UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2740
	:	SECTION "N" (5)
KAREN LAWRENCE,	:	JUDGE ENGELHARDT
	:	MAG. JUDGE NORTH
Plaintiff,	:	
	:	COMPLAINT & JURY DEMAND
v.	:	
	:	Civil Action No.: 17-1939
SANOFI-AVENTIS U.S. LLC, individually, and doing business as, WINTHROP U.S., SANOFI WINTHROP PHARMACEUTICALS INC, and SANOFI US SERVICES INC.	:	
Defendant(s).		

COMPLAINT

1. Plaintiff, KAREN LAWRENCE, by and through the undersigned counsel, alleges the following upon personal knowledge, information and belief, and investigation of counsel.

JURISDICTION AND VENUE

2. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

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

4. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the vicinage of Plaintiff's residence, as well as in this district. Pursuant to 20 U.S.C. § 1391(a), venue is proper in both districts.

NATURE OF THE CASE

5. KAREN LAWRENCE, seeks to recover damages for injuries sustained by Plaintiff as the direct and proximate result of the wrongful conduct of Defendants Sanofi-Aventis U.S. LLC, Sanofi Winthrop Pharmaceuticals, Inc., and Sanofi US Services Inc. ("Defendants") 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.

6. 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.

7. 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.

8. Defendants made these representations with the intent of inducing consumers in general, and medical providers in particular, to recommend, dispense and/or purchase Taxotere for use in the treatment of breast cancer. These representations evidence a callous, reckless, willful, depraved indifference to health, safety, and welfare of Plaintiff.

9. 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.

10. As a result of the foregoing acts and omissions, Plaintiff used Taxotere, and as a result suffered serious side effects 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. Consequently, Plaintiff seeks compensatory damage as a result of Plaintiff's use of the Taxotere

PARTY PLAINTIFF

11. Plaintiff, KAREN LAWRENCE, is of the age of majority and is a citizen and resident of the State of California, domiciled in Redding in Shasta County.

12. Plaintiff was prescribed Taxotere in the State of California, in or around October 2010 upon the discretion of her physician, Dr. Navjot Dhillon, MD, for the treatment of breast cancer. Plaintiff received the treatment at Mercy Medical Center (Oncology).

13. As a direct and proximate result of the use of Defendants' Taxotere, Plaintiff experienced permanent, disfiguring alopecia.

14. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and incurred damages, including 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.

PARTY DEFENDANTS

15. Defendant SANOFI-AVENTIS U.S. LLC is a Delaware limited liability company, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Defendant SANOFI-AVENTIS U.S. LLC does not have any members that are citizenships, residents, or domiciles of the State of California. SANOFI S.A. is the sole member of Sanofi-Aventis U.S., LLC.

16. 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.

17. Defendant Sanofi Winthrop Pharmaceuticals Inc. is a Delaware corporation, which, upon information and belief, has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

18. Defendant SANOFI US SERVICES INC. F/K/A SANOFI-AVENTIS U.S. INC. is a foreign corporation, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

19. At all times material to this lawsuit, Defendants Sanofi-Aventis U.S. LLC, Sanofi Winthrop Pharmaceuticals, Inc., and Sanofi US Services Inc. were engaged in the business of,

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

20. Sanofi S.A. is the corporate parent of Aventis Pharma S.A. and Defendants, and directs and controls their operations. 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 Defendants 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.

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.

FACTUAL BACKGROUND

22. 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.

23. 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.

24. 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.

25. 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.

26. The initial patent disclosing the formulation and computation of Taxotere was issued to Rhone-Poulence Santé and subsequently acquired by or merged with Defendant Aventis Pharma S.A in March 1989.

27. Before it was acquired by or merged into Aventis Pharma S.A., Rhône-Poulenc Rorer 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.

28. Also in 1989, Sanofi S.A. published 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.

29. On June 21, 1990, Sanofi S.A. began enrolling patients in Phase I clinical testing trials. 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 S.A. was not only involved in the patenting and assignment of the compound Taxotere (docetaxel), but Sanofi S.A. 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., Sanofi US Services Inc., 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.

30. 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."

31. 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.

32. 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.

33. 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).

34. 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.

35. 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."

36. 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.

37. As a result of these false and misleading statements, in 2009, the FDA issued a warning letter to Sanofi-Aventis at the address of Sanofi US Services Inc. citing these unsubstantiated claims of superiority over paclitaxel stating:

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a professional reprint carrier [US.DOC.07.04.078] for Taxotere (docetaxel) Injection Concentrate, Intravenous Infusion (Taxotere) submitted under cover of Form FDA 2253 by sanofi-aventis (SA) and obtained at the American Society of Clinical Oncology annual meeting in June 2008. The reprint carrier includes a reprint1[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

[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.

> 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]

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

39. Beginning in 1996, Sanofi S.A., Aventis Pharma S.A., Sanofi US Services Inc. 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).

40. 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.

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[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.

41. 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).

42. 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.

43. 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.

44. 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.

45. 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.

46. Beginning in the late 1990's, Sanofi S.A. and Aventis Pharma S.A. sponsored and/or were aware of a study titled the GEICAM 9805 study. In 2005, Sanofi S.A. and Aventis Pharma S.A. knew that the GEICAM 9805 study demonstrated that 9.2% of patients who took

Taxotere had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer, after taking Taxotere. Sanofi S.A. and Aventis Pharma S.A. knowingly, intentionally, and wrongfully withheld these results contained in the GEICAM 9805 study from physicians, healthcare providers, patients, and Plaintiff in the United States.

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

53. 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.

54. Defendants prayed 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.

55. 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.

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

57. Neither Plaintiff nor her treating healthcare providers were aware of or informed by Defendants that disfiguring permanent alopecia can occur following treatment with Taxotere.

58. Plaintiff met with her oncologist to discuss further treatment and decided to move forward with chemotherapy treatment that included Taxotere from approximately October 2008 through January 2009.

59. Plaintiff's use of, and her physician's prescription of, Taxotere was a use that Defendants reasonably anticipated.

60. Neither Plaintiff nor her treating healthcare providers were aware of, or informed by, Defendants that disfiguring permanent alopecia can occur following treatment with Taxotere.

61. Following the completion of chemotherapy, Plaintiff suffered from disfiguring permanent alopecia as a result of receiving chemotherapy with Taxotere.

62. As a result of Defendants' wrongful conduct, Plaintiff has continued to suffer and will suffer in the future from disfiguring permanent alopecia as a result of receiving chemotherapy with Taxotere.

NATURE OF THE CLAIMS

63. 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 regarding the risk of permanent alopecia, and they failed to disclose the results of additional studies as Defendants learned new facts regarding the defects and risks of their product.

64. 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;

(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.

65. During the years since first marketing Taxotere in the U.S., Defendants modified the U.S. labeling and prescribing information for Taxotere on multiple occasions. Defendants failed, however, to include any warning whatsoever related to permanent alopecia despite Defendants' awareness of the frequency and severity of this side effect until at the earliest, December 2015.

66. 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.

67. 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.

68. Defendants failed to adequately conduct complete and proper testing of Taxotere prior to filing their New Drug Application for Taxotere.

69. 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.

70. Defendants ignored the association between the use of Taxotere and the risk of disfiguring permanent alopecia.

71. Despite issuing numerous other label changes and safety warnings, Defendants failed to disclose information that they possessed regarding their failure to adequately test and study Taxotere related to the side effect of disfiguring permanent alopecia. Plaintiff and her

healthcare providers could not have discovered Defendants' false representations and failures to disclose information through the exercise of reasonable diligence.

72. 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

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

74. 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.

75. 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.

76. 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.

77. 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.

78. Defendants did not notify, inform, or disclose to Plaintiff, Plaintiff's prescribing health care professionals or the general consuming public that Defendants' Taxotere was defective and that its use carried with it the serious risk of developing the injuries Plaintiff has suffered and complained of herein until a safety labeling change issued in December 2015, although this change is inadequate as it fails to warn of the true risks related to permanent alopecia.

79. 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.

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

FIRST CLAIM FOR RELEIF
(Liability Under The California Products Liability Act)

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

82. Plaintiff's development of disfiguring permanent alopecia and other related injuries are the direct and proximate result of breaches of Defendants' obligations, particularly under to the California Products Liability Act (CPLA), to Plaintiff, including defects in design, marketing, manufacture, distribution, instructions and warnings by Defendants, which breaches and defects are listed more particularly, but not exclusively, as follows:

(a) Failure to instruct and/or warn of the serious risk of developing disfiguring permanent alopecia and other injuries;

(b) Failure to adequately instruct and/or warn healthcare providers, including those healthcare providers who administered Taxotere to Plaintiff, KAREN LAWRENCE, of the serious risk of developing disfiguring permanent alopecia and other injuries;

(c) Manufacturing, producing, promotion, formulating, creating, and/or designing Taxotere without adequately testing it;

(d) Failing to provide adequate warning of the dangers associated with Taxotere;

(e) The defects in designing, formulating, researching, developing, manufacturing, marketing, promoting and selling a medication when it knew or reasonably should have known of the propensity to cause disfiguring permanent alopecia and other injuries;

(f) Defendants' liability under the California Products Liability Act as a result of its design, development, manufacture, marketing, and sale of a medication which is defective and unreasonably dangerous for the risk of developing disfiguring permanent alopecia and other injuries;

(g) The continued production and sale of docetaxel (Taxotere) given Defendants' knowledge of the propensity of the medication to cause disfiguring permanent alopecia and other injuries;

(h) Providing inaccurate labeling and inadequate warnings and instructions;

(i) Utilizing testing methods which were not accurate, sensitive, specific, and/or reproducible;

(j) Other breaches and defects which may be shown through discovery or at trial; and

(k) Generally, the failure of Defendants to act with the required degree of care commensurate with the existing situation.

SECOND CLAIM FOR RELIEF
(Design Defect)

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

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

85. 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.

86. At those times, Taxotere was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.

87. The Taxotere designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants and used by Plaintiff 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.

88. The Taxotere designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants and used by Plaintiff 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.

89. 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.

90. 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.

91. 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.

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

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

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

95. 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.

96. 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.

97. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers and to Plaintiff in particular; and Defendants are therefore liable for the injuries sustained by Plaintiff in accordance with California Products Liability Act.

98. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Taxotere. This was demonstrated by the existence of other breast cancer medications which had a more established safety profile and a considerably lower risk profile, namely paclitaxel (TAXOL).

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

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

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

102. The Taxotere designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, including disfigurement and/or permanent disfiguring alopecia, as well as

other severe and permanent health consequences from Taxotere, they failed to provide adequate warnings to users or consumers of the product, and they continued to improperly advertise, market, and/or promote Taxotere.

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

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

105. The design defects in Defendants' drug Taxotere were a direct and proximate cause of Plaintiff's injuries.

106. Due to the unreasonably dangerous conditions of Taxotere, Defendants are liable to Plaintiff.

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

THIRD CLAIM FOR RELIEF
(Inadequate Warning)

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

109. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Taxotere into the stream of commerce, and in the course of same, directly advertised or marketed Taxotere to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and her physicians to warn of risks associated with the use of the product, including, but not limited to, permanent disfiguring alopecia.

110. Defendants had/have a duty to warn of adverse drug reactions, including, but not limited to, permanent disfiguring alopecia, which they knew or should have known can be caused by the use of Taxotere and/or are associated with the use of Taxotere.

111. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants and used by Plaintiff was defective in that it failed to include adequate warnings regarding all adverse side effects, including, but not limited to, permanent disfiguring alopecia, associated with the use of Taxotere. At the time the Taxotere used by Plaintiff left the Defendants control, 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.

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

113. Due to the inadequate warning regarding the serious risk for disfiguring permanent alopecia, Taxotere was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

114. Defendants' failure to adequately warn Plaintiff and her prescribing physicians of the serious risk of disfiguring permanent alopecia prevented Plaintiff's prescribing physicians and Plaintiff herself from correctly and fully evaluating the risks and benefits of Taxotere.

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

116. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the serious risk of disfiguring permanent alopecia associated with Taxotere, Plaintiff's physicians would have discussed the risks of disfiguring permanent alopecia with Plaintiff and/or would not have prescribed it.

117. As a direct and proximate result of Defendants' failure to warn of the aforementioned adverse effects of Taxotere, which potential severe effects were known to Defendants at the time the Taxotere ingested by Plaintiff left Defendants' control, Plaintiff suffered disfiguring permanent alopecia and related injuries.

118. 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)

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

120. At the time the Taxotere ingested by Plaintiff left Defendants' control, Defendants expressly warranted that it was safe and well accepted by users.

121. The subject Taxotere did not conform to these express representations, because it was not safe and had numerous serious side effects, including, but not limited to, permanent and disfiguring alopecia, many of which were not accurately warned about by Defendants.

122. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, disfigurement, losses, and damages.

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

124. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendants for use of Taxotere in recommending, prescribing, and/or dispensing Taxotere. Defendants breached the aforesaid express warranties, as their drug Taxotere was and is defective and causes harm and injury as discussed herein.

125. At the time of the making of express warranties, Defendants had knowledge of the purpose for which Taxotere was to be used, and warranted same to be in all respects safe, effective, and proper for such use.

126. 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.

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

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

FIFTH CLAIM FOR RELIEF
(Breach of Implied Warranty)

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

130. 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.

131. 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.

132. 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.

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

134. 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.

135. 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.

136. Taxotere was placed into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition.

137. 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.

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

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

PRAYER FOR RELIEF AND DEMAND FOR JURY TRIAL

140. As a result of the aforementioned breach of obligations by Defendants, Plaintiff, KAREN LAWRENCE, suffered and continues to suffer from the following items of damage, all past, present, and future, for which she is entitled to be compensated by Defendants, *in solido*, in an amount which is just and reasonable:

(a) Medical and related expenses;

(b) Physical injury and disability;

(c) Physical pain and suffering;

(d) Mental anguish and distress;

(e) Loss of enjoyment of life; and

(f) Other items of damage which may be shown through discovery or at trial.

141. By reason of the foregoing, Plaintiff prays for judgment against each Defendant, individually, jointly, severally and/or *in solido*, for compensatory damages in a sum in excess of $75,000.00, together with interest, costs of suit, and all such other and further relief as the Court deems proper.

142. WHEREFORE, Plaintiff KAREN LAWRENCE demands trial of this matter by jury and further demands judgment against Defendants, Sanofi-Aventis U.S. LLC individually and doing business as Winthrop U.S, Sanofi Winthrop Pharmaceuticals, Inc., and Sanofi US Services Inc., jointly, severally, and *in solido*, in an amount to be determined at trial by the trier of fact for her injuries, harms, damages, and losses as set forth above, costs, attorneys' fees, witness fees, pre- and post-judgment interest, all other injuries and damages as shall be proven at trial, and all other further relief as the Court may deem appropriate, just, and proper.

JURY DEMAND

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

Respectfully submitted this 7th day of March, 2017.

By: /s/ *Dennis C. Reich*
Dennis C. Reich (TX #16739600)
REICH AND BINSTOCK, LLP
Whitney Bank Bldg. River Oaks
4265 San Felipe #1000
Houston, TX 77027
Phone: (713) 622-7271
dreich@reichandbinstock.com

Attorneys for Plaintiff

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
KAREN LAWRENCE

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Dennis C. Reich of Reich and Binstock, LLP
4265 San Felipe, Suite 1000 Houston, TX 77002
Tel: 713-622-7271

DEFENDANTS
SANOFI-AVENTIS U.S. LLC, individually, and doing business as, WINTHROP U.S., et al

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

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

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
U.S.C. § 1332 - Diversity Jurisdiction

Brief description of cause:
Personal Injury due to defective product.

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ To be determined at trial

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Kurk D. Engelhardt DOCKET NUMBER MDL 2740

DATE 03/07/2017

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

KAREN LAWRENCE

Plaintiff(s)

v.

SANOFI-AVENTIS U.S. LLC, individually, and doing business as, WINTHROP U.S., et al

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sanofi US Services Inc.
55 Corporate Drive
Bridgewater, New Jersey 08807

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dennis C. Reich
Reich and Binstock, LLP
4265 San Felipe
Suite 1000
Houston, TX 77027

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

KAREN LAWRENCE

Plaintiff(s)

v.

SANOFI-AVENTIS U.S. LLC, individually, and doing business as, WINTHROP U.S., et al

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sanofi-Aventis U. S. LLC individually,and doing business as Winthrop U.S.
55 Corporate Drive
Bidgewater, New Jersey 08807

A lawsuit has been filed against you.

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

Dennis C. Reich
Reich and Binstock, LLP
4265 San Felipe
Suite 1000
Houston, TX 77027

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

KAREN LAWRENCE

Plaintiff(s)

v.

SANOFI-AVENTIS U.S. LLC, individually, and doing business as, WINTHROP U.S., et al

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sanofi Winthrop Pharmaceuticals Inc.
55 Corporate Drive,
Bridgewater, New Jersey 08807

A lawsuit has been filed against you.

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

Dennis C. Reich
Reich and Binstock, LLP
4265 San Felipe
Suite 1000
Houston, TX 77027

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset