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11
12 UNITED STATES DISTRICT COURT
13 CENTRAL DISTRICT OF CALIFORNIA

14
15 THERESE MARTINEZ,
16 Plaintiff,
17 v.
18 SANOFI S.A.,
19 AVENTIS PHARMA S.A., and
20 SANOFI-AVENTIS U.S. LLC,
separately, and doing business as
21 WINTHROP U.S.,
Defendants.

Case No.:

COMPLAINT AND DEMAND
FOR JURY TRIAL

22
23 **COMPLAINT**

24 Plaintiff, Therese Martinez (“Plaintiff”), by and through her undersigned counsel,
25 respectfully submits the following Complaint and Jury Demand against Defendants Sanofi S.A.;
26 Aventis Pharma S.A.; and Sanofi-Aventis U.S. LLC, separately, and doing business as Winthrop
27 U.S., (“Defendants”) and alleges the following upon personal knowledge, information and belief,
28 and investigation of counsel:

1 **NATURE OF THE ACTION**

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

7 **JURISDICTION AND VENUE**

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

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

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

25 **PARTIES**

26 5. Plaintiff Therese Martinez is and was at all relevant times a citizen and adult
27 resident of the State of California and was prescribed and used docetaxel (TAXOTERE®), which
28

1 was developed, manufactured, promoted, marketed, distributed, and sold by Defendants. Plaintiff
2 has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

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

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

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

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

19 **DEFENDANTS' OWNERSHIP AND**

20 **UNITY OF INTEREST**

21 10. Sanofi S.A. is a French multinational pharmaceutical parent company that operates
22 worldwide through a complex, consolidated, and intermingled web of more than 400 wholly-
23 owned subsidiaries, including Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC. As of 2013,
24 Sanofi S.A. was the world's fifth-largest pharmaceutical company by sales.

25 11. At all times relevant, Sanofi S.A. was engaged in the business of researching,
26 analyzing, licensing, designing, formulating, compounding, patenting, testing, manufacturing,
27 producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,
28 packaging, advertising, and/or selling the prescription drug docetaxel (TAXOTERE®) through its

1 numerous wholly-owned subsidiaries in the United States and throughout the world, including
2 Defendants Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC.

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

9 13. Aventis was formed in 1999 when the French company Rhône-Poulenc S.A.
10 merged with the German corporation Hoechst Marion Roussel, which itself was formed from the
11 1995 merger of Hoechst AG with Cassella, Roussel Uclaf, and Marion Merrell Dow. The merged
12 company was based in Schiltigheim, near Strasbourg, France.

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

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

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

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

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

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

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

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

21 22. As the corporate parent of these wholly-owned subsidiaries, Sanofi S.A. directs
22 and controls the operations of Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC. Accordingly,
23 there exists, and at all relevant times herein existed, a unity of interest, ownership, and conduct
24 between Sanofi S.A., Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC with regard to the
25 manufacture, distribution, development, testing, and labeling of the docetaxel (TAXOTERE®) in
26 question and with regard to other related conduct, such that any individuality and separateness
27 between Defendants had ceased and these Defendants became the alter-ego of one another.
28

1 23. Sanofi S.A., through its complicated web of various affiliates, wholly-owned
2 subsidiaries, and predecessor companies, including Aventis Pharma S.A. and Sanofi-Aventis U.S.
3 LLC, has been directly involved in and has overseen the invention, development, clinical trials,
4 and strategy for marketing, distributing, selling, and promoting Taxotere® (docetaxel) throughout
5 the world and in the United States. Sanofi S.A. markets Taxotere® (docetaxel) worldwide in over
6 100 different countries. When press releases are issued announcing the introduction, marketing,
7 and distribution of Taxotere® (docetaxel) in a new country, the press releases are issued by
8 Sanofi S.A., or before 2011 when Sanofi S.A. changed its name, by Sanofi-Aventis.

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

11 24. Docetaxel (TAXOTERE®) is a drug used in the treatment of various forms of
12 cancer, including but not limited to breast cancer. Docetaxel (TAXOTERE®) is a part of a family
13 of drugs commonly referred to as Taxanes.

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

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

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

25 28. The initial patent disclosing the formulation and computation of docetaxel
26 (TAXOTERE®) was issued to Rhone-Poulence Santé and subsequently assigned to Defendant
27 Aventis Pharma S.A in March 1989. Sanofi S.A. owns 100% of the shares or financial interest of
28 Aventis Pharma S.A., and Sanofi S.A. therefore directs and controls the operations and activities

1 of Aventis Pharma S.A. Since March 1989, Sanofi S.A., through its wholly-owned subsidiary,
2 Aventis Pharma S.A., has controlled the development and been the owner, holder, or assignee of
3 the patents related to docetaxel (TAXOTERE®).

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

7 30. Sanofi began enrolling patients in Phase I clinical testing trials on June 21, 1990.
8 The study reporting on these trials was called the "TAX 001" study, which continued until May
9 13, 1992. The results from the TAX 001 study were reported on May 24, 1994. Accordingly,
10 Sanofi was not only involved in the patenting and assignment of the compound Taxotere®
11 (docetaxel), but Sanofi was also directly involved in the clinical trials and testing of the
12 compound Taxotere® (docetaxel). Accordingly, Sanofi S.A. and Aventis Pharma S.A. have direct
13 and personal knowledge of the results of those tests and Sanofi S.A., Aventis Pharma S.A., and
14 Sanofi-Aventis U.S. LLC's decisions to withhold information and data from those tests from
15 physicians, healthcare providers, patients, and Plaintiff in the United States.

16 31. Rhône-Poulenc Rorer S.A., before it was acquired by or merged into Aventis
17 Pharma S.A., initially sought FDA approval for docetaxel (TAXOTERE®) in December 1994.
18 The FDA's Oncologic Drugs Advisory Committee panel unanimously recommended the rejection
19 of Rhône-Poulenc Rorer S.A.'s request for the approval of docetaxel (TAXOTERE®), because
20 docetaxel (TAXOTERE®) was more toxic than its competing drug TAXOL®, which had already
21 received FDA approval, and because more studies of docetaxel's side effects were needed.

22 32. Docetaxel (TAXOTERE®) was ultimately approved by the FDA on May 14,
23 1996. According to its product labeling, docetaxel (TAXOTERE®) was "indicated for the
24 treatment of patients with locally advanced or metastatic breast cancer after failure of prior
25 chemotherapy."

26 33. After the initial FDA approval, Defendants sought and were granted FDA approval
27 for additional indications for docetaxel (TAXOTERE®). Based on self-sponsored clinical trials,
28 Defendants claimed superiority over other chemotherapy products approved to treat breast cancer.

1 Defendants' marketing claims included claims of superior efficacy over the lower potency
2 Taxane product paclitaxel (TAXOL®), which was the primary competitor product to docetaxel
3 (TAXOTERE®).

4 34. Contrary to Defendants' claims of superior efficacy, post market surveillance has
5 shown that the more potent and more toxic docetaxel (TAXOTERE®) does not in fact offer
6 increased efficacy or benefits over other Taxanes, as Defendants have claimed and advertised.
7 Defendants concealed the existence of studies from the FDA, physicians, and patients that refuted
8 Defendants' claims. A study published in 2008 in the New England Journal of Medicine, titled
9 *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*, concluded that TAXOL®
10 (paclitaxel) was more effective than TAXOTERE® (docetaxel) for patients undergoing standard
11 adjuvant chemotherapy with doxorubicin and cyclophosphamide.

12 35. Despite the publication of this study, Defendants continued to make false and
13 misleading statements promoting the "superior efficacy" of docetaxel (TAXOTERE®) over the
14 competing product paclitaxel (TAXOL®). As a result of these false and misleading statements, in
15 2009, the FDA issued a warning letter to Sanofi-Aventis (the same company as Defendant Sanofi
16 S.A. before Sanofi-Aventis changed its name in 2011) citing these unsubstantiated claims of
17 superiority over paclitaxel stating:

18 The Division of Drug Marketing, Advertising, and
19 Communications (DDMAC) of the U.S. Food and Drug
20 Administration (FDA) has reviewed a professional reprint carrier
21 [US.DOC.07.04.078] for Taxotere (docetaxel) Injection
22 Concentrate, Intravenous Infusion (Taxotere) submitted under cover
23 of Form FDA 2253 by sanofi-aventis (SA) and obtained at the
24 American Society of Clinical Oncology annual meeting in June
25 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

26 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.

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

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

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

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

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

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DEFENDANTS’ COVERUP IN THE UNITED STATES
REGARDING THE CAUSAL RELATIONSHIP BETWEEN DOCETAXEL
(TAXOTERE®) AND PERMANENT DISFIGURING HAIR LOSS

40. 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.

41. 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.

42. 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.

43. 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®).

44. 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.

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

5 46. Despite Defendants’ knowledge of the relevant findings from the GEICAM 9805
6 study, as well as reports from patients who had taken docetaxel (TAXOTERE®) and suffered
7 from permanent disfiguring hair loss, Defendants failed to provide accurate information and
8 proper warnings to physicians, healthcare providers, and patients in the United States, including
9 Plaintiff, that patients who take docetaxel (TAXOTERE®) are at a significantly increased risk of
10 suffering from permanent disfiguring hair loss. Instead, Defendants chose to withhold this
11 information in the United States despite advising physicians, patients, and regulatory agencies in
12 other countries, including the European Union and Canada, that docetaxel (TAXOTERE®)
13 causes an increased risk of permanent disfiguring hair loss. Defendants instead continued to warn
14 or advise physicians, healthcare providers, patients, and Plaintiff in the United States only with
15 the generic, vague, and insufficient warning that “hair generally grows back” after taking
16 docetaxel (TAXOTERE®).

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

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

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

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

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

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

16 53. Plaintiff and numerous other women were the innocent victims of Defendants'
17 greed, recklessness, and willful and wanton conduct.

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

20 54. In or about July 2014, Plaintiff underwent imaging of her left breast which
21 identified three nodules, a 6 mm nodule with a 4 mm and 3 mm satellite nodules, followed by
22 biopsy of the 6 mm nodule. The biopsy was positive for invasive ductal carcinoma, with apocrine
23 features. Final diagnosis of multifocal T1 N0 breast cancer.

24 55. On or about August 27, 2014, Plaintiff began neoadjuvant chemotherapy which
25 continued until on or about December 10, 2014. As part of her chemotherapy treatments, Plaintiff
26 received injections of docetaxel (TAXOTERE®) manufactured sold, promoted, and/or distributed
27 by Defendants.

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1 56. In or about January 2015 she underwent bilateral mastectomy and left sentinel
2 node biopsy. Lymph node testing was negative.

3 57. Plaintiff consulted with health care providers regarding her options for
4 chemotherapy. The providers were not aware, nor had they been informed, of any warnings or
5 precautions or risks that disfiguring permanent alopecia could occur following treatment with
6 docetaxel (TAXOTERE®).

7 58. Plaintiff did not know or suspect until 2016 that she was suffering from continuing
8 hair loss as a result of taking docetaxel (TAXOTERE®). As a result of Defendants' wrongful
9 conduct, Plaintiff has continued to suffer and will suffer in the future from disfiguring permanent
10 alopecia as a result of receiving chemotherapy with docetaxel (TAXOTERE®).

11 59. Upon information and belief, considering their close involvement in the
12 development, promotion, selling, and distributing docetaxel (TAXOTERE®) within the Sanofi
13 consolidated and closely held group of companies, Defendants Sanofi S.A. and Aventis Pharma
14 S.A. were also involved in the development of the labeling submitted for docetaxel
15 (TAXOTERE®) in the United States. Defendants' labeling of docetaxel (TAXOTERE®) was
16 defective because it failed to adequately warn of the risk of disfiguring permanent alopecia.

17 **NATURE OF THE CLAIMS**

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

25 61. In particular, Defendants:

- 26 (a) failed to disclose their investigation and research from 2005, including but
27 not limited to the results of the GEICAM 9805 study, and failed to further
28 investigate, research, study, and define fully and adequately the safety
profile of docetaxel (TAXOTERE®) in response to these studies;

- 1 (b) failed to provide adequate warnings about the true safety risks associated
- 2 with the use of docetaxel (TAXOTERE®);
- 3 (c) failed to provide adequate warning regarding the pharmacokinetic and
- 4 pharmacodynamic variability of docetaxel (TAXOTERE®) and its effects
- 5 on the degree or severity of side effects related to permeant alopecia;
- 6 (d) failed to disclose in the “Warnings” Section that permeant alopecia is a
- 7 frequent side effect associated with the use of docetaxel (TAXOTERE®);
- 8 (e) failed to advise prescribing physicians, such as Plaintiff’s physicians, to
- 9 instruct patients that permanent alopecia was a side effect, much less a
- 10 frequent side effect, linked to docetaxel (TAXOTERE®);
- 11 (f) failed to provide adequate instructions on how to intervene and/or reduced
- 12 the risk of permanent alopecia related to the use of docetaxel
- 13 (TAXOTERE®);
- 14 (g) failed to provide adequate warnings and information related to the
- 15 increased risks of permeant alopecia in certain genome groups;
- 16 (h) failed to provide adequate warnings regarding the increased risk of
- 17 permeant alopecia with the use of docetaxel (TAXOTERE®) as compared
- 18 to other products designed to treat the same conditions as docetaxel
- 19 (TAXOTERE®); and
- 20 (i) failed to include a **“BOXED WARNING”** related to permanent or
- 21 persistent alopecia.

22 62. During the years since first marketing docetaxel (TAXOTERE®) in the U.S.,
23 Defendants modified the U.S. labeling and prescribing information for docetaxel (TAXOTERE®)
24 on multiple occasions. Defendants failed, however, to include any warning whatsoever related to
25 permanent alopecia despite Defendants’ awareness of the frequency and severity of this side
26 effect.

27 63. Before applying for and obtaining approval of docetaxel (TAXOTERE®),
28 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.

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.

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

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

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

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

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

23 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

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

26 71. Plaintiff is within the applicable statutes of limitations for the claims presented
27 herein because Plaintiff did not discover the defects and unreasonably dangerous condition of
28 Defendants' docetaxel (TAXOTERE®) and the risks associated with its use in the form of

1 disfiguring permanent alopecia, and could not reasonably have discovered the defects and
2 unreasonably dangerous condition of Defendants' docetaxel (TAXOTERE®) and the risks
3 associated with its use, due to the Defendants' failure to warn, suppression of important
4 information about the risks of the drug, including but not limited to the true risk benefit profile,
5 and the risk of disfiguring permanent alopecia and damages known by Defendants to result from
6 the use of docetaxel (TAXOTERE®), and other acts and omissions.

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

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

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

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

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

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

21 **FIRST CLAIM FOR RELIEF**

22 **(Product Liability for Negligence – Against All Defendants)**

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

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

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

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

- 10 (a) Manufacturing, producing, promoting, formulating, creating, and/or
11 designing docetaxel (TAXOTERE®) without thoroughly testing it;
- 12 (b) Manufacturing, producing, promoting, formulating, creating, and/or
13 designing docetaxel (TAXOTERE®) without adequately testing it;
- 14 (c) Not conducting sufficient testing programs to determine whether or not
15 docetaxel (TAXOTERE®) was safe for use in that Defendants knew or
16 should have known that docetaxel (TAXOTERE®) was unsafe and unfit
17 for use by reason of the dangers to its users;
- 18 (d) Selling docetaxel (TAXOTERE®) without disclosing its dangers and risks
19 and/or making proper and sufficient tests to determine the dangers and
20 risks to its users;
- 21 (e) Negligently failing to adequately and correctly warn Plaintiff, Plaintiffs’
22 physicians, the public, and the medical and healthcare profession of the
23 dangers of docetaxel (TAXOTERE®);
- 24 (f) Failing to provide adequate instructions regarding safety precautions to be
25 observed by users, handlers, and persons who would reasonably and
26 foreseeably come into contact with, and more particularly, use, docetaxel
27 (TAXOTERE®);
- 28 (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;

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- (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.

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

83. 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.

84. 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®);

- 1 (e) Failed to warn Plaintiff and Plaintiff's physicians of the severity and
2 duration of such adverse effects, as the warnings given did not accurately
3 reflect the symptoms, or severity, of the side effects;
- 4 (f) Failed to conduct adequate testing, including pre-clinical and clinical
5 testing and post-marketing surveillance, to determine the safety, dangers,
6 and risks associated with docetaxel (TAXOTERE®).
- 7 (g) Failed to warn Plaintiff and Plaintiff's physicians before actively
8 encouraging the sale of docetaxel (TAXOTERE®), either directly or
9 indirectly, orally or in writing, about the need for more comprehensive and
10 regular medical monitoring than usual to ensure early discovery of
11 potentially serious side effects; and
- 12 (h) Were otherwise careless and/or negligent.

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

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

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

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

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

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29 90. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to
30 suffer serious and dangerous side effects, severe and personal injuries that are permanent and
31 lasting in nature, and economic and non-economic damages, harms, and losses, including but not
32 limited to: past and future medical expenses; psychological counseling and therapy expenses; past

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

6 **SECOND CLAIM FOR RELIEF**

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

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

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

15 93. Docetaxel (TAXOTERE®) was expected to and did reach the usual consumers,
16 handlers, and persons coming into contact with said product without substantial change in the
17 condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

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

20 95. The docetaxel (TAXOTERE®) designed, researched, manufactured, tested,
21 advertised, promoted, marketed, sold, and distributed by Defendants was defective in design or
22 formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable
23 risks exceeded the benefits associated with the design or formulation of docetaxel
24 (TAXOTERE®).

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

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

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

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

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

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

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

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

20 104. The docetaxel (TAXOTERE®) designed, researched, manufactured, tested,
21 advertised, promoted, marketed, sold, and distributed by Defendants reached the intended users in
22 the same defective and unreasonably dangerous condition in which Defendants' docetaxel
23 (TAXOTERE®) was manufactured.

24 105. Defendants designed, researched, manufactured, tested, advertised, promoted,
25 marketed, sold, and distributed a defective product that created an unreasonable risk to the health
26 of consumers and to Plaintiff in particular; and Defendants are therefore strictly liable for the
27 injuries sustained by Plaintiff.
28

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

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

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

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

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

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

25 112. The defects in Defendants’ drug docetaxel (TAXOTERE®) were a producing
26 cause and a substantial factor in causing Plaintiff’s injuries.

27 113. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to
28 suffer serious and dangerous side effects, severe and personal injuries that are permanent and

1 lasting in nature, and economic and non-economic damages, harms, and losses, including but not
2 limited to: past and future medical expenses; psychological counseling and therapy expenses; past
3 and future loss of earnings; past and future loss and impairment of earning capacity; permanent
4 disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional
5 distress; increased risk of future harm; past, present, and future physical and mental pain,
6 suffering, and discomfort; and past, present, and future loss and impairment of the quality and
7 enjoyment of life.

8 **THIRD CLAIM FOR RELIEF**

9 **(Strict Products Liability – Failure to Warn**

10 **– Against All Defendants)**

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

13 115. The docetaxel (TAXOTERE®) designed, formulated, produced, manufactured,
14 sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants
15 was defective in that it failed to include adequate warnings regarding all adverse side effects
16 associated with the use of docetaxel (TAXOTERE®). The warnings given by Defendants did not
17 sufficiently and/or accurately reflect the symptoms, type, scope, severity, or duration of the side
18 effects and, in particular, the risks of disfiguring permanent alopecia. As the holder for the RLD
19 of brand-name TAXOTERE®, the Sanofi Defendants supplied the labeling for Winthrop U.S.’s
20 generic version of TAXOTERE®. This labeling was defective because it failed to adequately
21 warn of the risk of disfiguring permanent alopecia.

22 116. Defendants failed to provide adequate warnings to physicians and users, including
23 Plaintiff’s physicians and Plaintiff, of the increased risk of disfiguring permanent alopecia
24 associated with docetaxel (TAXOTERE®), and Defendants aggressively and fraudulently
25 promoted the product to physicians.

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

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

10 **FOURTH CLAIM FOR RELIEF**

11 **(Breach of Express Warranty – Against All Defendants)**

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

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

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

19 122. As a direct and proximate result of the breach of these warranties, Plaintiff
20 suffered and will continue to suffer severe and permanent personal injuries, disfigurement, harms,
21 and losses.

22 123. Plaintiff relied on Defendants' express warranties.

23 124. Members of the medical community, including physicians and other healthcare
24 professionals, relied upon the representations and warranties of Defendants for use of Docetaxel
25 (TAXOTERE®) in recommending, prescribing, and/or dispensing Docetaxel (TAXOTERE®).
26 Defendants breached the aforesaid express warranties, as their drug Docetaxel (TAXOTERE®)
27 was and is defective.
28

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

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

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

20 **FIFTH CLAIM FOR RELIEF**

21 **(Breach of Implied Warranty – Against All Defendants)**

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

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

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

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

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

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

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

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

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

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

24 138. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to
25 suffer serious and dangerous side effects, severe and personal injuries that are permanent and
26 lasting in nature, and economic and non-economic damages, harms, and losses, including but not
27 limited to: past and future medical expenses; psychological counseling and therapy expenses; past
28 and future loss of earnings; past and future loss and impairment of earning capacity; permanent

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

5 **SIXTH CLAIM FOR RELIEF**

6 **(Fraudulent Misrepresentation – Against All Defendants)**

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

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

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

17 142. Defendants concealed their knowledge of docetaxel’s (TAXOTERE®’s) defects
18 from Plaintiff, Plaintiff’s physicians, and the public in general and/or the medical community
19 specifically.

20 143. Defendants concealed their knowledge of the defects in their products from
21 Plaintiff, Plaintiff’s physicians, hospitals, pharmacists, and the public in general.

22 144. Defendants made these false representations with the intent of defrauding and
23 deceiving Plaintiff, Plaintiff’s physicians, the public in general, and the medical and healthcare
24 community in particular, and were made with the intent of inducing Plaintiff, Plaintiff’s
25 physicians, the public in general, and the medical community in particular, to recommend,
26 dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of
27 cancer, including but not limited to breast cancer, all of which evidenced a callous, reckless,
28 willful, wanton, and depraved indifference to the health, safety, and welfare of Plaintiff.

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

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

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

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

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

20 150. Defendants knew or should have known that docetaxel (TAXOTERE®) had a
21 potential to, could, and would cause severe and grievous injury to the users of docetaxel
22 (TAXOTERE®) and that docetaxel (TAXOTERE®) was inherently dangerous in a manner that
23 exceeded any purported, inaccurate, and/or down-played warnings.

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

26 152. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to
27 suffer serious and dangerous side effects, severe and personal injuries that are permanent and
28 lasting in nature, and economic and non-economic damages, harms, and losses, including but not

1 limited to: past and future medical expenses; psychological counseling and therapy expenses; past
2 and future loss of earnings; past and future loss and impairment of earning capacity; permanent
3 disfigurement including permanent alopecia; mental anguish; severe and debilitating emotional
4 distress; increased risk of future harm; past, present, and future physical and mental pain,
5 suffering, and discomfort; and past, present, and future loss and impairment of the quality and
6 enjoyment of life.

7 **SEVENTH CLAIM FOR RELIEF**

8 **(Fraudulent Concealment – Against All Defendants)**

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

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

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

16 156. In representations made to Plaintiff and Plaintiff’s healthcare providers,
17 Defendants fraudulently concealed and intentionally omitted the following material information:

- 18 (a) that docetaxel (TAXOTERE®) was not as safe as other forms of treatment
19 for which docetaxel (TAXOTERE®) was marketed and sold to cancer
20 patients;
- 21 (b) that the risks of adverse events with docetaxel (TAXOTERE®) were
22 higher than those with other forms of treatment for which docetaxel
23 (TAXOTERE®) was marketed and sold to cancer patients;
- 24 (c) that the risks of adverse events with docetaxel (TAXOTERE®) were not
25 adequately tested and/or known by Defendants;
- 26 (d) that Defendants were aware of dangers in docetaxel (TAXOTERE®), in
27 addition to and above and beyond those associated with other forms of
28 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;

- 1 (g) that docetaxel (TAXOTERE®) was manufactured defectively;
- 2 (h) that docetaxel (TAXOTERE®) was manufactured improperly;
- 3 (i) that docetaxel (TAXOTERE®) was designed negligently;
- 4 (j) that Docetaxel (TAXOTERE®) was designed defectively; and
- 5 (k) that docetaxel (TAXOTERE®) was designed improperly.

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

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

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

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

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

24 162. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to
25 suffer serious and dangerous side effects, severe and personal injuries that are permanent and
26 lasting in nature, and economic and non-economic damages, harms, and losses, including but not
27 limited to: past and future medical expenses; psychological counseling and therapy expenses; past
28 and future loss of earnings; past and future loss and impairment of earning capacity; permanent

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

5 **EIGHTH CLAIM FOR RELIEF**

6 **(Negligence Misrepresentation – Against All Defendants)**

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

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

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

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

19 167. Defendants concealed their knowledge of the defects in their products from
20 Plaintiff, Plaintiff’s physicians, hospitals, pharmacists, and the public in general.

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

24 169. Defendants made these misrepresentations with the intent of defrauding and
25 deceiving Plaintiff, Plaintiff’s physicians, the public in general, and the medical and healthcare
26 community in particular, and were made with the intent of inducing Plaintiff, Plaintiff’s
27 physicians, the public in general, and the medical community in particular, to recommend,
28

1 dispense, and/or purchase docetaxel (TAXOTERE®) for use in the treatments of various forms of
2 cancer, including but not limited to breast cancer.

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

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

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

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

22 **NINTH CLAIM FOR RELIEF**

23 **(Strict Product Liability for Misrepresentation – Against All Defendants)**

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

26 175. Defendants sold the docetaxel (TAXOTERE®) that Plaintiff's physician
27 prescribed for Plaintiff and that Plaintiff used.
28

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

3 177. Defendants misrepresented facts as set forth herein concerning the character or
4 quality of the docetaxel (TAXOTERE®) that would be material to potential prescribers and
5 purchasers or users of the product.

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

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

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

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

20 **TENTH CLAIM FOR RELIEF**

21 **(Fraud and Deceit – Against All Defendants)**

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

24 183. Defendants committed fraud by omission in applying for and gaining patent
25 protection for docetaxel (TAXOTERE®) resulting in increased sales and market penetration. This
26 increased market penetration was the proximal cause of Plaintiff's exposure to the side effects of
27 docetaxel (TAXOTERE®).

28

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

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

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

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

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

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

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

24 191. The information Defendants distributed to Plaintiff, Plaintiff's physicians, and the
25 public intentionally included false representations that Defendants' drug docetaxel
26 (TAXOTERE®) carried the same risks, hazards, and/or dangers as other forms of treatment for
27 the same conditions for which docetaxel (TAXOTERE®) was designed to treat.
28

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

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

8 194. These representations by Defendants were all false and misleading.

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

13 196. Defendants intentionally made material misrepresentations to Plaintiff, Plaintiff’s
14 physicians, and the public, including the medical profession, regarding the safety of docetaxel
15 (TAXOTERE®), specifically but not limited to docetaxel (TAXOTERE®) not having dangerous
16 and serious health and/or safety concerns.

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

22 198. It was Defendants’ intent and purpose in making these false representations to
23 deceive and defraud Plaintiff, Plaintiff’s physicians, and/or the public and to gain the confidence
24 of Plaintiff, Plaintiff’s physicians, the public, and/or healthcare professionals to falsely ensure the
25 quality and fitness for use of docetaxel (TAXOTERE®) and induce Plaintiff, Plaintiff’s
26 physicians, and the public, including the medical profession, to purchase, request, dispense,
27 prescribe, recommend, and/or continue to use docetaxel (TAXOTERE®).
28

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

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

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

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

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

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

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

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

28

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

6 208. Defendants willfully and intentionally failed to disclose, concealed, and/or
7 suppressed the material facts regarding the dangerous and serious health and/or safety concerns
8 related to docetaxel (TAXOTERE®).

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

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

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

24 212. At the time Defendants’ false representations were made, Plaintiff and/or
25 Plaintiff’s respective healthcare providers did not know the truth and were not with reasonable
26 diligence able to discover the truth with regard to the dangerous and serious health and/or safety
27 concerns of docetaxel (TAXOTERE®).
28

1 213. Plaintiff and her healthcare providers did not discover the true facts with respect to
2 Defendants' false representations and the dangerous and serious health and/or safety concerns of
3 docetaxel (TAXOTERE®), and Plaintiff and her healthcare providers with reasonable diligence
4 could not have discovered the true facts.

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

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

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

19 **ELEVENTH CLAIM FOR RELIEF**

20 **(Extreme and Outrageous Conduct /**

21 **Intentional Infliction of Emotional Distress**

22 **– Against All Defendants)**

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

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

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

28 220. Defendants' conduct caused Plaintiff severe emotional distress.

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

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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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff 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.

1 Dated: November 18, 2016

ROBINS KAPLAN LLP

By: /s/ Jill S. Casselman
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