



**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION**

ANGELA JONES

Plaintiff,

v.

Civil Action No. 3:16-cv-288 TSL-RHW

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

Defendants.

COMPLAINT AND JURY DEMAND

Plaintiff, Angela Jones, by and through her attorneys, respectfully submits the following Complaint and Jury Demand against Defendants Sanofi S.A.; Aventis Pharma S.A.; and Sanofi-Aventis U.S. LLC, separately, and doing business as Winthrop U.S., and alleges the following upon personal knowledge, information and belief, and investigation of counsel.

NATURE OF THE ACTION

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

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28. U.S.C. § 1332 (diversity jurisdiction). The amount in controversy exceeds \$75,000.00 exclusive of interest and costs. There is complete diversity of citizenship between Plaintiff and Defendants. Plaintiff is a resident and citizen of and is domiciled in the State of Mississippi. As set forth more fully below, all Defendants are entities organized in states other than the State of Mississippi, all Defendants have their principal place of business in a state other than the State of Mississippi, and none of the Defendants is a citizen or resident of the State of Mississippi.

3. This Court has personal jurisdiction over Defendants, each of which is licensed to conduct and/or is systematically and continuously conducting business in the State of Mississippi, including, but not limited to, the marketing, advertising, selling, and distributing of drugs, including docetaxel (TAXOTERE®), to the residents in this State.

4. To establish personal jurisdiction in a diversity case, a plaintiff must show both that jurisdiction is proper under the forum state's long-arm statute and that exercise of personal jurisdiction over the defendant comports with the Due Process Clause of the United States Constitution. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 753, 187 L. Ed. 2d 624 (2014); *see also Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 464, 105 S.Ct. 2174, 85 L.Ed.2d 528 (1985)

5. As set forth *supra*, the instant civil action is based on diversity jurisdiction pursuant to 28 U.S.C. § 1332.

6. The forum state in the instant case is the State of Mississippi.

7. Under Mississippi law, the United States District Court for the District of Mississippi may exercise personal jurisdiction to the full extent of the Due Process Clause of the

Fourteenth Amendment. *See Roxco, Ltd. v. Harris Specialty Chemicals, Inc.*, 133 F. Supp. 2d 911 (S.D. Miss. 2000); *Joshua Properties, LLC v. D1 Sports Holdings, LLC*, 130 So.3D 1089 (Miss.2014).

8. Mississippi's long-arm statute, Miss. Code Ann.3 13-3-57, establishes specific personal jurisdiction over a person or its agent engaging in the commission of a tortious act, in whole or in part, or who are doing business within the State of Mississippi.

9. As set forth *infra*, Plaintiff alleges that Defendant(s) and/or their agents engaged in the commission of a tortious act within the State of Mississippi.

10. Under the Due Process Clause of the Fourteenth Amendment, personal jurisdiction may be asserted over the Defendants if the Defendants have sufficient "minimum contacts" with the state, so that the imposition of jurisdiction would not violate "traditional notions of fair play and substantial justice." *See Helicopteros Nacionales De Columbia, S.A. v. Hall*, 466 U.S. 408, 414, 104 S.Ct. 1868, 1872, 80 L.Ed.2d 404 (1984) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S.Ct. 154, 158, 90 L.Ed. 95 (1945)).

11. Specific jurisdiction exists if a defendant has "purposefully directed" its activities toward the forum state, and if the lawsuit is based upon injuries that "arise out of" or "relate to" the defendant's contacts with the state. *See Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472, 105 S.Ct. 2174, 2182, 85 L.Ed.2d 528 (1985) (citing *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 774, 104 S.Ct. 1473, 1478, 79 L.Ed.2d 790 (1984) and *Helicopteros*, 466 U.S. at 414, 104 S.Ct. at 1872).

12. As alleged *infra*, Plaintiff's injuries complained of in the instant civil action "arise out of" or "relate to" the Defendant's contacts with the State of Mississippi.

13. Here, Defendants have sufficient “minimum contacts” with the State of Mississippi, so that the imposition of jurisdiction would not violate “traditional notions of fair play and substantial justice.”

14. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC has been “doing business” and has committed tortious acts, in whole or in part, within the State of Mississippi.

15. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC has employees in the State of Mississippi.

16. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC actively marketed docetaxel (TAXOTERE®) within the State of Mississippi by providing marketing information about the drug to medical doctors and providers of medical treatment throughout the State of Mississippi.

17. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC solicited purchases of docetaxel (TAXOTERE®) within the State of Mississippi by soliciting purchases of docetaxel (TAXOTERE®) from medical doctors and providers of medical treatment throughout the State of Mississippi.

18. Upon information and belief, at all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC provided product information about docetaxel (TAXOTERE®), and samples of docetaxel (TAXOTERE®) to, medical doctors and providers of medical treatment throughout the State of Mississippi.

19. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC sold docetaxel (TAXOTERE®) within the State of Mississippi by selling the drug to medical doctors and providers of medical treatment throughout the State of Mississippi.

20. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC shipped docetaxel (TAXOTERE®) to the State of Mississippi by shipping the drug to medical doctors and providers of medical treatment throughout the State of Mississippi.

21. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC expected that docetaxel (TAXOTERE®) would be sold, purchased, and used in the State of Mississippi.

22. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC purposefully directed its activities towards the State of Mississippi.

23. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC exercised the privilege of conducting business in the State of Mississippi.

24. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC enjoyed the benefits and protections of the laws of the State of Mississippi.

25. At all times relevant hereto, Defendant Sanofi-Aventis U.S. LLC's activities in the State of Mississippi were neither irregular nor casual; rather, those activities were systematic and continuous.

26. Defendant Sanofi-Aventis U.S. LLC had fair warning that it might be subject to personal jurisdiction in the State of Mississippi and that it might be haled into court in the State of Mississippi with respect to its systematic and continuous activities involved with the marketing, advertising, solicitation of purchases, and sales of docetaxel (TAXOTERE®) in the State of Mississippi.

27. Specific personal jurisdiction over Defendant Sanofi-Aventis U.S. LLC in the State of Mississippi is reasonable.

28. There is no burden on Defendant Sanofi-Aventis U.S. LLC in litigating the instant case in Mississippi as Defendant Sanofi-Aventis U.S. LLC, regularly systematically and continuously solicits and conducts business in the State of Mississippi, and already enjoys the benefits of the protections of the laws of the State of Mississippi.

29. Plaintiff has a substantial interest in containing convenient and effective relief in the State of Mississippi – the place where Defendants purposeful activities ultimately resulted in her injuries. On the other hand, if personal jurisdiction does not lie in Mississippi. Plaintiff will be forced to litigate her case(s) in New Jersey and/or France.

30. The interstate judicial system's interest in obtaining the most efficient resolution of controversies is maximized by having personal jurisdiction over Defendant Sanofi-Aventis U.S. LLC lie in the State of Mississippi as the sale of the docetaxel (TAXOTERE®) occurred in the State of Mississippi, Plaintiff suffered injury in the State of Mississippi, Plaintiff was treated in the State of Mississippi, and numerous witnesses to both the injury to, and harm suffered by, Plaintiff reside in the State of Mississippi.

31. The shared interest of the several States in furthering fundamental substantive social policies is maximized by having personal jurisdiction over Defendant Sanofi-Aventis U.S. LLC lie in the State of Mississippi; to wit, the State of Mississippi – just like the other States – has a strong interest in seeing that its citizens who are afflicted by crippling diseases such as cancer are protected from the tortious acts of nonresident corporations such as Defendant Sanofi-Aventis U.S. LLC who purposefully direct the sale of cancer treatment drugs into the State.

32. At all times relevant hereto, as set forth more fully *infra*, Defendant Sanofi-Aventis U.S. LLC is a wholly-owned subsidiary of Defendant Sanofi S.A. – 100% owned and controlled by Defendant Sanofi S.A.

33. At all times relevant hereto, as set forth more fully *infra*, Defendant Aventis-Pharma S.A. is a wholly-owned subsidiary of Defendant Sanofi S.A.

34. At all times relevant hereto, as set forth more fully *infra*, Defendant Aventis-Pharma S.A., a wholly-owned subsidiary of Defendant Sanofi S.A., was the patent-holder of docetaxel (TAXOTERE®). Indeed, Defendant Aventis-Pharma S.A., along with Defendant Sanofi-Aventis U.S. LLC, prosecutes patent infringement lawsuits with respect to docetaxel (TAXOTERE®) in the United States. *See, e.g., Aventis Pharma S.A. and Sanofi-Aventis US LLC v. Hospira, Inc.*, 743 F. Supp. 2d 305, 322 (D. Del. 2010) *aff'd*, 675 F.3d 1324 (Fed. Cir. 2012).

35. At all times relevant hereto, Defendant Sanofi-Aventis US LLC was the agent of Defendant Sanofi S.A. and its wholly-owned subsidiary Defendant Aventis-Pharma S.A. – the patent-holder of docetaxel (TAXOTERE®) for purposes of marketing, advertising, soliciting purchases, and selling docetaxel (TAXOTERE®) in the State of Mississippi.

36. At all times relevant hereto, Defendant Sanofi-Aventis US LLC was the alter ego of Defendant Sanofi S.A. and its wholly-owned subsidiary Defendant Aventis-Pharma S.A. – the patent-holder of docetaxel (TAXOTERE®) for purposes of marketing, advertising, soliciting purchases, and selling docetaxel (TAXOTERE®) in the State of Mississippi.

37. Plaintiff's use of, and ultimately injury by, docetaxel (TAXOTERE®) in the State of Mississippi was not an isolated occurrence, but arose from the purposeful efforts of Defendant Sanofi S.A. and Defendant Aventis-Pharma S.A., through Defendant Sanofi S.A.'s and Defendant

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

38. Defendant Sanofi S.A. and Defendant Aventis-Pharma S.A. placed docetaxel (TAXOTERE®) into the stream of commerce with the intent that it would be marketed, advertised, and sold by their agent and/or alter ego Defendant Sanofi-Aventis US LLC in the State of Mississippi.

39. At all times relevant hereto, the activities of Defendant Sanofi-Aventis US LLC were of such character as to amount to doing the business of Defendant Sanofi S.A. and Defendant Aventis-Pharma S.A. – the patent-holder of docetaxel (TAXOTERE®) – in the State of Mississippi.

40. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants marketed, advertised, and distributed the dangerous product in this District; Plaintiff resides in this District; Plaintiff's harms, losses, and damages occurred in this District; Defendants do substantial business in the State of Mississippi and within this District; and at all times relevant hereto, Defendants developed, manufactured, promoted, marketed, distributed, warranted, and sold docetaxel (TAXOTERE®) in interstate commerce.

PARTIES

41. Plaintiff Angela Jones is and was at all relevant times a citizen and adult resident of the State of Mississippi and was prescribed and used docetaxel (TAXOTERE®), which was developed, manufactured, promoted, marketed, distributed, and sold by Defendants. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

42. 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.

43. 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.

44. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant Sanofi-Aventis U.S. LLC is a subsidiary of Defendant Sanofi S.A. Defendant Sanofi S.A. is the only member and owns 100% of the membership interest (both financial and voting) of Defendant Sanofi-Aventis U.S. LLC. Defendant Sanofi-Aventis U.S. LLC does not have any members that are citizens, residents, or domiciles of the State of Mississippi.

45. 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.

**DENFENDANTS' OWNERSHIP AND
UNITY OF INTEREST**

46. 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.

47. 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 docetaxel (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.

48. 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*.

49. 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.

50. Sanofi-Aventis S.A. was formed in 2004 with the merger of Aventis and Sanofi-Synthelabo, each of which had previously been formed through mergers. Sanofi-Aventis changed its name to Sanofi S.A. on May 6, 2011, after receiving approval at its annual general meeting. The reason given by the company for the change was to make its name easier to pronounce in other countries such as China.

51. 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.

52. 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.

53. 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."

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

55. 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 docetaxel (TAXOTERE®) to the general public, including Plaintiff.

56. At all times material to this lawsuit, Defendants were authorized to do business within the State of Mississippi; did in fact transact and conduct business in the State of Mississippi; derived substantial revenue from goods and products used in the State of Mississippi; and supplied docetaxel (TAXOTERE®) within the State of Mississippi.

57. 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 docetaxel (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.

58. 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 docetaxel (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.

59. 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)**

60. Docetaxel (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.

61. 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.

62. Paclitaxel (TAXOL®), which was developed, manufactured, and distributed by Bristol-Myers Squibb and is the main competitor drug to docetaxel (TAXOTERE®), was first approved by the U.S. Food and Drug Administration (FDA) in December 1992.

63. The drug and chemical compound that would become known as docetaxel (TAXOTERE®) was invented and developed by Michel Colin, Daniel Guenard, Francoise Gueritte–Voegelein, and Pierre Potier of Rhone-Poulence Santé. Docetaxel (TAXOTERE®) was designed as an increased potency Taxane.

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

65. 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.

66. 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® (docetaxel), but Sanofi was also directly involved in the clinical trials and testing of the compound Taxotere® (docetaxel). 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.

67. Rhône-Poulenc Rorer S.A., before it was acquired by or merged into Aventis Pharma S.A., initially sought FDA approval for docetaxel (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 docetaxel (TAXOTERE®), because docetaxel (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.

68. Docetaxel (TAXOTERE®) was ultimately approved by the FDA on May 14, 1996. According to its product labeling, docetaxel (TAXOTERE®) was "indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy."

69. After the initial FDA approval, Defendants sought and were granted FDA approval for additional indications for docetaxel (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 docetaxel (TAXOTERE®).

70. Contrary to Defendants' claims of superior efficacy, post market surveillance has shown that the more potent and more toxic docetaxel (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.

71. 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).

72. 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® (docetaxel) for patients undergoing standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

73. Despite the publication of these studies, Defendants continued to make false and misleading statements promoting the “superior efficacy” of docetaxel (TAXOTERE®) over the competing product paclitaxel (TAXOL®). In June 2008, Sanofi-Aventis utilized marketing and promotional materials for docetaxel (TAXOTERE®) at the annual meeting for the American Society of Clinical Oncology, comparing the efficacy of docetaxel (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.”

74. 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.

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

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

76. 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

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

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

(TAXOTERE®). *See U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, Civil Action No. 02-2964 (E.D. Pa. 2015).

77. 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 docetaxel (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 docetaxel (TAXOTERE®) in unapproved settings; and second, Defendants paid healthcare providers illegal kickbacks in the form of sham grants, speaking fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free reimbursement assistance to incentivize healthcare providers to prescribe docetaxel (TAXOTERE®) for off-label uses. As a direct result of Defendants' fraudulent marketing scheme, Defendants dramatically increased revenue on sales of docetaxel (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).

78. As a direct result of their wrongful conduct and illegal kickback schemes, Defendants directly caused thousands of individuals to be exposed to docetaxel's (TAXOTERE®) increased toxicity as compared to other available less toxic products.

79. 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**

80. 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.

81. Defendants knew or should have known that the rate of permanent alopecia related to docetaxel (TAXOTERE®) was far greater than with other products available to treat the same condition as Defendants' product.

82. Permanent baldness (permanent alopecia) is a disfiguring condition, especially for women. Women who experienced disfiguring permanent alopecia as a result of the use of docetaxel (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.

83. Although women might accept the possibility of permanent baldness as a result of the use of docetaxel (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 docetaxel (TAXOTERE®), there were already similar products on the market that were at least as effective as docetaxel (TAXOTERE®) and did not subject female users to the same risk of disfiguring permanent alopecia as does docetaxel (TAXOTERE®).

84. 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 docetaxel (TAXOTERE®) had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer, after taking docetaxel (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.

85. 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 docetaxel (TAXOTERE®) suffered from permanent disfiguring hair loss for years after the patients had stop taking docetaxel (TAXOTERE®).

86. Despite Defendants' knowledge of the relevant findings from the GEICAM 9805 study, as well as reports from patients who had taken docetaxel (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 docetaxel (TAXOTERE®) are at a significantly increased risk of suffering from permanent disfiguring hair loss.

87. 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 docetaxel (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 docetaxel (TAXOTERE®).

88. Users of docetaxel (TAXOTERE®) were not presented with the opportunity to make an informed choice as to whether the benefits of docetaxel (TAXOTERE®) were worth its associated risks. Defendants engaged in a pattern of deception by overstating the benefits of docetaxel (TAXOTERE®) as compared to other alternatives while simultaneously failing to warn of the risk of disfiguring permanent alopecia.

89. Although Defendants publish information in other countries to individual patients as well as regulatory agencies related to docetaxel (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.

90. 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.

91. 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 docetaxel (TAXOTERE®) over other comparable products was justified.

92. 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.

93. Docetaxel (TAXOTERE®) was defective in its design. Docetaxel (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.

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

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

95. On January 24, 2012, plaintiff was diagnosed with Invasive ductal carcinoma, of the right breast. On or around January 2012, Plaintiff underwent a right breast total/simple mastectomy performed by Dr. Sharla Patterson, M.D. at University of MS Medical Center, 2500 N. State Street, Jackson, MS 39216.

96. On March 3, 2014, Plaintiff was diagnosed with Invasive ductal of the left breast. On or around March 2014, Plaintiff underwent a left simple/complete mastectomy and axillary node dissection by Dr. Shawn McKinney, M.D., at University of MS Medical Center, 2500 N. State Street, Jackson, MS 39216.

97. Following the January 2012 right breast total/simple mastectomy and March 2014 left breast simple/complete mastectomy, Plaintiff met with her oncologist to discuss further treatment. Neither Plaintiff nor her treating healthcare providers were aware of or informed by Defendants that disfiguring permanent alopecia can occur following treatment with

TAXOTERE®. Accordingly, Plaintiff did not know or suspect until early 2016 that she was suffering from continuing hair loss as a result of taking docetaxel (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 docetaxel (TAXOTERE®).

98. Plaintiff received docetaxel (TAXOTERE®) distributed by Winthrop U.S., which is a business unit of or division within Sanofi-Aventis U.S. LLC. As the holder for the reference listed drug (RLD) of brand-name TAXOTERE®, Defendant Sanofi-Aventis U.S. LLC supplied the labeling for Winthrop U.S.'s generic version of TAXOTERE®. Upon information and belief, considering their close involvement in the development, promotion, selling, and distributing docetaxel (TAXOTERE®) within the Sanofi consolidated and closely held group of companies, Defendants Sanofi S.A. and Aventis Pharma S.A. were also involved in the development of the labeling submitted for docetaxel (TAXOTERE®) in the United States. Defendants' labeling of docetaxel (TAXOTERE®) was defective because it failed to adequately warn of the risk of disfiguring permanent alopecia.

NATURE OF THE CLAIMS

99. Despite the fact that Defendants disclosed risks associated with docetaxel (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 docetaxel (TAXOTERE®) regarding the side effect of disfiguring permanent alopecia. Defendants failed to update the warnings for

docetaxel (TAXOTERE®), and they failed to disclose the results of additional studies as Defendants learned new facts regarding the defects and risks of their product.

100. 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 docetaxel (TAXOTERE®) in response to these studies;
- (b) failed to provide adequate warnings about the true safety risks associated with the use of docetaxel (TAXOTERE®);
- (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of docetaxel (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 docetaxel (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 docetaxel (TAXOTERE®);
- (f) failed to provide adequate instructions on how to intervene and/or reduced the risk of permanent alopecia related to the use of docetaxel (TAXOTERE®);
- (g) failed to provide adequate warnings and information related to the increased risks of permanent alopecia in certain genome groups;
- (h) failed to provide adequate warnings regarding the increased risk of permanent alopecia with the use of docetaxel (TAXOTERE®) as compared to other products designed to treat the same conditions as docetaxel (TAXOTERE®); and
- (i) failed to include a **“BOXED WARNING”** related to permanent or persistent alopecia.

101. During the years since first marketing docetaxel (TAXOTERE®) in the U.S., Defendants modified the U.S. labeling and prescribing information for docetaxel (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.

102. Before applying for and obtaining approval of docetaxel (TAXOTERE®), Defendants knew or should have known that consumption of docetaxel (TAXOTERE®) was associated with and/or would cause disfiguring side effects including disfiguring permanent alopecia.

103. Despite knowing that docetaxel (TAXOTERE®) was likely to result in increased rates of alopecia and disfiguring permanent alopecia, Defendants produced, marketed, and distributed docetaxel (TAXOTERE®) in the United States.

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

105. From the date Defendants received FDA approval to market docetaxel (TAXOTERE®), Defendants made, distributed, marketed, and sold docetaxel (TAXOTERE®) without adequate warning to Plaintiff or Plaintiff's prescribing physicians that docetaxel (TAXOTERE®) was associated with disfiguring permanent alopecia.

106. Defendants ignored the association between the use of docetaxel (TAXOTERE®) and the risk of disfiguring permanent alopecia.

107. 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 docetaxel (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.

108. 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

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

110. 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' docetaxel (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' docetaxel (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 docetaxel (TAXOTERE®), and other acts and omissions.

111. 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' docetaxel (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 docetaxel (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 docetaxel (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 docetaxel (TAXOTERE®).

112. Defendants had a duty to disclose that docetaxel (TAXOTERE®) was defective, unreasonably dangerous and that the use of Defendants' docetaxel (TAXOTERE®) carried with it the serious risk of developing disfiguring permanent alopecia as the Plaintiff has suffered. Defendants breached that duty.

113. 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' docetaxel (TAXOTERE®) or the true risks associated with her use at the time she purchased and used Defendants' docetaxel (TAXOTERE®) until, at the earliest December 2015.

114. Defendants did not notify, inform, or disclose to Plaintiff, Plaintiff's prescribing health care professionals or the general consuming public that Defendants' docetaxel (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.

115. Because Defendants failed in their duty to notify Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public that their docetaxel (TAXOTERE®) was defective until early 2016 and, further, actively attempted to conceal this fact, Defendants should be estopped from asserting defenses based on statutes of limitation or repose.

116. 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 docetaxel (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 statutes 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.

FIRST CLAIM FOR RELIEF
(Product Liability for Negligence – Against All Defendants)

117. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 116 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

118. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of docetaxel (TAXOTERE®) into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

119. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of docetaxel (TAXOTERE®) into interstate commerce in that Defendants knew or should have known that using docetaxel (TAXOTERE®) created a high risk of unreasonable, disfiguring side effects, including personal injuries that are permanent and lasting in nature such as disfiguring permanent alopecia, mental anguish, and diminished enjoyment of life, economic loss, and loss of economic opportunity.

120. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing docetaxel (TAXOTERE®) without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing docetaxel (TAXOTERE®) without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not docetaxel (TAXOTERE®) was safe for use in that Defendants knew or should have known that docetaxel (TAXOTERE®) was unsafe and unfit for use by reason of the dangers to its users;

- (d) Selling docetaxel (TAXOTERE®) without disclosing its dangers and risks and/or making proper and sufficient tests to determine the dangers and risks to its users;
- (e) Negligently failing to adequately and correctly warn Plaintiff, Plaintiffs' physicians, the public, and the medical and healthcare profession of the dangers of docetaxel (TAXOTERE®);
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, docetaxel (TAXOTERE®);
- (g) Failing to test docetaxel (TAXOTERE®) and/or failing to adequately, sufficiently, and properly test docetaxel (TAXOTERE®);
- (h) Negligently advertising and recommending the use of docetaxel (TAXOTERE®) without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that docetaxel (TAXOTERE®) was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently and falsely representing that docetaxel (TAXOTERE®) was superior to other commercially available products designed to treat the same forms of cancer docetaxel (TAXOTERE®) was designed to treat;
- (k) Negligently designing docetaxel (TAXOTERE®) in a manner that was dangerous to its users;
- (l) Negligently manufacturing docetaxel (TAXOTERE®) in a manner that was dangerous to its users;
- (m) Negligently producing docetaxel (TAXOTERE®) in a manner that was dangerous to its users;
- (n) Negligently assembling docetaxel (TAXOTERE®) in a manner that was dangerous to its users;
- (o) Concealing information from Plaintiff, Plaintiff's physicians, the public, and the FDA in knowing that docetaxel (TAXOTERE®) was unsafe, dangerous, and/or non-conforming with FDA regulations; and

- (p) Improperly concealing from and/or misrepresenting information to Plaintiff, Plaintiff's physicians, other healthcare professionals, and/or the FDA concerning the severity of risks and dangers of docetaxel (TAXOTERE®) compared to other forms of treatment for breast cancer.

121. Defendants underreported, underestimated, and downplayed the serious dangers and risk associated with docetaxel (TAXOTERE®).

122. Defendants negligently conveyed that the safety risks and/or dangers of docetaxel (TAXOTERE®) were comparable with other forms of treatment for the same conditions for which docetaxel (TAXOTERE®) was prescribed to treat.

123. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and selling of docetaxel (TAXOTERE®) in that they:

- (a) Failed to use due care in designing and manufacturing docetaxel (TAXOTERE®) so as to avoid the aforementioned risks to individuals when docetaxel (TAXOTERE®) was used for the treatment of breast cancer;
- (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of docetaxel (TAXOTERE®);
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the risks and dangers associated with docetaxel (TAXOTERE®);
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning docetaxel (TAXOTERE®);
- (e) Failed to warn Plaintiff and Plaintiff's physicians of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity, of the side effects;

- (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance, to determine the safety, dangers, and risks associated with docetaxel (TAXOTERE®).
- (g) Failed to warn Plaintiff and Plaintiff's physicians before actively encouraging the sale of docetaxel (TAXOTERE®), either directly or indirectly, orally or in writing, about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and
- (h) Were otherwise careless and/or negligent.

124. Despite the fact that Defendants knew or should have known that docetaxel (TAXOTERE®) caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute, and/or sell docetaxel (TAXOTERE®) to consumers, including Plaintiff.

125. Defendants negligently and improperly failed to perform sufficient tests, forcing Plaintiff, Plaintiff's physicians, and/or hospitals to rely on safety information that did not accurately represent the risks and benefits associated with the use of docetaxel (TAXOTERE®) as compared to other products already commercially available to treat the same types of cancer docetaxel (TAXOTERE®) was designed to treat.

126. Defendants knew or should have known that consumers such as Plaintiff would use their product and would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care, as set forth above.

127. Defendants' negligence was the proximate cause of Plaintiff's injuries, harms, damages, and losses.

128. As a direct and proximate result of the use of docetaxel (TAXOTERE®), Plaintiff experienced disfiguring permanent alopecia.

129. 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.

SECOND CLAIM FOR RELIEF
**(Strict Products Liability – Design and Manufacturing Defects –
Against All Defendants)**

130. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 129 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

131. At all times relevant, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the entities that have designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed docetaxel (TAXOTERE®) as hereinabove described that was used by Plaintiff.

132. Docetaxel (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.

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

134. The docetaxel (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 docetaxel (TAXOTERE®).

135. The docetaxel (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.

136. At all times relevant, docetaxel (TAXOTERE®) was in a defective condition and unsafe, and Defendants knew or had reason to know that docetaxel (TAXOTERE®) was defective and unsafe, especially when used in the form and manner as provided by Defendants.

137. Defendants knew, or should have known, that at all times relevant, docetaxel (TAXOTERE®) was in a defective condition and was and is inherently dangerous and unsafe.

138. At the time of Plaintiff's use of docetaxel (TAXOTERE®), the docetaxel (TAXOTERE®) was being used for the purposes and in a manner normally intended, namely for the treatment of breast cancer.

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

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

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

142. The docetaxel (TAXOTERE®) designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was manufactured defectively and was unreasonably dangerous to its intended users.

143. The docetaxel (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' docetaxel (TAXOTERE®) was manufactured.

144. 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 strictly liable for the injuries sustained by Plaintiff.

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

146. The docetaxel (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.

147. The docetaxel (TAXOTERE®) designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

148. The docetaxel (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, as well as other severe and permanent health consequences from docetaxel (TAXOTERE®), they failed to provide adequate warnings to users or consumers of the product, and they continued to improperly advertise, market, and/or promote docetaxel (TAXOTERE®).

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

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

151. The defects in Defendants' drug docetaxel (TAXOTERE®) were a producing cause and a substantial factor in causing Plaintiff's injuries.

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.

THIRD CLAIM FOR RELIEF
(Strict Products Liability – Failure to Warn
– Against All Defendants)

153. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 152 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

154. The docetaxel (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 associated with the use of docetaxel (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. As the holder for the RLD of brand-name TAXOTERE®, the Sanofi Defendants supplied the labeling for Winthrop U.S.'s generic version of TAXOTERE®. This labeling was defective because it failed to adequately warn of the risk of disfiguring permanent alopecia.

155. 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 docetaxel (TAXOTERE®), and Defendants aggressively and fraudulently promoted the product to physicians.

156. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of docetaxel (TAXOTERE®), Plaintiff suffered disfiguring permanent alopecia and other conditions.

157. 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.

FOURTH CLAIM FOR RELIEF
(Breach of Express Warranty – Against All Defendants)

158. Plaintiff repeats, reiterates, and re-alleges Paragraphs 1 through 157 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

159. Defendants expressly warranted that Docetaxel (TAXOTERE®) was safe and well accepted by users.

160. Docetaxel (TAXOTERE®) does not conform to these express representations, because Docetaxel (TAXOTERE®) is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants.

161. 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, harms, and losses.

162. Plaintiff relied on Defendants' express warranties.

163. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendants for use of Docetaxel (TAXOTERE®) in recommending, prescribing, and/or dispensing Docetaxel (TAXOTERE®). Defendants breached the aforesaid express warranties, as their drug Docetaxel (TAXOTERE®) was and is defective.

164. Defendants expressly represented to Plaintiff, Plaintiff's physicians, and/or healthcare providers that docetaxel (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.

165. Defendants knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue in that docetaxel (TAXOTERE®) was not safe and fit for the use intended, and, in fact, docetaxel (TAXOTERE®) produced serious injuries to the users that were not accurately identified and represented by Defendants.

166. 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
(Breach of Implied Warranty – Against All Defendants)

167. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 166 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

168. 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.

169. 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.

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

171. 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.

172. 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.

173. 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.

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

175. 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.

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

177. 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 Misrepresentation – Against All Defendants)

178. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 177 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

179. Defendants falsely and fraudulently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, 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.

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

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

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

183. 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.

184. Defendants made these false representations with the intent of defrauding and deceiving Plaintiff, Plaintiff's physicians, 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.

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

186. 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.

187. 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.

188. 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.

189. 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.

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

191. 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
(Fraudulent Concealment – Against All Defendants)

192. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 191 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

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

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

195. In representations made to Plaintiff and Plaintiff's healthcare providers, 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.

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

197. 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.

198. 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®).

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

200. 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.

201. 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
(Negligence Misrepresentation – Against All Defendants)

202. Plaintiff repeats, reiterates, and re-alleges Paragraphs 1 through 201 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

203. Defendants had a duty to represent to Plaintiff, Plaintiff's physicians, the medical and healthcare community, 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.

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

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

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

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

208. 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.

209. 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.

210. 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.

211. 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.

212. 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®).

213. 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
(Strict Product Liability for Misrepresentation – Against All Defendants)

214. Plaintiff repeats, reiterates, and re-alleges Paragraphs 1 through 213 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

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

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

217. 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.

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

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

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

221. 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
(Fraud and Deceit – Against All Defendants)

222. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 221 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

223. 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®).

224. 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®).

225. 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, and/or the public that docetaxel (TAXOTERE®) was safe and effective for use in the treatment of various forms of cancer, including breast cancer.

226. 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, and/or the public.

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

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

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

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

231. The information Defendants distributed to Plaintiff, Plaintiff's physicians, and the public 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.

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

233. The information Defendants distributed to Plaintiff, Plaintiff's physicians, and the public 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.

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

235. 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.

236. Defendants intentionally made material misrepresentations to Plaintiff, Plaintiff's physicians, 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.

237. Defendants intentionally made material misrepresentations to Plaintiff, Plaintiff's physicians, 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.

238. It was Defendants' intent and purpose in making these false representations to deceive and defraud Plaintiff, Plaintiff's physicians, and/or the public and to gain the confidence of Plaintiff, Plaintiff's physicians, the public, and/or healthcare professionals 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®).

239. Defendants made the aforementioned false claims and false representations with the intent of convincing Plaintiff, Plaintiff's physicians, the public, and/or healthcare professionals

that docetaxel (TAXOTERE®) was fit and safe for use as treatment for certain types of cancer, including breast cancer.

240. Defendants made the aforementioned false claims and false representations with the intent of convincing Plaintiff, Plaintiff's physicians, the public, and/or healthcare professionals 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.

241. Defendants made false claims and false representations in its documents submitted to Plaintiff, Plaintiff's physicians, the public, and healthcare professionals that docetaxel (TAXOTERE®) did not present risks related to disfigurement secondary to permanent alopecia.

242. Defendants made false claims and false representations in its documents submitted to Plaintiff, Plaintiff's physicians, 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.

243. 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.

244. Defendants made these and other representations with the intention of deceiving and defrauding Plaintiff and Plaintiff's respective healthcare professionals.

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

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

247. 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.

248. 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®).

249. 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®).

250. 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.

251. 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.

252. 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®).

253. 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.

254. 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®).

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

256. 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.

ELEVENTH CLAIM FOR RELIEF
(Extreme and Outrageous Conduct /
Intentional Infliction of Emotional Distress
– Against All Defendants)

257. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 256 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

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

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

260. Defendants' conduct caused Plaintiff severe emotional distress.

261. 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.

TWELFTH CLAIM FOR RELIEF
(Punitive Damages)

261. Plaintiff repeats, reiterates, and realleges Paragraphs 1 through 261 of this Complaint inclusive, with the same force and effect as if fully set forth herein.

262. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the side effects of the docetaxel (TAXOTERE®). Defendants intentionally concealed the true facts and information regarding the serious risks associated with the products, and intentionally downplayed the type, nature, and extent of the adverse side effects despite Defendants' knowledge and awareness of the serious side effects and risks associated with the docetaxel (TAXOTERE®) product.

263. Defendants had knowledge of, and were in possession of evidence demonstrating that the docetaxel (TAXOTERE®) product caused serious side effects. Notwithstanding Defendants' knowledge of the serious side effects, Defendants continued to market the drug products by providing false and misleading information with regard to the product's safety to the regulatory agencies, the medical community, and consumers of the docetaxel (TAXOTERE®) product.

264. Defendants failed to provide warning that would have dissuaded health care professionals and consumers from purchasing and ingesting the docetaxel (TAXOTERE®)

product, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing or consuming the product.

265. Defendant knew of the product's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs in a conscious or negligent disregard of the foreseeable harm caused.

266. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiffs and for the primary purpose of increasing Defendants' profits from the sale and distribution of the products. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

WHEREFORE, Plaintiff Angela Jones 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 19th day of April, 2016.

Respectfully submitted,



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Telephone: 601-957-3101

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

Angela Jones

(b) County of Residence of First Listed Plaintiff

(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

McGartland Law Firm, PLLC
 Michael P. McGartland
 800 S. University Dr., Suite 500
 FT. Worth, TX 76107

DEFENDANTS

Sanofi S.A., Aventis Pharma S.A. and
 Sanofi-Aventis U.S. LLC, separately and jointly
 County of Residence of First Listed Defendant

(IN U.S. PLAINTIFF CASES ONLY)

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

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

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

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

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

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC § 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC § 158 <input type="checkbox"/> 423 Withdrawal 28 USC § 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS - Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

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

VI. CAUSE OF ACTION

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

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

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

DEMAND \$

CHECK YES only if demanded in complaint:

greater than \$15,000.00 JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE: 4/13/16 SIGNATURE OF ATTORNEY OF RECORD: [Signature]

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

#3464303 8908