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 all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

96. 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®).

97. Plaintiff and Plaintiff's physicians could not, by the exercise of reasonable care, have discovered TAXOTERE®'s defects mentioned herein and perceived its danger.

98. 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.

99. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate

warnings and/or inadequate testing.

100. 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®.

101. By reason of the foregoing, Defendants are liable to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of TAXOTERE®, a defective product.

102. Defendants' defective design, manufacturing defect, and inadequate warnings of TAXOTERE® were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

103. The defects in Defendants' drug TAXOTERE® were a substantial and contributing factors in causing Plaintiff's injuries.

104. Due to the unreasonably dangerous conditions of TAXOTERE®, Defendants are liable to Plaintiff.

105. 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)**

106. Plaintiff repeats, reiterates, and re-alleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

107. 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.

108. 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®.

109. 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.

110. 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.

111. 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.

112. 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®.

113. Had Plaintiff been adequately warned of the serious risk of disfiguring permanent alopecia associated with TAXOTERE®, Plaintiff would not have taken TAXOTERE®.

114. 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.

115. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of TAXOTERE®, Plaintiff suffered disfiguring permanent alopecia.

116. 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)**

117. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

118. Defendants expressly warranted that TAXOTERE® was safe and well accepted by users.

119. 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.

120. 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.

121. Plaintiff and Plaintiff's physicians relied on Defendants' express warranties. Furthermore, the express warranties represented by Defendants were a part of the basis for Plaintiff's and Plaintiff's physicians' use of TAXOTERE® and she relied upon these warranties in deciding to use TAXOTERE®.

122. 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.

123. 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.

124. 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.

125. 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.

126. 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 Implied Warranty)**

127. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

128. At all times relevant, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold docetaxel (TAXOTERE®) and/or have recently acquired the entities that have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold docetaxel (TAXOTERE®) for the treatment of various forms of cancer.

129. At the time Defendants marketed, sold, and distributed docetaxel (TAXOTERE®) for use by Plaintiff, Defendants knew of the use for which docetaxel (TAXOTERE®) was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

130. Defendants impliedly represented and warranted to the users of docetaxel (TAXOTERE®) and their physicians, healthcare providers, and/or the FDA that docetaxel (TAXOTERE®) was safe and of merchantable quality and fit for the ordinary purpose for which it was to be used.

131. Defendants' aforementioned representations and warranties were false, misleading, and inaccurate in that docetaxel (TAXOTERE®) was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

132. Plaintiff, Plaintiff's physicians, members of the medical community, and healthcare professionals relied on this implied warranty of merchantability of fitness for a particular use and

purpose.

133. Plaintiff, Plaintiff's physicians, and Plaintiff's healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether docetaxel (TAXOTERE®) was of merchantable quality and safe and fit for its intended use.

134. Docetaxel (TAXOTERE®) was placed into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition.

135. Docetaxel (TAXOTERE®) was expected to and did reach users, handlers, and persons coming into contact with docetaxel (TAXOTERE®) without substantial change in the condition in which it was sold.

136. Defendants breached the aforementioned implied warranties, as their drug docetaxel (TAXOTERE®) was not fit for its intended purposes and uses.

137. 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; 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.

**FIFTH CLAIM FOR RELIEF**  
**(Fraudulent Misrepresentation)**

138. Plaintiff incorporates by reference each preceding and succeeding paragraph as

though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

139. Defendants falsely and fraudulently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, the FDA, and the public in general that docetaxel (TAXOTERE®) had been tested and was found to be safe and effective for the treatment of certain forms of cancer.

140. When warning of safety and risks of docetaxel (TAXOTERE®), Defendants fraudulently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, the FDA, and the public in general that docetaxel (TAXOTERE®) had been tested and was found to be safe and/or effective for its indicated use.

141. Defendants concealed their knowledge of docetaxel's (TAXOTERE®'s) defects from Plaintiff, Plaintiff's physicians, the FDA, and the public in general and/or the medical community specifically.

142. Defendants concealed their knowledge of the defects in their products from Plaintiff, Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

143. Defendants fraudulently misrepresented the novel nature of their product to the USPTO in order to gain a market advantage resulting in billions of dollars in revenues at the expense of vulnerable cancer victims.

144. Defendants made these false representations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff, Plaintiff's physicians, the public in general, and the medical community in particular, to recommend,

dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer, including but not limited to breast cancer, all of which evidenced a callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Plaintiff.

145. Defendants made these false representations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, the FDA, the USPTO as well as the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer, including but not limited to breast cancer.

146. When Defendants made these representations, Defendants knew those representations were false, and Defendants willfully, wantonly, and recklessly disregarded whether the representations were true.

147. At the time Defendants made the aforesaid representations, and, at the time Plaintiff used docetaxel (TAXOTERE®), Plaintiff and Plaintiff's physicians were unaware of the falsity of Defendants' representations, and Plaintiff and Plaintiff's physicians reasonably believed them to be true.

148. In reliance upon Defendants' representations, Plaintiff and Plaintiff's physicians were induced to and did use and prescribe docetaxel (TAXOTERE®), which caused Plaintiff to sustain severe, permanent, and disfiguring personal injuries.

149. Defendants knew and were aware or should have been aware that docetaxel (TAXOTERE®) had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

150. Defendants knew or should have known that docetaxel (TAXOTERE®) had a

potential to, could, and would cause severe and grievous injury to the users of docetaxel (TAXOTERE®) and that docetaxel (TAXOTERE®) was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

151. Defendants brought docetaxel (TAXOTERE®) to the market and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

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; 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.

**SIXTH CLAIM FOR RELIEF**  
**(Fraudulent Concealment)**

153. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

154. At all times during the course of dealing between Defendants and Plaintiff, Plaintiff's healthcare providers, the USPTO, and/or the FDA, Defendants misrepresented the design characteristics and safety of docetaxel (TAXOTERE®) for its intended use.

155. Defendants knew or were reckless in not knowing that its representations were false.

156. In representations made to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- (a) that docetaxel (TAXOTERE®) was not as safe as other forms of treatment for which docetaxel (TAXOTERE®) was marketed and sold to cancer patients;
- (b) that the risks of adverse events with docetaxel (TAXOTERE®) were higher than those with other forms of treatment for which docetaxel (TAXOTERE®) was marketed and sold to cancer patients;
- (c) that the risks of adverse events with docetaxel (TAXOTERE®) were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in docetaxel (TAXOTERE®), in addition to and above and beyond those associated with other forms of treatment for cancer patients;
- (e) that docetaxel (TAXOTERE®) was defective in that it caused dangerous side effects as well as other severe and permanent health consequences in a much more and significant rate than other forms of treatment for cancer patients;
- (f) that docetaxel (TAXOTERE®) was manufactured negligently;
- (g) that docetaxel (TAXOTERE®) was manufactured defectively;
- (h) that docetaxel (TAXOTERE®) was manufactured improperly;
- (i) that docetaxel (TAXOTERE®) was designed negligently;
- (j) that Docetaxel (TAXOTERE®) was designed defectively; and

(k) that docetaxel (TAXOTERE®) was designed improperly.

157. Defendants had a duty to disclose to Plaintiff, Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of docetaxel (TAXOTERE®), including but not limited to the heightened risks of disfiguring permanent alopecia.

158. Defendants had sole access to material facts concerning the defective nature of docetaxel (TAXOTERE®) and its propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used docetaxel (TAXOTERE®), including Plaintiff, in particular.

159. Defendants' concealment and omissions of material facts concerning the safety of docetaxel (TAXOTERE®) was made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, hospitals, and healthcare providers into reliance on the continued use of Docetaxel (TAXOTERE®) and to cause them to purchase, prescribe, and/or dispense docetaxel (TAXOTERE®) and/or use docetaxel (TAXOTERE®).

160. Defendants knew that Plaintiff, Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, including the material omissions of facts surrounding docetaxel (TAXOTERE®) set forth herein.

161. Plaintiff, Plaintiff's physicians, healthcare providers, and/or hospitals reasonably relied on information revealed by Defendants that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

162. 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; 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.

**SEVENTH CLAIM FOR RELIEF**  
**(Negligent Misrepresentation)**

163. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

164. Defendants had a duty to represent to Plaintiff, Plaintiff's physicians, the medical and healthcare community, the FDA, and the public in general that docetaxel (TAXOTERE®) had been tested and found to be safe and effective for the treatment of various forms of cancer.

165. When warning of safety and risks of docetaxel (TAXOTERE®), Defendants negligently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, the FDA, and the public in general that docetaxel (TAXOTERE®) had been tested and was found to be safe and/or effective for its indicated use.

166. Defendants concealed their knowledge of docetaxel's (TAXOTERE®) defects from Plaintiff, Plaintiff's physicians, the FDA, and the public in general and/or the medical community specifically.

167. Defendants concealed their knowledge of the defects in their products from

Plaintiff, Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

168. Defendants misrepresented the novel nature of their product to the USPTO in order to gain a market advantage resulting in billions of dollars in revenues at the expense of vulnerable cancer victims such as Plaintiff.

169. Defendants made these misrepresentations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff, Plaintiff's physicians, the public in general, and the medical community in particular, to recommend, dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer, including but not limited to breast cancer.

170. Defendants made these misrepresentations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, the FDA, the USPTO, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff, Plaintiff's physicians, the public in general, and the medical community in particular, to recommend, dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of cancer, including but not limited to breast cancer.

171. Defendants failed to exercise ordinary and reasonable care in their representations of docetaxel (TAXOTERE®) while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, and Defendants negligently misrepresented docetaxel's (TAXOTERE®'s) high risk of unreasonable, dangerous side effects.

172. Defendants breached their duty in misrepresenting docetaxel's (TAXOTERE®'s) serious side effects to Plaintiff, Plaintiff's physicians, the medical and healthcare community, the FDA, and the public in general.

173. Plaintiff and Plaintiff's physicians reasonably relied on Defendants to fulfill their obligations to disclose all facts within their knowledge regarding the serious side effects of docetaxel (TAXOTERE®).

174. 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; 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.

**EIGHTH CLAIM FOR RELIEF**  
**(Strict Product Liability for Misrepresentation)**

175. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

176. Defendants sold the docetaxel (TAXOTERE®) that Plaintiff's physician prescribed for Plaintiff and that Plaintiff used.

177. Defendants were engaged in the business of selling the docetaxel (TAXOTERE®) for resale, use, or consumption.

178. Defendants misrepresented facts as set forth herein concerning the character or

quality of the docetaxel (TAXOTERE®) that would be material to potential prescribers and purchasers or users of the product.

179. Defendants' misrepresentations were made to potential prescribers and/or purchasers or users as members of the public at large.

180. As a purchaser or user, Plaintiff reasonably relied on the misrepresentation.

181. Plaintiff was a person who would reasonably be expected to use, consume, or be affected by the docetaxel (TAXOTERE®).

182. 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; 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.

**NINTH CLAIM FOR RELIEF**  
**(Fraud and Deceit)**

183. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

184. Defendants committed fraud by omission in applying for and gaining patent

protection for docetaxel (TAXOTERE®) resulting in increased sales and market penetration. This increased market penetration was the proximal cause of Plaintiff's exposure to the side effects of docetaxel (TAXOTERE®).

185. Defendants fraudulently claimed superior efficacy over other products designed to treat the same conditions for which docetaxel (TAXOTERE®) was designed to treat. These fraudulent representations were the proximal cause of Plaintiff's exposure to the side effects of docetaxel (TAXOTERE®).

186. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally distributed false information, including but not limited to assuring Plaintiff, Plaintiff's physicians, hospitals, healthcare professionals, the public, and/or the FDA that docetaxel (TAXOTERE®) was safe and effective for use in the treatment of various forms of cancer, including breast cancer.

187. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and or research to Plaintiff, Plaintiff's physicians, healthcare professionals, the public, and/or the FDA.

188. Defendants had a duty when disseminating information to Plaintiff, Plaintiff's physicians, and the public to disseminate truthful information.

189. Defendants had a duty when disseminating information to Plaintiff, Plaintiff's physicians, and the public not to deceive Plaintiff, Plaintiff's physicians, the public, the USPTO, and/or the FDA.

190. The information Defendants distributed to Plaintiff, Plaintiff's physicians, the public, and the FDA, including but not limited to reports, press releases, advertising campaigns, and other forms of media contained material representations of fact and/or omissions.

191. The information Defendants distributed to Plaintiff, Plaintiff's physicians, the public, and the FDA intentionally included false representations that Defendants' drug docetaxel (TAXOTERE®) was safe and effective for the treatment of various forms of cancer, including breast cancer.

192. The information Defendants distributed to Plaintiff, Plaintiff's physicians, the public, and the FDA intentionally included false representations that Defendants' drug docetaxel (TAXOTERE®) carried the same risks, hazards, and/or dangers as other forms of treatment for the same conditions for which docetaxel (TAXOTERE®) was designed to treat.

193. The information Defendants distributed to Plaintiff, Plaintiff's physicians, the public, and the FDA intentionally included false representations that docetaxel (TAXOTERE®) was not injurious to the health and/or safety of its intended users.

194. The information Defendants distributed to Plaintiff, Plaintiff's physicians, the public, and the FDA intentionally included false representations that docetaxel (TAXOTERE®) was no more injurious to the health and/or safety of its intended users as other forms of cancer treatments for which docetaxel (TAXOTERE®) was designed to treat.

195. These representations by Defendants were all false and misleading.

196. Defendants intentionally suppressed, ignored, and disregarded test results not favorable to Defendants and that demonstrated that docetaxel (TAXOTERE®) was not safe as a means of treatment for certain types of cancer for which docetaxel (TAXOTERE®) was designed to treat.

197. Defendants intentionally made material misrepresentations to Plaintiff, Plaintiff's physicians, the FDA, and the public, including the medical profession, regarding the safety of docetaxel (TAXOTERE®), specifically but not limited to docetaxel (TAXOTERE®) not having

dangerous and serious health and/or safety concerns.

198. Defendants intentionally made material misrepresentations to Plaintiff, Plaintiff's physicians, the FDA, and the public in general, including the medical profession, regarding the safety of docetaxel (TAXOTERE®), specifically but not limited to docetaxel (TAXOTERE®) being as safe as other products designed to treat the same conditions docetaxel (TAXOTERE®) was designed to treat.

199. It was Defendants' intent and purpose in making these false representations to deceive and defraud Plaintiff, Plaintiff's physicians, the public, and/or the FDA, and to gain the confidence of Plaintiff, Plaintiff's physicians, the public, healthcare professionals, and/or the FDA to falsely ensure the quality and fitness for use of docetaxel (TAXOTERE®) and induce Plaintiff, Plaintiff's physicians, and the public, including the medical profession, to purchase, request, dispense, prescribe, recommend, and/or continue to use docetaxel (TAXOTERE®).

200. Defendants made the aforementioned false claims and false representations with the intent of convincing Plaintiff, Plaintiff's physicians, the public, healthcare professionals, and/or the FDA that docetaxel (TAXOTERE®) was fit and safe for use as treatment for certain types of cancer, including breast cancer.

201. Defendants made the aforementioned false claims and false representations with the intent of convincing Plaintiff, Plaintiff's physicians, the public, healthcare professionals, and/or the FDA that docetaxel (TAXOTERE®) was fit and safe for use as treatment of certain forms of cancer and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for which docetaxel (TAXOTERE®) was designed to treat.

202. Defendants made false claims and false representations in its documents submitted

to Plaintiff, Plaintiff's physicians, the FDA, the public, and healthcare professionals that docetaxel (TAXOTERE®) did not present risks related to disfigurement secondary to permanent alopecia.

203. Defendants made false claims and false representations in its documents submitted to Plaintiff, Plaintiff's physicians, the FDA, the public, and healthcare professionals that docetaxel (TAXOTERE®) did not present health and/or safety risks greater than other forms of treatment for the same conditions docetaxel (TAXOTERE®) was designed to treat.

204. Defendants made these and other representations with a pretense of actual knowledge when Defendants had no knowledge of the truth or falsity of these representations, and Defendants made these representations recklessly and without regard to the actual facts.

205. Defendants made these and other representations with the intention of deceiving and defrauding Plaintiff, Plaintiff's respective healthcare professionals, and/or the FDA.

206. Defendants made these and other representations in order to induce Plaintiff and Plaintiff's respective healthcare professionals to rely upon the misrepresentations.

207. Defendants' false misrepresentations caused Plaintiff and/or Plaintiff's healthcare professionals to purchase, use, rely on, request, dispense, recommend, and/or prescribe docetaxel (TAXOTERE®).

208. Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®) to the public at large, and Plaintiff and Plaintiff's physicians in particular, for the purpose of influencing the marketing of a product Defendants knew was dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for cancer.

209. Defendants willfully and intentionally failed to disclose, concealed, and/or suppressed the material facts regarding the dangerous and serious health and/or safety concerns

related to docetaxel (TAXOTERE®).

210. Defendants willfully and intentionally failed to disclose the truth and material facts related to docetaxel (TAXOTERE®) and made false representations with the purpose and design of deceiving and lulling Plaintiff and Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff and Plaintiff's healthcare professionals would rely on Defendants' representations to purchase, use, dispense, prescribe, and/or recommend docetaxel (TAXOTERE®).

211. Defendants, through their public relations efforts, which included but were not limited to public statements and press releases, knew or should have known that the public, including Plaintiff and Plaintiff's respective healthcare professionals, would rely upon the information being disseminated.

212. Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe Defendants' false representations to be true at the time they were made, and they relied upon Defendants' false representations and superior knowledge of how docetaxel (TAXOTERE®) would treat certain forms of cancer for which docetaxel (TAXOTERE®) was designed to treat.

213. At the time Defendants' false representations were made, Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth and were not with reasonable diligence able to discover the truth with regard to the dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®).

214. Plaintiff and her healthcare providers did not discover the true facts with respect to Defendants' false representations and the dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®), and Plaintiff and her healthcare providers with reasonable diligence

could not have discovered the true facts.

215. Had Plaintiff and her healthcare providers known the true facts with respect to the dangerous and serious health and/or safety concerns of docetaxel (TAXOTERE®), Plaintiff would not have purchased, used, and/or relied on Defendants' drug docetaxel (TAXOTERE®).

216. Defendants' aforementioned conduct constitutes fraud and deceit, and it was committed and/or perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

217. 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; 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.

**TENTH CLAIM FOR RELIEF**  
**(Violation of Consumer Protection Laws)**

218. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

219. Defendants have a statutory duty to refrain from making false and/or fraudulent representations and/or from engaging in deceptive acts or practices in the sale and promotion of

docetaxel (TAXOTERE®) pursuant to state law.

220. Defendants engaged in unfair, deceptive, false, and/or fraudulent acts and/or trade practices in violation of the Consumer Protection Act of Plaintiff's state of residence, including but not limited to:

- (a) Publishing instructions and product material containing inaccurate and incomplete factual information regarding docetaxel (TAXOTERE®);
- (b) Misrepresenting the nature, quality, and characteristics of docetaxel (TAXOTERE®);
- (c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding;
- (d) Misrepresenting the alleged benefits of docetaxel (TAXOTERE®);
- (e) Failing to disclose material information concerning known side effects of docetaxel (TAXOTERE®);
- (f) Misrepresenting the quality of docetaxel (TAXOTERE®); and
- (g) Uniformly communicating the purported benefits of docetaxel (TAXOTERE®) while failing to disclose the serious and dangerous side-effects related to the use of docetaxel (TAXOTERE®) and its safety, efficacy, and usefulness.

221. Defendants' conduct in connection with docetaxel (TAXOTERE®) was impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely, and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of docetaxel (TAXOTERE®).

222. These deceptive trade practices occurred in the course of Defendants' business.

223. These deceptive trade practices significantly impacted Plaintiff and the public as actual or potential consumers of Defendants' product docetaxel (TAXOTERE®).

224. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff in the marketing and advertising campaign described herein.

225. Plaintiff was an actual consumer of Defendants' product docetaxel (TAXOTERE®).

226. Defendants' conduct as described above was a material cause of Plaintiff's decision to purchase docetaxel (TAXOTERE®).

227. As a direct, foreseeable, and proximate cause of Defendants' deceptive trade practices, Plaintiff suffered actual damages, including personal injuries, economic damages, and non-economic damages.

228. Defendants' conduct was wanton, egregious, and reckless.

229. 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; 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.

230. As a result of the foregoing acts, omissions, and wrongful conduct of Defendants, Plaintiff is entitled to treble damages, attorneys' fees, and costs.

**ELEVENTH CLAIM FOR RELIEF**  
**(Extreme and Outrageous Conduct / Intentional Infliction of Emotional Distress)**

231. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads this Court in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiff's resident State.

232. Defendants' conduct, as set forth above, was extreme and outrageous.

233. Defendants' actions were done recklessly or with the intent of causing Plaintiff severe emotional distress; and

234. Defendants' conduct caused Plaintiff severe emotional distress.

235. 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; 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.

**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.; 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 this 14<sup>th</sup> day of December, 2016.

Respectfully submitted,

LOWE LAW GROUP

/s/ T. Aaron Stringer  
T. Aaron Stringer (UT Bar # 12681)  
Zachary P. Lowe (UT Bar # 13792)  
Nathan Buttars (UT Bar # 13659)  
Lowe Law Group  
6028 S. Ridgeline Dr., Ste. 200  
Ogden, UT 84405  
Telephone: 801-917-8500  
Facsimile: 801-917-8484  
[aaron@lowelawgroup.com](mailto:aaron@lowelawgroup.com)  
[pete@lowelawgroup.com](mailto:pete@lowelawgroup.com)  
[nate@lowelawgroup.com](mailto:nate@lowelawgroup.com)

*Counsel for Plaintiff*

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

Tanya Francis

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

(c) Attorneys (Firm Name, Address, and Telephone Number) Lowe Law Group 6028 S. Ridgeline Dr., Ste 200, Ogden, UT 84405 Tel: 801-917-8500

DEFENDANTS

Sanofi S.A.; Aventis Pharma S.A.; Sanofi-Aventis U.S. LLC, DBA Winthrop U.S.

County of Residence of First Listed Defendant Unknown (IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known) Unknown

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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories and checkboxes.

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 U.S.C. 1332 Diversity

Brief description of cause: Action for injuries as a result of Defendants' product(s).

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ 75,001.00 CHECK YES only if demanded in complaint: JURY DEMAND: X Yes [ ] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Kurt D. Engelhardt DOCKET NUMBER MDL No. 2740

DATE 12/14/2016 SIGNATURE OF ATTORNEY OF RECORD /s/ T. Aaron Stringer

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

Tanya Francis

Plaintiff(s)

v.

Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC, separately, and doing business as Winthrop U.S.

Defendant(s)

Civil Action No. 2:16-cv-17410

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) SANOFI S.A. 54 rue La Boetie 75008 Paris 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:

T. Aaron Stringer, Zachary P. Lowe LOWE LAW GROUP 6028 S. Ridgeline Drive Suite 200 Ogden, UT 84405 Tel: 801-917-8500

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

Civil Action No. 2:16-cv-17410

**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

Tanya Francis

Plaintiff(s)

v.

Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC, separately, and doing business as Winthrop U.S.

Defendant(s)

Civil Action No. 2:16-cv-17410

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:

T. Aaron Stringer, Zachary P. Lowe LOWE LAW GROUP 6028 S. Ridgeline Drive Suite 200 Ogden, UT 84405 Tel: 801-917-8500

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

Civil Action No. 2:16-cv-17410

**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

Tanya Francis

Plaintiff(s)

v.

Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC, separately, and doing business as Winthrop U.S.

Defendant(s)

Civil Action No. 2:16-cv-17410

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) SANOFI-AVENTIS U.S. LLC
c/o Corporation Service Company
Princeton South Corporate Ctr, Ste 160
100 Charles Ewing Blvd
Ewing, NJ 08807

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:

T. Aaron Stringer, Zachary P. Lowe
LOWE LAW GROUP
6028 S. Ridgeline Drive
Suite 200
Ogden, UT 84405
Tel: 801-917-8500

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

Civil Action No. 2:16-cv-17410

**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: