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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

BERTHA RENEE SCHMITZ,

Plaintiff,

v.

SANOFI S.A., AVENTIS PHARMA S.A., and SANOFI-AVENTIS U.S. LLC,

Defendants.

Case No.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Bertha Renee Schmitz 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, and alleges the following upon personal knowledge, information and belief, and investigation of counsel.

NATURE OF THE CASE

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 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 California. As set forth more fully below, all Defendants are entities organized in states other than the State of California, all Defendants have their principal place of business in a state other than the State of California, and none of the Defendants is a citizen or resident of the State of California.

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 California, including, but not limited to, the marketing, advertising, selling, and distributing of drugs, including TAXOTERE®, to the residents in this State.

4. 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 California and within this District; and at all times relevant hereto, Defendants developed, manufactured, promoted, marketed, distributed, warranted, and sold TAXOTERE® in interstate commerce.

INTRADISTRICT ASSIGNMENT

5. Assignment to the San Francisco division of this Court is appropriate under Civil Local Rule 3-2(c) and (d) as a substantial part of the events or omission which give rise to the claim occurred in Marin County.

PARTIES

6. Plaintiff Bertha Renee Schmitz is a citizen and adult resident of Greenbrae, California, and was prescribed and administered TAXOTERE®, which was developed, manufactured, promoted, marketed, distributed, and sold by Defendants. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

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

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

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

10. Defendant Sanofi-Aventis U.S. LLC sometimes operates, promotes, markets, sells, distributes pharmaceutical products, and does business under the name of Winthrop U.S., which is not a separately existing legal entity but rather is a business unit or division operating within and part of Sanofi-Aventis U.S. LLC.

DEFENDANTS' OWNERSHIP AND UNITY OF INTEREST

11. Sanofi S.A. is a French multinational pharmaceutical parent company that operates worldwide through a complex, consolidated, and intermingled web of more than 400

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

12. At all times relevant, Sanofi S.A. was engaged in the business of researching, analyzing, licensing, designing, formulating, compounding, patenting, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling the prescription drug TAXOTERE® through its numerous wholly-owned subsidiaries in the United States and throughout the world, including Defendants Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC.

13. The predecessor to the entity now known as Sanofi S.A. was founded in 1973 as a subsidiary of Elf Aquitaine, a French oil company subsequently acquired by Total, when Elf Aquitaine took control of the Labaz group pharmaceutical company. In 1993, Sanofi entered the U.S. pharmaceutical market by first partnering with and then later acquiring Sterling Winthrop and its prescription pharmaceutical business in 1994. Sanofi was incorporated under the laws of France in 1994 as a *société anonyme*.

14. Aventis was formed in 1999 when the French company Rhône-Poulenc S.A. merged with the German corporation Hoechst Marion Roussel, which itself was formed from the 1995 merger of Hoechst AG with Cassella, Roussel Uclaf, and Marion Merrell Dow. The merged company was based in Schiltigheim, near Strasbourg, France.

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

16. Sanofi S.A.'s shares are listed on the New York Stock Exchange and the NASDAQ Global Market. Sanofi S.A. is required by law to register its securities in the United States under section 12(g) of the Securities Exchange Act of 1934 on Form 20-F and to file its annual reports on Form 20-F.

17. According to Sanofi S.A.'s Form 20-F filed with the U.S. Securities and Exchange Commission for the fiscal year ended December 31, 2014, Sanofi S.A. owns 100% of the membership and voting interest of Sanofi-Aventis U.S. LLC. Therefore, Sanofi S.A. controls and directs the operations of Sanofi-Aventis U.S. LLC.

18. Sanofi-Aventis U.S. LLC, according to Sanofi S.A.'s Form 20-F, was formed on June 28, 2000 as a Delaware limited liability company whose principal activity was identified as "Pharmaceuticals."

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

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

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

22. At all relevant times, and as more fully set forth below, Defendants acted in conjunction with other affiliated, related, jointly owned and/or controlled entities or subsidiaries, including each other, in the development, marketing, production, labeling, promoting, packaging, advertising, and/or selling of TAXOTERE® to the general public, including Plaintiff. Defendants acted jointly and/or as each other's agents, within the course and scope of the agency, with respect to the conduct alleged in this Complaint, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another and are jointly-liable for their misconduct and wrongful acts as alleged herein.

23. As the corporate parent of these wholly-owned subsidiaries, Sanofi S.A. directs and controls the operations of Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC. Accordingly, there exists, and at all relevant times herein existed, a unity of interest, ownership, and conduct between Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC with regard to the manufacture, distribution, development, testing, and labeling of the TAXOTERE® in question and with regard to other related conduct, such that any individuality and separateness between Defendants had ceased and these Defendants became the alter-ego of one another.

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

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

25. TAXOTERE® is a drug used in the treatment of various forms of cancer, including but not limited to breast cancer. TAXOTERE® is a part of a family of drugs commonly referred to as Taxanes.

26. Taxanes are diterpenes produced by the plants of the genus Taxus (yews) featuring a taxadiene core. Taxanes are widely used as chemotherapy agents. Taxane agents include paclitaxel (TAXOL®) and TAXOTERE®. Taxane agents also exist as cabazitaxel and in generic forms as well.

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

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

29. The initial patent disclosing the formulation and computation of 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 TAXOTERE®.

30. In 1989, Sanofi issued the prior art publication F. Lavelle, *Experimental Properties of RP 56976*, a taxol derivative. RP 56976 was the number that Rhone-Polunec, Aventis Pharma S.A.'s predecessor, assigned to docetaxel.

31. Sanofi began enrolling patients in Phase I clinical testing trials on June 21, 1990. The study reporting on these trials was called the "TAX 001" study, which continued until May 13, 1992. The results from the TAX 001 study were reported on May 24, 1994. Accordingly, Sanofi was not only involved in the patenting and assignment of the compound Taxotere® (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.

32. Rhône-Poulenc Rorer S.A., before it was acquired by or merged into Aventis Pharma S.A., initially sought FDA approval for TAXOTERE® in December 1994. The FDA's Oncologic Drugs Advisory Committee panel unanimously recommended the rejection of Rhône-Poulenc Rorer S.A.'s request for the approval of TAXOTERE®, because TAXOTERE® was

more toxic than its competing drug TAXOL®, which had already received FDA approval, and because more studies of docetaxel's side effects were needed.

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

34. After the initial FDA approval, Defendants sought and were granted FDA approval for additional indications for TAXOTERE®. Based on self-sponsored clinical trials, Defendants claimed superiority over other chemotherapy products approved to treat breast cancer. Defendants' marketing claims included claims of superior efficacy over the lower potency Taxane product paclitaxel (TAXOL®), which was the primary competitor product to TAXOTERE®.

35. Contrary to Defendants' claims of superior efficacy, post market surveillance has shown that the more potent and more toxic TAXOTERE® does not in fact offer increased efficacy or benefits over other Taxanes, as Defendants have claimed and advertised. Defendants concealed the existence of studies from the FDA, physicians, and patients that refuted Defendants' claims.

36. A study of available clinical studies concerning the relative efficacy of Taxanes in the treatment of breast cancer, published in the August 2007 journal *Cancer Treatment Review*, concluded that no significant differences were found in the efficacy and outcomes obtained with TAXOTERE® (docetaxel) or TAXOL® (paclitaxel).

37. A study published in 2008 in the New England Journal of Medicine, titled *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*, concluded that TAXOL® (paclitaxel) was more effective than TAXOTERE® (docetaxel) for patients undergoing standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

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

Oncology, comparing the efficacy of TAXOTERE® versus paclitaxel (TAXOL®). Specifically, Sanofi-Aventis utilized a "reprint carrier," citing a clinical study published in the August 2005 edition of the Journal of Clinical Oncology ("JCO"). The 2005 JCO study concluded that "TAXOTERE® demonstrated superior efficacy compared with paclitaxel (TAXOL®), providing significant clinical benefit in terms of survival and time to disease progression, with a numerically higher response rate and manageable toxicities."

39. Whatever the merits of the 2005 JCO study may have been, Defendants' statements in the "reprint carrier" marketing the conclusions of the 2005 JCO study were false and/or misleading in light of the 2007 and 2008 studies finding that TAXOTERE® was not more effective than paclitaxel (TAXOL®) in the treatment of breast cancer.

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

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a professional reprint carrier [US.DOC.07.04.078] for Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion (Taxotere) submitted under cover of Form FDA 2253 by sanofi-aventis (SA) and obtained at the American Society of Clinical Oncology annual meeting in June 2008. The reprint carrier includes a reprint[1] 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]

41. A Qui Tam lawsuit was also filed against Sanofi-Aventis and its affiliates in the United States District Court for the Eastern District of Pennsylvania by a former employee

[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.

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

42. Beginning in 1996, Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC and their predecessors and affiliates designed, directed, and/or engaged in a marketing scheme that promoted TAXOTERE® for off-label uses not approved by the FDA. The scheme took two forms: first, Defendants trained and directed their employees to misrepresent the safety and effectiveness of the off-label use of Taxotere to expand the market for TAXOTERE® in unapproved settings; and second, Defendants paid healthcare providers illegal kickbacks in the form of sham grants, speaking fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free reimbursement assistance to incentivize healthcare providers to prescribe TAXOTERE® for off-label uses. As a direct result of Defendants' fraudulent marketing scheme, Defendants dramatically increased revenue on sales of TAXOTERE® from $424 million in 2000 to $1.4 billion in 2004. *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 508 (E.D. Pa. 2015).

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

44. As a direct result of their aforementioned conduct, Defendants caused thousands of individuals to be exposed to increased frequency and more severe side effects, including but not limited to disfiguring permanent alopecia (hair loss).

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

45. Although alopecia, or hair loss, is a common side effect related to chemotherapy drugs, permanent alopecia is not. Defendants, through their publications and marketing materials, misled Plaintiff, the public, and the medical community to believe that, as with other chemotherapy drugs that cause alopecia, patients' hair would grow back.

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

47. Permanent baldness (permanent alopecia) is a disfiguring condition, especially for women. Women who experienced disfiguring permanent alopecia as a result of the use of TAXOTERE® suffer great mental anguish as well as economic damages, including but not limited to loss of work or inability to work due to significant psychological damage.

48. Although women might accept the possibility of permanent baldness as a result of the use of TAXOTERE® if no other product were available to treat their cancer, this was not the case. Before Defendants' wrongful conduct resulted in thousands of women being exposed to the side effects of TAXOTERE®, there were already similar products on the market that were at least as effective as TAXOTERE® and did not subject female users to the same risk of disfiguring permanent alopecia as does TAXOTERE®.

49. Beginning in the late 1990s, Sanofi S.A. and Aventis Pharma S.A. sponsored and/or were aware of a study titled the GEICAM 9805 study. In 2005, Sanofi S.A. and Aventis Pharma S.A. knew that the GEICAM 9805 study demonstrated that 9.2% of patients who took TAXOTERE® had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer, after taking TAXOTERE®. Sanofi S.A. and Aventis Pharma S.A. knowingly, intentionally, and wrongfully withheld these results contained in the GEICAM 9805 study from physicians, healthcare providers, patients, and Plaintiff in the United States.

50. In 2006, Defendants knew or should have known that a Denver-based oncologist in the United States had observed that an increased percentage (6.3%) of his patients who had taken TAXOTERE® suffered from permanent disfiguring hair loss for years after the patients had stop taking TAXOTERE®.

51. Despite Defendants' knowledge of the relevant findings from the GEICAM 9805 study, as well as reports from patients who had taken TAXOTERE® and suffered from permanent disfiguring hair loss, Defendants failed to provide accurate information and proper warnings to physicians, healthcare providers, and patients in the United States, including

Plaintiff, that patients who take TAXOTERE® are at a significantly increased risk of suffering from permanent disfiguring hair loss.

52. Defendants chose to withhold this information in the United States despite advising physicians, patients, and regulatory agencies in other countries, including the European Union and Canada, that TAXOTERE® causes an increased risk of permanent disfiguring hair loss. Defendants instead continued to warn or advise physicians, healthcare providers, patients, and Plaintiff in the United States only with the generic, vague, and insufficient warning that "hair generally grows back" after taking TAXOTERE®.

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

54. Although Defendants publish information in other countries to individual patients as well as regulatory agencies related to TAXOTERE® and the risk of permanent alopecia, the words permanent alopecia or permanent hair loss do not appear in any information published by Defendants in the United States.

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

56. As a direct result of Defendants' failure to warn patients of the risk of disfiguring permanent alopecia in the United States, thousands of women, including Plaintiff, as well as their health care providers, were deprived of the opportunity to make an informed decision as to whether the benefits of using TAXOTERE® over other comparable products was justified.

57. Defendants preyed on one of the most vulnerable groups of individuals at the most difficult time in their lives. Defendants obtained billions of dollars in increased revenues at the expense of unwary cancer victims simply hoping to survive their condition and return to a normal life.

58. TAXOTERE® was defective in its design. TAXOTERE® was designed as an increased potency Taxane. This increased potency resulted in increased toxicity, which can be directly related to increased adverse events. The most likely reason Defendants designed the increased potency Taxane was to enable them to obtain a patent (and the concurrent market advantage) on a product that in fact was not novel but instead only more dangerous.

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

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

60. Plaintiff Bertha Renee Schmitz was diagnosed with HER2-negative cancer in her right breast in 2009.

61. Following her diagnosis, Plaintiff met with her oncologist to discuss 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 underwent chemotherapy that included TAXOTERE®. Following the completion of chemotherapy, Plaintiff suffered from disfiguring permanent alopecia as a result of receiving chemotherapy with TAXOTERE®.

NATURE OF THE CLAIMS

62. Despite the fact that Defendants disclosed risks associated with TAXOTERE® and permanent alopecia to patients and regulatory agencies in other countries, Defendants failed to either alert Plaintiff, the public, and the scientific community in the United States or perform further investigation into the safety of TAXOTERE® regarding the side effect of disfiguring permanent alopecia. Defendants failed to update the warnings for TAXOTERE®, and they failed to disclose the results of additional studies as Defendants learned new facts regarding the defects and risks of their product.

63. In particular, Defendants:

(a) failed to disclose their investigation and research from 2005, including but not limited to the results of the GEICAM 9805 study, and failed to further

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

(b) failed to provide adequate warnings about the true safety risks associated with the use of TAXOTERE®;

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of TAXOTERE® and its effects on the degree or severity of side effects related to permeant alopecia;

(d) failed to disclose in the "Warnings" Section that permeant alopecia is a frequent side effect associated with the use of TAXOTERE®;

(e) failed to advise prescribing physicians, such as Plaintiff's physicians, to instruct patients that permanent alopecia was a side effect, much less a frequent side effect, linked to TAXOTERE®;

(f) failed to provide adequate instructions on how to intervene and/or reduced the risk of permanent alopecia related to the use of TAXOTERE®;

(g) failed to provide adequate warnings and information related to the increased risks of permeant alopecia in certain genome groups;

(h) failed to provide adequate warnings regarding the increased risk of permeant alopecia with the use of TAXOTERE® as compared to other products designed to treat the same conditions as TAXOTERE®; and

(i) failed to include a **"BOXED WARNING"** related to permanent or persistent alopecia.

64. During the years since first marketing TAXOTERE® in the U.S., Defendants modified the U.S. labeling and prescribing information for TAXOTERE® on multiple occasions. Defendants failed, however, to include any warning whatsoever related to permanent alopecia despite Defendants' awareness of the frequency and severity of this side effect.

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

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

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

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

69. Defendants ignored the association between the use of TAXOTERE® and the risk of disfiguring permanent alopecia.

70. Defendants failed to disclose information that they possessed regarding their failure to adequately test and study TAXOTERE® related to the side effect of disfiguring permanent alopecia. Plaintiff and her healthcare providers could not have discovered Defendants' false representations and failures to disclose information through the exercise of reasonable diligence.

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

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

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

73. Plaintiff is within the applicable statutes of limitations for the claims presented herein because Plaintiff did not discover the defects and unreasonably dangerous condition of Defendants' TAXOTERE® and the risks associated with its use in the form of disfiguring permanent alopecia, and could not reasonably have discovered the defects and unreasonably dangerous condition of Defendants' TAXOTERE® and the risks associated with its use, due to the Defendants' failure to warn, suppression of important information about the risks of the drug, including but not limited to the true risk benefit profile, and the risk of disfiguring permanent alopecia and damages known by Defendants to result from the use of TAXOTERE®, and other acts and omissions.

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

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

76. Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public, had no knowledge of, and no reasonable way of discovering, the defects found in Defendants' TAXOTERE® or the true risks associated with her use at the time she purchased and used Defendants' TAXOTERE®.

77. Defendants did not notify, inform, or disclose to Plaintiff, Plaintiff's prescribing health care professionals or the general consuming public that Defendants' TAXOTERE® was defective and that its use carried with it the serious risk of developing the injuries Plaintiff has suffered and complained of herein.

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

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

80. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

81. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of

TAXOTERE® into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

82. 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 TAXOTERE® into interstate commerce in that Defendants knew or should have known that using 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.

83. 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 TAXOTERE® without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing TAXOTERE® without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not TAXOTERE® was safe for use in that Defendants knew or should have known that TAXOTERE® was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling 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 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, TAXOTERE®;

(g) Failing to test TAXOTERE® and/or failing to adequately, sufficiently, and properly test TAXOTERE®;

(h) Negligently advertising and recommending the use of TAXOTERE® without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that TAXOTERE® was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently and falsely representing that TAXOTERE® was superior to other commercially available products designed to treat the same forms of cancer TAXOTERE® was designed to treat;

(k) Negligently designing TAXOTERE® in a manner that was dangerous to its users;

(l) Negligently manufacturing TAXOTERE® in a manner that was dangerous to its users;

(m) Negligently producing TAXOTERE® in a manner that was dangerous to its users;

(n) Negligently assembling 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 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 TAXOTERE® compared to other forms of treatment for breast cancer.

84. Defendants underreported, underestimated, and downplayed the serious dangers and risk associated with TAXOTERE®.

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

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

(a) Failed to use due care in designing and manufacturing TAXOTERE® so as to avoid the aforementioned risks to individuals when 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 TAXOTERE®;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the risks and dangers associated with TAXOTERE®;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning 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 TAXOTERE®.

(g) Failed to warn Plaintiff and Plaintiff's physicians before actively encouraging the sale of 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.

87. Despite the fact that Defendants knew or should have known that TAXOTERE® caused unreasonably dangerous side effects, namely the serious risk of developing disfiguring permanent alopecia, Defendants continued and continue to market, manufacture, distribute, and/or sell TAXOTERE® to consumers, including Plaintiff.

88. 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 TAXOTERE® as compared to other products already commercially available to treat the same types of cancer TAXOTERE® was designed to treat.

89. 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.

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

91. As a direct and proximate result of the use of TAXOTERE®, Plaintiff experienced disfiguring permanent alopecia.

92. 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.

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SECOND CLAIM FOR RELIEF

(Strict Products Liability – Design and Manufacturing Defects – Against All Defendants)

93. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

94. 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 TAXOTERE® as hereinabove described that was used by Plaintiff.

95. 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.

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

97. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of TAXOTERE®.

98. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and it was more dangerous and posed risk greater than an ordinary consumer would expect.

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

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

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

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

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

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

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

106. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants reached the intended users in the same defective and unreasonably dangerous condition in which Defendants' TAXOTERE® was manufactured.

107. 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.

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

109. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions, as Defendants knew or should have known that the product created a risk of serious and dangerous side effects including disfigurement from permanent alopecia as well as other severe and personal injuries that are permanent and lasting in nature, and Defendants failed to adequately warn of these risks.

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

111. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including disfigurement from permanent alopecia, as well as other severe and permanent health consequences from TAXOTERE®, they failed to provide adequate warnings to users or consumers of the product, and they continued to improperly advertise, market, and/or promote TAXOTERE®.

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

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

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

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

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THIRD CLAIM FOR RELIEF

(Strict Products Liability – Failure to Warn – Against All Defendants)

116. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

117. The TAXOTERE® designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants was defective in that it failed to include adequate warnings regarding all adverse side effects associated with the use of TAXOTERE®. The warnings given by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side effects and, in particular, the risks of disfiguring permanent alopecia. 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.

118. Defendants failed to provide adequate warnings to physicians and users, including Plaintiff's physicians and Plaintiff, of the increased risk of disfiguring permanent alopecia associated with TAXOTERE®, and Defendants aggressively and fraudulently promoted the product to physicians.

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

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

FOURTH CLAIM FOR RELIEF

(Breach of Express Warranty – Against All Defendants)

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

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

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

124. As a direct and proximate result of the breach of these warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, including, but not limited to, permanent alopecia disfigurement, harms, and losses.

125. Plaintiff relied on Defendants' express warranties.

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

127. Defendants expressly represented to Plaintiff, Plaintiff's physicians, and/or healthcare providers that TAXOTERE® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for cancer, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

128. Defendants knew or should have known that, in fact, their representations and warranties were false, misleading, and untrue in that TAXOTERE® was not safe and fit for the use intended, and, in fact, TAXOTERE® produced serious injuries including, but not limited to, disfiguring permanent alopecia, to the users that were not accurately identified and represented by Defendants.

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; 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)

130. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

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

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

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

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

135. 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.

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

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

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

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

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

SIXTH CLAIM FOR RELIEF

(Fraudulent Misrepresentation – Against All Defendants)

141. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

142. Defendants falsely and fraudulently represented to Plaintiff, Plaintiff's physicians, the medical and healthcare community, and the public in general that TAXOTERE®

had been tested and was found to be safe and effective for the treatment of certain forms of cancer.

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

144. 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 including, but not limited to, concealing their knowledge of the risk of developing disfiguring permanent alopecia.

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

146. 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 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.

147. 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 TAXOTERE® for use in the treatments of various forms of cancer, including but not limited to breast cancer.

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

149. At the time Defendants made the aforesaid representations, and, at the time Plaintiff used 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.

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

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

152. Defendants knew or should have known that TAXOTERE® had a potential to, could, and would cause severe and grievous injury to the users of TAXOTERE®, including, but not limited to, the development of permanent disfiguring alopecia, and that TAXOTERE® was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

153. Defendants brought TAXOTERE® to the market and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

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

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SEVENTH CLAIM FOR RELIEF

(Fraudulent Concealment – Against All Defendants)

155. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

156. 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 TAXOTERE® for its intended use.

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

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

(a) that TAXOTERE® was not as safe as other forms of treatment for which TAXOTERE® was marketed and sold to cancer patients;

(b) that the risks of adverse events with TAXOTERE® were higher than those with other forms of treatment for which TAXOTERE® was marketed and sold to cancer patients;

(c) that the risks of adverse events with TAXOTERE® were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in TAXOTERE®, in addition to and above and beyond those associated with other forms of treatment for cancer patients;

(e) that 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 TAXOTERE® was manufactured negligently;

(g) that TAXOTERE® was manufactured defectively;

(h) that TAXOTERE® was manufactured improperly;

(i) that TAXOTERE® was designed negligently;

(j) that TAXOTERE® was designed defectively; and

(k) that TAXOTERE® was designed improperly.

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

160. Defendants had sole access to material facts concerning the defective nature of TAXOTERE® and its propensity to cause serious and dangerous side effects, including, but not limited to, disfiguring permanent alopecia, and therefore cause damage to persons who used TAXOTERE®, including Plaintiff, in particular.

161. Defendants' concealment and omissions of material facts concerning the safety of 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 TAXOTERE® and to cause them to purchase, prescribe, and/or dispense TAXOTERE® and/or use TAXOTERE®.

162. 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 TAXOTERE® set forth herein.

163. 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.

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

EIGHTH CLAIM FOR RELIEF

(Negligent Misrepresentation – Against All Defendants)

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

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

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

168. 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.

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

170. 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.

171. 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 TAXOTERE® for use in the treatments of various forms of cancer, including but not limited to breast cancer.

172. 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 TAXOTERE® for use in the treatments of various forms of cancer, including but not limited to breast cancer.

173. Defendants failed to exercise ordinary and reasonable care in their representations of 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.

174. Defendants breached their duty in misrepresenting docetaxel's (TAXOTERE®'s) serious side effects including, but not limited to disfiguring permanent alopecia, to Plaintiff, Plaintiff's physicians, the medical and healthcare community, the FDA, and the public in general.

175. 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 TAXOTERE®.

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

NINTH CLAIM FOR RELIEF

(Strict Product Liability for Misrepresentation – Against All Defendants)

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

178. Defendants sold the TAXOTERE® that Plaintiff's physician prescribed for Plaintiff and that Plaintiff used.

179. Defendants were engaged in the business of selling the TAXOTERE® for resale, use, or consumption.

180. Defendants misrepresented facts as set forth herein concerning the character or quality of the TAXOTERE® that would be material to potential prescribers and purchasers or users of the product.

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

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

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

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

TENTH CLAIM FOR RELIEF

(Fraud and Deceit – Against All Defendants)

185. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

186. Defendants committed fraud by omission in applying for and gaining patent protection for 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 TAXOTERE®.

187. Defendants fraudulently claimed superior efficacy over other products designed to treat the same conditions for which TAXOTERE® was designed to treat. These fraudulent

representations were the proximal cause of Plaintiff's exposure to the side effects of TAXOTERE®.

188. 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 TAXOTERE® was safe and effective for use in the treatment of various forms of cancer, including breast cancer.

189. 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.

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

191. 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.

192. 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.

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

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

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

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

197. These representations by Defendants were all false and misleading, as TAXOTERE® carried with it the serious risk of developing disfiguring permanent alopecia.

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

199. Defendants intentionally made material misrepresentations to Plaintiff, Plaintiff's physicians, and the public, including the medical profession, regarding the safety of TAXOTERE®, specifically but not limited to TAXOTERE® not having dangerous and serious health and/or safety concerns.

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

201. 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 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 TAXOTERE®.

202. 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 TAXOTERE® was fit and safe for use as treatment for certain types of cancer, including breast cancer.

203. 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 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 TAXOTERE® was designed to treat.

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

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

206. 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.

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

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

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

210. Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of 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.

211. 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 TAXOTERE®.

212. Defendants willfully and intentionally failed to disclose the truth and material facts related to 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 TAXOTERE®.

213. 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.

214. 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 TAXOTERE® would treat certain forms of cancer for which TAXOTERE® was designed to treat.

215. 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 TAXOTERE®.

216. 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 TAXOTERE®, and Plaintiff and her healthcare providers with reasonable diligence could not have discovered the true facts.

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

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

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

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

220. Plaintiff repeats, reiterates, and realleges all paragraphs of this Complaint, with the same force and effect as if fully set forth herein.

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

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

223. Defendants' conduct caused Plaintiff severe emotional distress.

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

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff Schmitz, demands judgment against Defendants Sanofi S.A.; Aventis Pharma S.A.; and Sanofi-Aventis U.S. LLC, 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.

DATED: August 12, 2016

Respectfully submitted,

GIBBS LAW GROUP LLP

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