

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO**

HATTIE CARSON,

Plaintiff,

vs.

SANOFI S.A.,
AVENTIS PHARMA S.A.,
SANOFI-AVENTIS U.S., INC.,
SANOFI-AVENTIS U.S. LLC, and
SANOFI US SERVICES INC.,

Defendants.

§ Civil Case No. _____
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§ Judge _____
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COMPLAINT AND JURY DEMAND

Plaintiff, Hattie Carson, by and through her attorneys, Ford, Gold, Kovoov & Simon, Ltd., respectfully submits the following Complaint and Jury Demand against Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi-Aventis U.S., Inc.; Sanofi-Aventis U.S. LLC; and Sanofi US Services Inc. and alleges the following upon personal knowledge, information and belief, and investigation of counsel:

NATURE OF THE ACTION

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

JURISDICTION AND VENUE

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

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

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

PARTIES

5. Plaintiff Hattie Carson is and was at all relevant times a citizen and adult resident of the State of Ohio and was prescribed and used TAXOTERE®. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

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

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

8. Defendant Sanofi-Aventis U.S., Inc., is a foreign corporation, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

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

10. Defendant Sanofi US Services Inc. is a Delaware corporation, which has its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

11. Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi-Aventis U.S., Inc.; Sanofi-Aventis U.S. LLC; and Sanofi US Services Inc. are sometimes collectively referred to herein as the “Sanofi Defendants.”

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

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

14. There exists, and at all relevant times herein existed, a unity of interest and ownership between Defendants with regard to the manufacture, distribution, 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.

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

FACTUAL ALLEGATIONS

16. 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.

17. 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.

18. Paclitaxel was first approved by the U.S. Food and Drug Administration (FDA) in December 1992.

19. TAXOTERE® was first 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.”

20. Defendants designed TAXOTERE® as an increased potency Taxane. Defendants applied for patents with the U.S. Patent and Trademark Office (USPTO) claiming that the product was novel and merited patent protection. The USPTO granted two patents to the designer of TAXOTERE®: U.S. Patent Nos. 5,714,512 and 5,750,561.

21. As a direct result of the market exclusivity granted by the aforementioned patents, Defendants were able to restrict competition and obtain billions of dollars in revenues from sales of TAXOTERE®.

22. Based on studies and clinical trials sponsored by Defendants, FDA market approval for TAXOTERE® was granted. After the initial FDA approval, Defendants sought and were granted FDA approval for additional indications for TAXOTERE®. Based on these self-sponsored Clinical Trials, Defendants claimed superiority over chemotherapy products approved to treat breast cancer. Defendants’ marketing claims included claims of superior efficacy over the lower potency Taxane product paclitaxel, which was the primary competitor product to TAXOTERE®.

23. 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.

24. As a result of Defendants' public statements related to superior efficacy over competing products, the FDA issued a warning letter to Defendants citing their unsubstantiated claims of superiority over paclitaxel stating:

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

25. On September 27, 2010, the Honorable Gregory Sleet of the U.S. District Court for the District of Delaware held that Defendants' patents were invalid as a result of Defendants' inequitable conduct, including but not limited to withholding prior art in the patent application. See Aventis Pharma S.A. v. Hospira, Inc., 743 F.Supp.2d 305 (D. Del. 2010) aff'd, 675 F.3d

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

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

1324 (Fed. Cir. 2012). Judge Sleet also held that Defendants' patents were invalid due to indefiniteness and obviousness. As previously reported regarding Judge Sleet's ruling,

Sanofi filed an infringement action against Hospira and Apotex in November 2007 alleging that the companies infringed U.S. Patent Nos. 5,714,512 and 5,750,561 by filing NDAs for docetaxel (*see* "Court Report," November 18, 2007). In November 2009, following a bench trial in the U.S. District Court for the District of Delaware, the parties were ordered to present post-trial proposed findings of fact and conclusions of law concerning the validity and enforceability of the '512 and '561 patents.

On September 27, Judge Gregory Sleet ruled that the defendants had established by clear and convincing evidence that Sanofi's '512 and '561 patents were invalid due to indefiniteness and obviousness, and unenforceable due to inequitable conduct. In a lengthy opinion, Judge Sleet found that the specific formula for Taxotere was obvious in view of U.S. Patent No. 4,814,470, which issued in 1989. Judge Sleet also found that Sanofi did not disclose two highly material prior art references to the Patent Office during the prosecution of the '512 and '561 patents, thus rendering them unenforceable.³

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

27. As a direct result of obtaining the patents through inequitable conduct for TAXOTERE®, Defendants gained billions of dollars in revenues.

28. As a direct result of obtaining the patents through inequitable conduct as well as illegal kickback schemes, Defendants directly caused thousands of individuals to be exposed to

³ See Sanofi's Taxotere Patents Found Invalid. <http://www.patentdocs.org/2010/09/index.html>; Accessed December 16, 2015.

TAXOTERE®'s increased potency and toxicity as compared to other available less potent and less toxic products.

29. 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).

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

31. 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.

32. 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.

33. 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®.

34. 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.

35. 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.

36. 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.

37. 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.

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

39. 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.

40. Plaintiff Hattie Carson, as well as numerous other women, was the innocent victim of Defendants' greed, recklessness, and willful and wanton conduct.

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

41. On or around April 15th, 2004, Plaintiff underwent a core biopsy of her right breast after receiving abnormal results from a routine a mammogram.

42. The April 15th, 2004 biopsy demonstrated an infiltrating ductal carcinoma, nuclear grade 3, and a ducal carcinoma, solid type with microcalcification.in her right breast.

43. Following a May 6th, 2004 surgery during which a lumpectomy and sentinel node biopsy were performed on her right breast, Plaintiff met with her oncologist to discuss further treatment. Neither Plaintiff nor her treating healthcare providers were aware of or informed by Defendants that disfiguring permanent alopecia can occur following treatment with TAXOTERE®. Accordingly, Plaintiff underwent chemotherapy that included TAXOTERE®. Following the completion of chemotherapy, Plaintiff suffered from disfiguring permanent alopecia as a result of receiving chemotherapy with TAXOTERE®.

NATURE OF THE CLAIMS

44. Despite the fact that Defendants disclosed risks associated with TAXOTERE® and permanent alopecia to patients and regulatory agencies in other countries, Defendants failed to either alert Plaintiff, the public, and the scientific community in the United States or perform further investigation into the safety of TAXOTERE® regarding the side effect of disfiguring permanent alopecia. Defendants failed to update the warnings for TAXOTERE®, and they failed

to disclose the results of additional studies as Defendants learned new facts regarding the defects and risks of their product.

45. In particular, Defendants:

- (a) failed to disclose their investigation and research and failed to further investigate, research, study, and define fully and adequately the safety profile of TAXOTERE®;
- (b) failed to provide adequate warnings about the true safety risks associated with the use of TAXOTERE®;
- (c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of TAXOTERE® and its effects on the degree or severity of side effects related to permanent alopecia;
- (d) failed to disclose in the “Warnings” Section that permanent alopecia is a frequent side effect associated with the use of TAXOTERE®;
- (e) failed to advise prescribing physicians, such as Plaintiff’s physicians, to instruct patients that permanent alopecia was a side effect, much less a frequent side effect, linked to TAXOTERE®;
- (f) failed to provide adequate instructions on how to intervene and/or reduced the risk of permanent alopecia related to the use of TAXOTERE®;
- (g) failed to provide adequate warnings and information related to the increased risks of permanent alopecia in certain genome groups;
- (h) failed to provide adequate warnings regarding the increased risk of permanent alopecia with the use of TAXOTERE® as compared to other products designed to treat the same conditions as TAXOTERE®; and
- (i) failed to include a **“BOXED WARNING”** related to permanent or persistent alopecia.

46. 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.

47. 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.

48. 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.

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

50. 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.

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

52. 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.

53. 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.

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

54. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing TAXOTERE® without thoroughly testing it;

- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing TAXOTERE® without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not TAXOTERE® was safe for use in that Defendants knew or should have known that TAXOTERE® was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling TAXOTERE® without disclosing its dangers and risks and/or making proper and sufficient tests to determine the dangers and risks to its users;
- (e) Negligently failing to adequately and correctly warn Plaintiff, Plaintiffs' physicians, the public, the medical and healthcare profession, and the FDA of the dangers of TAXOTERE®;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, TAXOTERE®;
- (g) Failing to test TAXOTERE® and/or failing to adequately, sufficiently, and properly test TAXOTERE®;
- (h) Negligently advertising and recommending the use of TAXOTERE® without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that TAXOTERE® was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently and falsely representing that TAXOTERE® was superior to other commercially available products designed to treat the same forms of cancer TAXOTERE® was designed to treat;
- (k) Negligently designing TAXOTERE® in a manner that was dangerous to its users;
- (l) Negligently manufacturing TAXOTERE® in a manner that was dangerous to its users;
- (m) Negligently producing TAXOTERE® in a manner that was dangerous to its users;
- (n) Negligently assembling TAXOTERE® in a manner that was dangerous to its users;

- (o) Concealing information from Plaintiff, Plaintiff's physicians, the public, and the FDA in knowing that TAXOTERE® was unsafe, dangerous, and/or non-conforming with FDA regulations; and
- (p) Improperly concealing from and/or misrepresenting information to Plaintiff, Plaintiff's physicians, other healthcare professionals, and/or the FDA concerning the severity of risks and dangers of TAXOTERE® compared to other forms of treatment for breast cancer.

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

59. Defendants negligently compared the safety risk and/or dangers of TAXOTERE® with other forms of treatment for the same conditions for which TAXOTERE® was prescribed to treat.

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

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

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

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

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

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

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

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

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

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

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

67. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

69. 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.

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

71. The TAXOTERE® designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design or formulation

in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of TAXOTERE®.

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

73. 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.

74. 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.

75. 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.

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

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

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

79. 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.

80. 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.

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

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

83. 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.

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

85. 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, 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®.

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

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

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

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

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

90. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

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

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

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

95. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

99. Plaintiff relied on Defendants' express warranties.

100. 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.

101. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and/or the FDA 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.

102. 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.

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

FIFTH CLAIM FOR RELIEF
(Breach of Implied Warranty – Against All Defendants)

104. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

105. 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.

106. 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.

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

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

109. 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.

110. 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.

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

112. 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.

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

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

SIXTH CLAIM FOR RELIEF
(Fraudulent Misrepresentation – Against All Defendants)

115. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SEVENTH CLAIM FOR RELIEF
(Fraudulent Concealment – Against All Defendants)

130. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

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

- (e) that TAXOTERE® was defective in that it caused dangerous side effects as well as other severe and permanent health consequences in a much more and significant rate than other forms of treatment for cancer patients;
- (f) that TAXOTERE® was manufactured negligently;
- (g) that TAXOTERE® was manufactured defectively;
- (h) that TAXOTERE® was manufactured improperly;
- (i) that TAXOTERE® was designed negligently;
- (j) that TAXOTERE® was designed defectively; and
- (k) that TAXOTERE® was designed improperly.

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

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

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

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

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

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.

EIGHTH CLAIM FOR RELIEF
(Negligence Misrepresentation – Against All Defendants)

140. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

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

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

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

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

148. Defendants failed to exercise ordinary and reasonable care in their representations of TAXOTERE® while involved in its manufacture, sale, testing, quality assurance, quality

control, and/or distribution into interstate commerce, and Defendants negligently misrepresented TAXOTERE®'s high risk of unreasonable, dangerous side effects.

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

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

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

NINTH CLAIM FOR RELIEF
(Strict Product Liability for Misrepresentation – Against All Defendants)

152. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

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

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

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

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

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

TENTH CLAIM FOR RELIEF
(Fraud and Deceit – Against All Defendants)

160. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

161. Defendants committed fraud by omission in applying for and gaining patent protection for TAXOTERE® resulting in increased sales and market penetration. This increased market penetration was the proximal cause of Plaintiff's exposure to the side effects of TAXOTERE®.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

191. Plaintiff and her healthcare providers did not discover the true facts with respect to Defendants' false representations and the dangerous and serious health and/or safety concerns

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

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

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

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

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

195. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

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

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

198. Defendants' conduct caused Plaintiff severe emotional distress.

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

TWELFTH CLAIM FOR RELIEF
(Punitive Damages)

200. Plaintiff adopts by reference and incorporates herein the allegations set forth in the paragraphs above.

201. The conduct of Defendants in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of TAXOTERE®, and in failing to warn Plaintiff and other members of the public of the dangers inherent in the use of TAXOTERE®, was done with malice, aggravated and egregious fraud by intentional, deliberate and extremely reckless behavior demonstrating a conscious disregard for the rights and safety of others from the probability of great and substantial harm, particularly Plaintiff. Defendants acted in conscious disregard for the safety of others. Such conduct includes, but is not limited to the following:

- a. Upon information and belief, Defendants actually knew of TAXOTERE®'s defective nature, as set forth herein, but continued to design, manufacture, market, and sell TAXOTERE® so as to maximize sales and profits at the

expense of the health and safety of the consuming public, including Plaintiff, and in conscious disregard of the foreseeable substantial harm caused by TAXOTERE®;

- b. Defendants, who spent millions of dollars a year researching and developing TAXOTERE®, and aggressively marketing TAXOTERE®, devoted far less attention to conducting sufficient pre-clinical and clinical testing and adequate post-marketing surveillance of the same;
- c. Defendants continued to promote the safety and efficacy of TAXOTERE®, while providing to consumers no warnings at all about the actual risk of permanent alopecia associated with it, even after Defendants knew of those risks;

202. Defendants willfully downplayed the known risks.

203. 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 Hattie Carson demands judgment against Defendants Sanofi S.A.; Aventis Pharma S.A.; Sanofi-Aventis U.S., Inc.; Sanofi-Aventis U.S. LLC; and Sanofi US Services Inc. in an amount to be determined at trial by the trier of fact for her injuries, harms, damages, and losses as set forth above, special damages, treble damages, costs, expert witness fees, attorneys' fees, filing fees, pre- and post-judgment interest, all other injuries and damages

as shall be proven at trial, and such other further relief as the Court may deem appropriate, just, and proper.

JURY DEMAND

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

DATED: January 22, 2016

/s/ Ned C. Gold, Jr.

Ned C. Gold, Jr. (Ohio Sup. Ct. Bar No. 0018306)
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(*Pro Hac Vice* Motion to be submitted)

Co-Counsel for Plaintiff

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

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

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

DEFENDANTS

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, 2 U.S. Government Defendant, 3 Federal Question, 4 Diversity

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

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

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

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

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

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District, 6 Multidistrict Litigation

VI. CAUSE OF ACTION

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

VII. REQUESTED IN COMPLAINT:

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO**

I. Civil Categories: (Please check one category only).

1. General Civil
2. Administrative Review/Social Security
3. Habeas Corpus Death Penalty

*If under Title 28, §2255, name the SENTENCING JUDGE:

CASE NUMBER:

II. **RELATED OR REFILED CASES.** See LR 3.1 which provides in pertinent part: "If an action is filed or removed to this Court and assigned to a District Judge after which it is discontinued, dismissed or remanded to a State court, and subsequently refiled, it shall be assigned to the same Judge who received the initial case assignment without regard for the place of holding court in which the case was refiled. Counsel or a party without counsel shall be responsible for bringing such cases to the attention of the Court by responding to the questions included on the Civil Cover Sheet."

This action is **RELATED** to another **PENDING** civil case. This action is **REFILED** pursuant to **LR 3.1**.

If applicable, please indicate on page 1 in section VIII, the name of the Judge and case number.

III. In accordance with Local Civil Rule **3.8**, actions involving counties in the Eastern Division shall be filed at any of the divisional offices therein. Actions involving counties in the Western Division shall be filed at the Toledo office. For the purpose of determining the proper division, and for statistical reasons, the following information is requested.

ANSWER ONE PARAGRAPH ONLY. ANSWER PARAGRAPHS 1 THRU 3 IN ORDER. UPON FINDING WHICH PARAGRAPH APPLIES TO YOUR CASE, ANSWER IT AND STOP.

(1) **Resident defendant.** If the defendant resides in a county within this district, please set forth the name of such county

COUNTY:

Corporation For the purpose of answering the above, a corporation is deemed to be a resident of that county in which it has its principal place of business in that district.

(2) **Non-Resident defendant.** If no defendant is a resident of a county in this district, please set forth the county wherein the cause of action arose or the event complained of occurred.

COUNTY:

(3) **Other Cases.** If no defendant is a resident of this district, or if the defendant is a corporation not having a principle place of business within the district, and the cause of action arose or the event complained of occurred outside this district, please set forth the county of the plaintiff's residence.

COUNTY:

IV. The Counties in the Northern District of Ohio are divided into divisions as shown below. After the county is determined in Section III, please check the appropriate division.

EASTERN DIVISION

AKRON	(Counties: Carroll, Holmes, Portage, Stark, Summit, Tuscarawas and Wayne)
CLEVELAND	(Counties: Ashland, Ashtabula, Crawford, Cuyahoga, Geauga, Lake, Lorain, Medina and Richland)
YOUNGSTOWN	(Counties: Columbiana, Mahoning and Trumbull)

WESTERN DIVISION

TOLEDO	(Counties: Allen, Auglaize, Defiance, Erie, Fulton, Hancock, Hardin, Henry, Huron, Lucas, Marion, Mercer, Ottawa, Paulding, Putnam, Sandusky, Seneca VanWert, Williams, Wood and Wyandot)
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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 six 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. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- 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. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

_____)	
<i>Plaintiff</i>)	
)	
v.)	Civil Action No.
)	
_____)	
<i>Defendant</i>)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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:

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 \$ _____.

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

_____)	
<i>Plaintiff</i>)	
)	
v.)	Civil Action No.
)	
_____)	
<i>Defendant</i>)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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:

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 \$ _____.

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

_____)	
<i>Plaintiff</i>)	
)	
v.)	Civil Action No.
)	
_____)	
<i>Defendant</i>)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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:

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 \$ _____.

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

_____)	
<i>Plaintiff</i>)	
)	
v.)	Civil Action No.
)	
_____)	
<i>Defendant</i>)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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:

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))

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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 \$ _____.

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

_____)	
<i>Plaintiff</i>)	
)	
v.)	Civil Action No.
)	
_____)	
<i>Defendant</i>)	

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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:

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 \$ _____.

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: