



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)	
)	
)	C.A. No.
Plaintiffs,)	Jury Trial Demanded
)	
)	
v.)	
)	
SANOFI U.S. SERVICES INC., formerly known as)	
SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS U.S.)	
LLC, separately and doing business as WINTHROP U.S.;)	
HOSPIRA WORLDWIDE, INC.; SUN PHARMA)	
GLOBAL INC.; McKESSON CORPORATION doing)	
business as McKESSON PACKAGING; SANDOZ INC.;)	
ACCORD HEALTHCARE LTD.; ACCORD)	
HEALTHCARE, INC.; INTAS PHARMACEUTICALS)	
LIMITED; SANOFI S.A.; AVENTIS PHARMA S.A.; and)	
DOES, INC.)	
)	
Defendants.)	

COMPLAINT

COMMON ALLEGATIONS

A. PARTIES

1. At all times relevant hereto, Plaintiff Dena Strother (“Plaintiff” or “Dena Strother”) was a resident of the state of South Carolina.

2. At all times relevant hereto, Plaintiff Christopher Strother (“Spousal Plaintiff”), was a resident of the state of South Carolina and the spouse of Plaintiff.

3. Sanofi U.S. Services Inc., f/k/a Sanofi-Aventis U.S. Inc., is incorporated under the laws of the State of Delaware, with its principal place of business located at 55 Corporate Dr., Bridgewater, NJ 08807.

4. Upon information and belief, Sanofi U.S. Services Inc., is a wholly owned

subsidiary of Sanofi-Aventis, and is one of the largest pharmaceutical companies in the United States.

5. Sanofi U.S. Services Inc. develops products in therapeutic areas including cardiovascular disease, central nervous systems, internal medicine, metabolic disorder, oncology, ophthalmology, and thrombosis.

6. The predecessor to Sanofi U.S. Services Inc. was founded in 1950 and until 2006, was known as Sanofi-Aventis U.S. Inc.

7. Sanofi U.S. Services Inc. develops, manufactures, markets, and distributes pharmaceutical products in the United States.

8. Sanofi U.S. Services Inc. operates pharmaceutical research sites in Bridgewater, NJ, Malvern, PA, Cambridge MA, and Tucson, AZ.

9. Sanofi U.S. Services Inc. has a distribution center in Forest Park, GA, a manufacturing facility in Kansas City, MO, and a packaging services facility in St. Louis, MO.

10. Sanofi U.S. Services Inc. markets its parent's products in the U.S. through its substantial number of field sales professionals.

11. One of Sanofi U.S. Services Inc.'s key products is the cancer treatment drug, Taxotere (docetaxel).

12. Sanofi-Aventis U.S. LLC is a limited liability company, formed under the laws of the State of Delaware, with its principal place of business located at 55 Corporate Dr., Bridgewater, NJ 08807.

13. Sanofi-Aventis U.S. LLC is a healthcare company that was founded in 1999 and discovers, develops, produces, and markets therapeutic solutions focused on patients' needs in the United States.

14. Upon information and belief, Sanofi-Aventis U.S. LLC is one of the current holders of the approved New Drug Application (“NDA”) and supplemental NDAs for Taxotere.

15. Upon information and belief, Defendant Sanofi-Aventis U.S. LLC sometimes operates, promotes, markets, sells, distributes pharmaceutical products, and does business under the name Winthrop U.S., which is a division within Sanofi-Aventis U.S. LLC.

16. Defendant Sanofi S.A. is a corporation, or “Société Anonyme,” under the laws of France, with its principal place of business located at 54 rue La Boétie, 75008 Paris, France.

17. Upon information and belief, Sanofi S.A. is a global pharmaceutical parent company that operates in the United States, through an intricate network of approximately 400 wholly owned subsidiaries, including Aventis Pharma S.A. and Sanofi-Aventis U.S.

18. Upon information and belief, Sanofi S.A.’s predecessor was from a subsidiary of a French oil company that acquired the Labaz Group Pharmaceutical Company. This entity, in or about May of 1999, merged with a Delaware incorporated pharmaceutical company named Synthélabo Inc.

19. Upon information and belief, at all relevant times hereto, Synthélabo had its principal place of business located at 90 Park Avenue, New York, New York 10016.

20. Upon information and belief, Aventis was formed when a French company, Rhone-Poulenc S.A., merged with a German corporation Hoechst Marion Roussel.

21. Upon information and belief, Aventis merged with Sanofi-Synthélabo, to become Sanofi-Aventis S.A. which later changed its name to Sanofi S.A. on or about May 6, 2011.

22. Defendant Aventis Pharma S.A. is a corporation, or “Société Anonyme,” under the laws of France, with its principal place of business located at 20 avenue Raymond Aron, 92160 Antony, France.

23. Upon information and belief, on or about March of 1989, Sanofi S.A. acquired 100% of the shares and/or financial interest of Aventis Pharma S.A. and has directed and controlled the operations and activities of Aventis Pharma S.A. and since March of 1989, Aventis Pharma S.A. has been a wholly owned subsidiary of Sanofi S.A.

24. Defendant Sanofi-Aventis U.S. LLC is a limited liability company formed under the laws of the State of Delaware, with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

25. Upon information and belief, Sanofi-Aventis U.S. LLC was formed on or about June 28, 2000 under the laws of the State of Delaware.

26. At all times relevant hereto, according to Sanofi S.A.’s Form 20-F filed with the U.S. Securities and Exchange Commission for the fiscal year ending on December 31, 2014, Defendant Sanofi-Aventis U.S. was a wholly owned subsidiary of Defendant Sanofi S.A. and was the only member and owned 100% of the membership interest of Sanofi-Aventis U.S.

27. Upon information and belief, Taxotere (docetaxel) was invented and developed by the predecessor to Aventis Pharma S.A. and also was the holder of the initial patent disclosing the formulation and computation of Taxotere (docetaxel).

28. At all times relevant hereto, Defendants Sanofi S.A., Aventis Pharma S.A., and/or Sanofi-Aventis U.S. LLC were engaged in transactions and conducted business within the State of Delaware and has derived substantial revenue from goods and products disseminated and used in the State of Delaware. At all times relevant hereto, as part of its

business, Sanofi S.A., Aventis Pharma S.A., and/or Sanofi-Aventis U.S. LLC were involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiff.

29. At all times relevant hereto, Defendants worked in conjunction with each other and they were affiliated, related, jointly owned, and/or controlled entities or subsidiaries during the researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel).

30. Defendants Sanofi S.A., Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC, shall be referred to herein individually by name or jointly as “Defendants.”

31. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

32. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

33. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into

interstate commerce throughout the United States, which necessarily includes Delaware, either directly or indirectly through third parties, subsidiaries or related entities, the drug Taxotere.

34. Upon information and belief, Defendant Hospira Worldwide, Inc., (“Hospira”), is incorporated under the laws of the State of Delaware, with its principal place of business located at 275 N. Field Drive, Lake Forest, Illinois 60045.

35. Sun Pharma Global Inc. (“Sun Pharma”), is a foreign company formed under the International Business Companies Act, Cap. 291 of British Virgin Islands with its principal place of business at International Trust Building, Road Town, British Virgin Islands and has the mailing address of P.O. Box 659, Road Town, British Virgin Islands.

36. Upon information and belief, Sun Pharmaceuticals Industries LTD. is the parent company of Sun Pharma Global Inc.

37. Defendant McKesson Corporation, doing business as McKesson Packaging, (“McKesson”) is a corporation formed under the laws of the State of Delaware with its principal place of business located at One Post Street, San Francisco, California 94104.

38. Defendant Sandoz, Inc. (“Sandoz”) is incorporated under the laws of the State of Colorado, with its principal place of business located at 100 College Road West, Princeton, New Jersey 08540.

39. Upon information and belief, Defendant Accord Healthcare LTD., is a company through the Registrar of Companies for England and Wales with its principal place of business located at Sage House, 319 Pinner Road, North Harrow HA1 4HF, United Kingdom.

40. Accord Healthcare, Inc. (“Accord”) is a corporation formed under the laws of the State of North Carolina with its principal place of business located at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

41. Upon information and belief, Defendant Intas Pharmaceuticals LTD. was formed under the laws of India and has its principal place of business located at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmebadad, 380009, Gujarat, India.

B. NATURE OF THE CASE

42. Plaintiffs brings this case against Sanofi U.S. Services Inc., Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi S.A. (herein collectively referred to as the “Sanofi Defendants”) and/or Winthrop U.S. LLC., and/or Hospira Worldwide Inc., and/or Sun Pharma Global Inc., and/or McKesson Corporation doing business as McKesson Packaging, and/or Sandoz Inc., and/or Accord Healthcare LTD., and/or Accord Healthcare Inc., and/or Intas Pharmaceuticals Limited (herein collectively referred to as “Generic non-bioequivalent Defendants”), for damages associated with the Plaintiff’s infusion of the pharmaceutical drug Taxotere (docetaxel), which was designed, manufactured, marketed, sold and/or distributed by Defendants. Specifically, Plaintiff suffered various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of Plaintiff’s use of Taxotere (docetaxel) and/or its generic non-bioequivalent.

43. At all relevant times, all Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and/or distribute Taxotere (docetaxel) to treat various forms of cancer, including but not limited to breast cancer.

44. Taxotere (docetaxel) was developed, manufactured, researched, marketed, tested, advertised, promoted, and sold by Sanofi Defendants and began enrolling test patients in or about 1990 in the Phase 1 clinical trial also known as “TAX 001” study.

45. Taxotere is a part of the chemotherapy family of drugs known as “Taxanes.” Taxanes are a type of chemicals called “diterpenoids,” which specifically contain a taxadiene core within the molecule, which is produced by yew trees.

46. Taxanes are widely used as chemotherapy agents, and several taxanes are available for cancer treatment, including but not limited to Taxol, generically known as paclitaxel, Jevtana, generically known as cabazitaxel, and of course Taxotere, generically known as docetaxel.

47. Upon information and belief, the TAX 001 study concluded in or about May 1992 and subsequently reported in or about May 1994.

48. Taxol (paclitaxel) was developed, manufactured, distributed, and marketed by Bristol Meyers Squibb (BMS) and was first approved by the U.S. Food and Drug Administration (FDA) in December of 1992.

49. Upon information and belief, Aventis Pharma S.A., sought FDA approval for Taxotere in or about December of 1994 and the FDA’s Oncologic Drugs Advisory Committee Panel had unanimously recommended the rejection of the approval for Taxotere because the Taxotere was more toxic than Taxol, and recommended more testing and studies for Taxotere’s side effects.

50. On or about May 14, 1996, Sanofi Defendants obtained FDA approval for the “treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.”

51. Sanofi Defendants continued to seek additional indications for Taxotere and based on self-sponsored clinical trials, Sanofi Defendants alleged superiority over other

chemotherapy products approved for the treatment of breast cancer. Sanofi Defendants' marketing claims included superior efficacy over the lower potency Taxanes, including Taxol.

52. Despite Sanofi Defendants' claims of superior efficacy, post market surveillance demonstrated that the more potent and more toxic Taxotere, in fact, did not have higher efficacy or benefits compared to the other Taxanes and Defendants concealed the existence of studies from the FDA, physicians, patients, and the public that refuted Sanofi Defendants' claims and advertisements of superior efficacy.

53. In or about August of 2007, the journal, *Cancer Treatment Review*, published a comparison of the relative efficacy of Taxanes in the treatment of breast cancer. This study concluded that there were no significant differences between the efficacy and outcomes obtained from Taxotere treatment and Taxol treatment.

54. In or about April of 2008, the *New England Journal of Medicine* published a study titled, *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*, which concluded that Taxol was more effective than Taxotere for patients undergoing the standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

55. Sanofi Defendants continued to make false and misleading statements, promoting the "superior efficacy" of Taxotere over the competing product Taxol, despite the studies that concluded otherwise. Specifically, in or about June 2008, Sanofi-Aventis used a "reprint carrier" citing a clinical study published in August of 2005 from the *Journal of Clinical Oncology* that concluded Taxotere had superior efficacy compared to Taxol "providing significant clinical benefit in terms of survival and time to disease progression, with a numerically higher response rate and manageable toxicities" in the marketing and promotional materials for Taxotere.

56. Sanofi Defendants' statements in the "reprint carrier" materials highlighting the conclusions of the 2005 study were false and/or misleading due to the 2007 and 2008 studies finding Taxotere was not more effective than Taxol in the treatment of breast cancer.

57. Consequently, on or about April 16, 2009, Keith Olin, from the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC), issued a warning letter to MaryRose Salvacion, the Director of US Regulatory Affairs Marketed Products for Sanofi-Aventis, regarding the NDA #20-449, Taxotere (docetaxel). In this letter, the DDMAC stated:

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)

58. In addition, a Qui Tam lawsuit was filed against Sanofi-Aventis and its affiliates in the U.S. District Court for the Eastern District of Pennsylvania, by a former employee stating Sanofi-Aventis and its affiliates engaged in fraudulent marketing schemes, paid kickbacks, and provided other unlawful incentives to entice physicians to use docetaxel. *See U.S. dx rel. Ghoil v. Sanofi-Aventis U.S. Inc.*, CA No. 02-2964 (E.D. Pa. 2015).

59. Beginning in or around 1996, Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S., LLC, Sanofi U.S. Services, Inc., and their predecessors and affiliates, designed, directed, and/or engaged in a marketing plot that promoted Taxotere for indications not approved by the

FDA, also known as off label promotion. The plot had two prongs. The first prong was training and directing employees to misrepresent the safety and effectiveness of the off-label use of Taxotere, to get a foothold in other types of cancer treatment markets. The other prong was paying healthcare providers illegal kickbacks in the form of grants, speaker fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free reimbursement assistance to incentivize healthcare providers to prescribe Taxotere for off label treatment.

60. The Sanofi Defendants fraudulent marketing and illegal kickback scheme increased the Taxotere the revenue of sales by approximately one billion dollars from 2000's \$424 million to 2004's \$1.4 billion. *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 508 (E.D. Pa. 2015).

61. Sanofi Defendants' fraudulent and illegal conduct drastically increased the number of victims to be exposed to a more toxic chemotherapy treatment with no better efficacy than less toxic chemotherapy treatments already available.

62. Sanofi Defendants' fraudulent and illegal conduct caused thousands of individuals to be exposed to more frequent and/or more severe side effects, including but not limited to disfiguring and permanent alopecia (hair loss).

C. SANOFI DEFENDANTS' COVER UP OF THE KNOWN RISK OF PERMANENT HAIR LOSS

63. It is well known that cancer treatments like radiation and chemotherapy can cause temporary hair loss during treatment. However, permanent alopecia is not common place. Sanofi Defendants, through their marketing and promotional materials, misled the medical community, the public, and the Plaintiff, to believe Taxotere, as with other chemotherapy treatment, would cause temporary hair loss, but that the hair would grow back.

64. Sanofi Defendants knew, or should have known, that the rate of permanent alopecia related to Taxotere (docetaxel) was far greater than with other chemotherapy treatments for the same conditions as Taxotere (docetaxel).

65. Permanent alopecia, hair loss, is disfiguring, especially for women. Women who experienced this disfigurement as a result of the use of Taxotere suffered and continue to suffer great mental anguish, as well as economic damage, including but not limited to, loss of work or inability due to work due to significant psychological damage.

66. Women might have accepted the possibility of permanent baldness as a result of exposure to Taxotere if no other treatment were available for their cancer. However, this is not the case.

67. There were similar products on the market that were at least as effective as Taxotere and did not subject the female users to the same risk of disfiguring levels of alopecia.

68. Plaintiff would not have agreed to Taxotere treatment if the true risk of permanent alopecia was made available to her.

69. Beginning in the late 1990's, Sanofi Defendants sponsored, and/or were aware of the GEICAM 9805 study. By 2005, Sanofi Defendants' knew that the GEICAM 9805 study demonstrated that 9.2% of patients who were administered Taxotere, had persistent alopecia for up to 10 years and 5 months and in some cases even longer. Despite this knowledge, Sanofi Defendants purposefully and unjustly withheld these results contained in the GEICAM 9805 study from the physicians, healthcare providers, and patients in the U.S., including Plaintiff.

70. By 2006, Sanofi Defendants knew, or should have known, that a Denver based oncologist in the U.S. had observed that an increased percentage, 6.3% specifically, of his

patients who had Taxotere treatment suffered from permanent and disfiguring hair loss for years after the patient had ended their Taxotere treatment.

71. Sanofi Defendants knew of relevant findings from GEICAM 9805 and knew of the patient reports from the Denver oncologist, and failed, to date, to provide accurate information and proper warnings to the physicians, healthcare providers, and patients in the U.S., including Plaintiff, that Taxotere has a significantly increased risk of experiencing permanent and disfiguring alopecia.

72. Sanofi Defendants chose to withhold this information from the U.S. market despite physicians, patients, and regulatory agencies in other countries, including, but not limited to, the European Union and Canada, that Taxotere caused an increased risk of permanent and disfiguring alopecia. Sanofi Defendants continued to tell the U.S. physicians, healthcare providers, patients, and Plaintiff, that “hair generally grows back” after taking Taxotere.

73. Taxotere consumers were not given the opportunity to make an informed decision because they were unable to perform a risk benefit analysis due to the systematic and continuous deception perpetrated by Sanofi Defendants by overstating and/or misrepresenting the benefits and failing to warn of the true risks of permanent and disfiguring alopecia while other less potent but equally effective alternatives were available.

74. It is notable that Sanofi Defendants publish information in other countries to individual patients, as well as regulatory agencies, informing patients of a risk of permanent alopecia relating to Taxotere use, however despite the numerous U.S. label changes and safety warnings issued by Sanofi Defendants during the near, two decades Taxotere has been on the U.S. market, the words “permanent alopecia” or “permanent hair loss” did not appear in any published information from Sanofi Defendants until December 2015.

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

76. Sanofi Defendants' failure to warn patients of the true risk of disfiguring and permanent alopecia in the U.S., to healthcare providers, physicians, and patients, including Plaintiff, deprived them of the chance to make an informed decision as to exposing oneself to Taxotere (docetaxel) when other comparably effective products were available.

77. Sanofi Defendants took advantage of vulnerable groups of individuals during one of the most difficult times of their lives. Sanofi Defendants made billions of dollars in increased revenues at the expense of unwary cancer victims who wanted a chance at a normal life again.

78. Taxotere was defective in its design. Taxotere was designed as a more potent Taxane. This increased potency resulted in increased toxicity, which can be directly related to the increased adverse events. The most likely reason Sanofi Defendants designed a more potent Taxane was to enable them to obtain a patent, and grab the current market, on a patent that was, in fact, not novel, but only more dangerous.

79. Sanofi Defendants' reckless, willful, and wanton conduct permanently disfigured Plaintiff, as well as many other innocent victims to satisfy the Sanofi Defendants' avarice.

D. GENERIC NON-BIOEQUIVALENT DEFENDANTS' CONDUCT

80. Defendant Hospira filed for a NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel anhydrous. The FDA granted Hospira's NDA on or about March 8, 2011 and Hospira put the docetaxel anhydrous on the market on or about March 8, 2011.

81. Defendant Sun Pharma filed for an NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docefrez. The FDA granted Sun Pharma's NDA on or about May 2, 2011 and Sun Pharma put docefrez on the market on or about May 2, 2011.

82. Defendant McKesson filed an NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel anhydrous. The FDA granted McKesson's NDA on or about June 8, 2011, and McKesson put docetaxel anhydrous on the market on or about June 8, 2011.

83. Defendant Sandoz filed an NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel. The FDA granted Sandoz's NDA on or about July 22, 2015 and Sandoz put docetaxel on the market on or about July 22, 2015.

84. Upon information and belief, Defendant Accord filed for two (3) NDAs with the FDA for generic non-bioequivalents of Taxotere (docetaxel).

85. Upon information and belief, Defendant Accord was approved by the FDA for the first generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel on or about June 30, 2011 and Accord put docetaxel on the market on or about June 30, 2011.

86. Defendant Accord was approved by the FDA for the second generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel anhydrous (20 mg/0.5 mL and 80 mg/2 mL) on or about July 1, 2012 and Accord put docetaxel anhydrous on the market on or about July 1, 2012.

87. Upon information and belief, Defendant Accord was approved by the FDA for the third generic non-bioequivalent of Taxotere (docetaxel) in another form of docetaxel

anhydrous in a more concentrated form, on or about May 15, 2013 and Accord put the more concentrated docetaxel anhydrous on the market on or about May 15, 2013.

E. THE PLAINTIFF'S USE OF TAXOTERE AND RESULTING INJURIES

88. By reason of the foregoing acts and omissions, the Plaintiff suffered permanent alopecia, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and medical treatment.

89. Upon information and belief, despite the permanent alopecia findings in studies and other clinical evidence, all Defendants failed to adequately conduct complete and proper testing of Taxotere prior to filing their New Drug Application for Taxotere.

90. Upon information and belief, from the date all Defendants received FDA approval to market Taxotere (docetaxel) and/or its generic non-bioequivalent forms, all Defendants made, distributed, marketed, and sold Taxotere (docetaxel) and/or its generic non-bioequivalent form, without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Taxotere (docetaxel), and/or its generic non-bioequivalent form, was associated with and/or could cause permanent hair loss in patients who used it, and that all Defendants had not adequately conducted complete and proper testing and studies of Taxotere (docetaxel), and/or its generic non-bioequivalent form, with regard to permanent nature of the alopecia.

91. Upon information and belief, Taxotere (docetaxel), and/or its generic non-bioequivalent form, concealed and failed to completely disclose their knowledge that Taxotere (docetaxel), and/or its generic non-bioequivalent form, was associated with or could cause permanent alopecia as well as their knowledge that they had failed to fully test or study said risk.

92. Upon information and belief, all Defendants ignored the association between the

use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, and the risk of developing permanent and disfiguring alopecia.

93. Upon information and belief, all Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of permanent hair loss of Taxotere (docetaxel), and/or its generic non-bioequivalent form, but similar efficacy compared to less potent products.

94. All of the Defendants' failures to disclose information that they possessed regarding the failure to adequately test and study Taxotere (docetaxel), and/or its generic non-bioequivalent form, for permanent hair loss risk further rendered warnings for this medication inadequate.

95. By reason of the forgoing acts and omissions, Plaintiffs have suffered damages and harm, including, but not limited to, emotional distress, medical expenses, other economic harm, as well as a loss of consortium, services, society, companionship, love and comfort.

FACTUAL ALLEGATIONS

96. On or about November 1, 2008, Plaintiff was first prescribed and began taking Taxotere (docetaxel), and/or its generic non-bioequivalent form, upon the direction of her physician for the treatment of breast cancer. Subsequently, as a direct result of being exposed to Taxotere (docetaxel), and/or its generic non-bioequivalent form, on or about January 1, 2016, Plaintiff was diagnosed with permanent and severe alopecia at Spring Valley Family Medicine located in Columbia, South Carolina.

97. As a direct result of being prescribed Taxotere for this period of time, Plaintiff suffered significant injuries, such as those described above.

98. As a proximate result of all of the Defendants' acts and omissions, Plaintiff

suffered the injuries described hereinabove due to Plaintiff's exposure to Taxotere (docetaxel), and/or its generic non-bioequivalent form,. Plaintiff accordingly seeks damages associated with these injuries.

99. Plaintiff would not have used Taxotere (docetaxel), and/or its generic non-bioequivalent form, had all of the Defendants properly disclosed the risks associated with its use.

COUNT I: STRICT LIABILITY

100. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

101. At all times relevant times hereto, Defendants were engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Taxotere (docetaxel), and/or its generic non-bioequivalent form, at issue in this lawsuit. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, manufactured by Defendants reached Plaintiff without substantial change and was infused as directed. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

102. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of permanent alopecia and other injuries associated with the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, were inadequate.

103. Plaintiffs did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

104. Defendants had a continuing duty to provide consumers, including Plaintiff, and Plaintiff's physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with Taxotere (docetaxel), and/or its generic non-bioequivalent form,, as it became or could have become available to Defendants.

105. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Taxotere (docetaxel), and/or its generic non-bioequivalent form, to health care providers empowered to prescribe and dispense Taxotere to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Taxotere (docetaxel), and/or its generic non-bioequivalent form, which resulted in injury to Plaintiff.

106. Despite the fact that Defendants knew or should have known that Taxotere (docetaxel), and/or its generic non-bioequivalent form, caused unreasonable and permanent side effects, they continued to promote and market Taxotere (docetaxel), and/or its generic non-bioequivalent form, without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

107. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

108. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the

following ways:

- a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Taxotere (docetaxel), and/or its generic non-bioequivalent form, including, among other things, permanent alopecia;
- b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, permanent alopecia;
- c. Defendants continued to aggressively promote and sell Taxotere (docetaxel), and/or its generic non-bioequivalent form, even after they knew or should have known of the unreasonable risks of permanent alopecia from this drug.

109. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Taxotere (docetaxel), and/or its generic non-bioequivalent form, and/or that there existed safer and more or equally effective alternative drug products.

110. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Taxotere (docetaxel), and/or its generic non-bioequivalent form, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

111. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

112. As a direct and proximate result of the actions and inactions of the Defendants as

set forth above, Plaintiff was exposed to Taxotere (docetaxel), and/or its generic non-bioequivalent form, and suffered the injuries and damages set forth hereinabove.

COUNT II: STRICT LIABILITY – DESIGN DEFECT,

MARKETING DEFECT AND MANUFACTURING DEFECT

113. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

114. Taxotere (docetaxel), and/or its generic non-bioequivalent form, was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Taxotere (docetaxel), and/or its generic non-bioequivalent form, could cause injuries such as those suffered by Plaintiff during foreseeable use. This fact was known to Defendants at the time Taxotere (docetaxel), and/or its generic non-bioequivalent form, was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including Plaintiff. Nonetheless, Defendants failed to warn that Taxotere (docetaxel), and/or its generic non-bioequivalent form, as designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Such a failure to warn rendered the Taxotere (docetaxel), and/or its generic non-bioequivalent form, unreasonably dangerously defective as designed and marketed.

115. At all times material to these allegations, Defendants manufactured, distributed, tested, packaged, promoted, marketed, labeled, designed and sold Taxotere (docetaxel), and/or its generic non-bioequivalent form, as alleged herein.

116. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field.

117. The Taxotere (docetaxel), and/or its generic non-bioequivalent form,

administered to Plaintiff was defective in design or formulation in the following respects:

- a. When it left the hands of Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;
- b. Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as Defendants intended;
- c. The dosages and/or formulation of Taxotere (docetaxel), and/or its generic non-bioequivalent form, sold by Defendants was unreasonably dangerous;
- d. There are no patients for whom the benefits of Taxotere (docetaxel), and/or its generic non-bioequivalent form, outweighed the risks;
- e. The subject product was not made in accordance with Defendants' specifications or performance standards;
- f. There are no patients for whom Taxotere (docetaxel), and/or its generic non-bioequivalent form, is a safer and more efficacious drug than other drug products in its class; and/or
- g. There were safer alternatives that did not carry the same risks and dangers that Defendants' Taxotere (docetaxel), and/or its generic non-bioequivalent form, had.

118. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, administered to Plaintiff was defective at the time it was distributed by Defendants or left their control.

119. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, administered to Plaintiff was expected to reach the user without substantial change in the

condition in which it was sold.

120. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, administered to Plaintiff reached Plaintiff without substantial change in the condition in which it was sold.

121. There were safer alternative methods and designs for Defendants' Taxotere (docetaxel), and/or its generic non-bioequivalent form.

122. Plaintiff was a patient who Defendants reasonably expected would be administered Taxotere (docetaxel), and/or its generic non-bioequivalent form.

123. Defendants were at liberty to withdraw Taxotere (docetaxel), and/or its generic non-bioequivalent form, from the market at any time, but failed to do so.

124. The defective and unreasonably dangerous design and marketing of Taxotere (docetaxel), and/or its generic non-bioequivalent form, was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case, including punitive damages.

125. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff was injured as described herein. All of said injuries caused Plaintiff's damages, for which Plaintiff is entitled to damages.

126. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff was required to obtain reasonable and necessary healthcare treatment and services and incurred expenses for which Plaintiff is entitled to damages.

127. As a direct and proximate result of the design, marketing and manufacturing defects of Defendants' product, Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff suffered the injuries as previously alleged herein.

COUNT III: NEGLIGENCE

128. Plaintiffs incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

129. Defendants owed a duty to the general public and specifically to the Plaintiff to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Taxotere (docetaxel), and/or its generic non-bioequivalent form, at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Taxotere (docetaxel), and/or its generic non-bioequivalent form, because as designed, it was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Taxotere (docetaxel), and/or its generic non-bioequivalent form, because they failed to warn, that as designed, Taxotere (docetaxel), and/or its generic non-bioequivalent form, was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use.

130. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

- a. Failing to use due care in developing, testing, designing and manufacturing Taxotere so as to avoid the aforementioned risks to individuals when Taxotere was being used for treatment;
- b. Failing to accompany their product with proper or adequate warnings or labeling

regarding adverse side effects and health risks associated with the use of Taxotere and the comparative severity and duration of such adverse effects;

- c. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;
- d. Failing to accompany their products with proper or adequate rate of incidence or prevalence of permanent hair loss;
- e. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;
- f. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Taxotere (docetaxel), and/or its generic non-bioequivalent form;
- g. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;
- h. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Taxotere (docetaxel), and/or its generic non-bioequivalent form, and patients taking Taxotere (docetaxel), and/or its generic non-bioequivalent form;
- i. Failing to adequately test and/or warn about the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, including, without limitations, the possible adverse side effects and health risks caused by the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form;

- j. Failing to design and/or manufacture a product that could be used safely;
- k. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff;
- l. Failing to remove Taxotere (docetaxel), and/or its generic non-bioequivalent form, from the market when Defendants' knew or should have known of the likelihood of serious and permanent side effects and injury to its users;
- m. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of permanent hair loss and related conditions to individuals taking Taxotere (docetaxel), and/or its generic non-bioequivalent form; and
- n. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

131. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, that injured Plaintiff was in substantially the same condition when Plaintiff was infused with it as it was in when it left the control of Defendants. Taxotere's (docetaxel), and/or its generic non-bioequivalent form's, ability to cause serious and permanent personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff was infused the Taxotere (docetaxel), and/or its generic non-bioequivalent form, as directed and without change in its form or substance.

132. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Taxotere (docetaxel), and/or its generic non-bioequivalent form, was a proximate cause of Plaintiff's injuries and damages.

133. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

COUNT IV: BREACH OF WARRANTY - BREACH OF EXPRESS WARRANTY

134. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

135. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Taxotere (docetaxel), and/or its generic non-bioequivalent form, in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Plaintiff, or persons responsible for consumer.

136. Taxotere (docetaxel), and/or its generic non-bioequivalent form, materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of Taxotere (docetaxel), and/or its generic non-bioequivalent form, respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and was infused with in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Taxotere (docetaxel), and/or its generic non-bioequivalent form, sold to Plaintiff.

137. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered permanent and grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff purchased and was infused with Taxotere (docetaxel), and/or its generic non-bioequivalent form, as prescribed and instructed by Plaintiff's physician, leading to Plaintiff's injuries.

COUNT V: BREACH OF WARRANTY – BREACH OF IMPLIED WARRANTY

138. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

139. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Taxotere (docetaxel), and/or its generic non-bioequivalent form, in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

140. Defendants impliedly warranted their Taxotere (docetaxel), and/or its generic non-bioequivalent form, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

141. Defendants breached their implied warranties of the Taxotere (docetaxel), and/or its generic non-bioequivalent form, sold to Plaintiff because this product was not fit for its common, ordinary, and intended use.

142. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiff suffered permanent and grievous bodily injury and consequential economic and other losses, as described above, when Plaintiff was infused with Taxotere (docetaxel), and/or its generic non-bioequivalent form, in reasonable reliance upon the implied warranties.

COUNT VI: LOSS OF CONSORTIUM

143. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth and further alleges as follows:

144. Christopher Strother, was at all times relevant hereto the spouse of Dena Strother

145. For the reasons set forth herein, Christopher Strother has been caused presently and in the future, to suffer the loss of Dena Strother's companionship and society, and accordingly, Christopher Strother has been caused great mental anguish.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiffs for the injuries Plaintiffs have suffered and or will suffer. Plaintiffs further demand judgment against each of the Defendants for punitive damages. Plaintiffs further demand payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiffs further demand payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

NAPOLI SHKOLNIK LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiffs

Dated: December 19, 2016

**SUPERIOR COURT
CIVIL CASE INFORMATION STATEMENT (CIS)**

Filed: Dec 30 2016 07:54AM EST
Transaction ID 60007313
Case No. N16C-12-422 VLM



COUNTY: N K S

CIVIL ACTION NUMBER: _____

<p>Caption: DENA STROTHER AND CHRISTOPHER STROTHER</p> <hr/> <p>v. SANOFI U.S. SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC;</p> <hr/> <p>SANOFI-AVENTIS U.S. LLC, separately and doing business as WINTHROP U.S.;</p> <hr/> <p>HOSPIRA WORLDWIDE, INC.; McKESSON CORPORATION doing business as</p> <hr/> <p>McKESSON PACKAGING; SANDOZ INC.; ACCORD HEALTHCARE LTD.;</p> <hr/> <p>INTAS PHARMACEUTICALS LIMITED; SANOFI S.A.; AVENTIS PHARMA S.A.; and DOES, INC.</p> <hr/>	<p>Civil Case Code: <u>CPRL</u></p> <p>Civil Case Type: <u>Product Liability</u> <small>(SEE REVERSE SIDE FOR CODE AND TYPE)</small></p> <p>Name and Status of Party filing document: Plaintiffs, DENA STROTHER AND CHRISTOPHER STROTHER</p> <hr/> <p>Document Type: (E.G.; COMPLAINT; ANSWER WITH COUNTERCLAIM) Complaint</p> <hr/> <p style="text-align: center;">JURY DEMAND: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p>
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<p>ATTORNEY NAME(S): James D. Heisman</p> <hr/> <p>ATTORNEY ID(S): 2746</p> <hr/> <p>FIRM NAME: Napoli Shkolnik, LLC</p> <hr/> <p>ADDRESS: 919 North Market Street, Suite 1801</p> <hr/> <p>Wilmington, DE 09801</p> <hr/> <p>TELEPHONE NUMBER: 302-330-8025</p> <hr/> <p>FAX NUMBER: 646-843-7603</p> <hr/> <p>E-MAIL ADDRESS: JHeisman@Napolilaw.com</p> <hr/>	<p>IDENTIFY ANY RELATED CASES NOW PENDING IN THE SUPERIOR COURT OR ANY RELATED CASES THAT HAVE BEEN CLOSED IN THIS COURT WITHIN THE LAST TWO YEARS BY CAPTION AND CIVIL ACTION NUMBER INCLUDING JUDGE'S INITIALS: <u>Gradney et al., v. Sanofi US Services Inc., et al. CA No: N16C-11-090 VLM</u></p> <hr/> <p>EXPLAIN THE RELATIONSHIP(S): <u>The complaints are similar in nature regarding the injury sustained by plaintiffs though not identical, defendants named in the litigation, and the pharmaceutical product they were exposed to which allegedly caused the injuries alleged in the complaints.</u></p> <hr/> <p>OTHER UNUSUAL ISSUES THAT AFFECT CASE MANAGEMENT: _____ _____ _____</p> <hr/> <p>(IF ADDITIONAL SPACE IS NEEDED, PLEASE ATTACH PAGE)</p>
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THE PROTHONOTARY WILL NOT PROCESS THE COMPLAINT, ANSWER, OR FIRST RESPONSIVE PLEADING IN THIS MATTER FOR SERVICE UNTIL THE CASE INFORMATION STATEMENT (CIS) IS FILED. THE FAILURE TO FILE THE CIS AND HAVE THE PLEADING PROCESSED FOR SERVICE MAY RESULT IN THE DISMISSAL OF THE COMPLAINT OR MAY RESULT IN THE ANSWER OR FIRST RESPONSIVE PLEADING BEING STRICKEN.

SUPERIOR COURT CIVIL CASE INFORMATION STATEMENT (CIS) INSTRUCTIONS

CIVIL CASE TYPE

Please select the appropriate civil case code and case type (e.g., **CODE** - **AADM** and **TYPE** - **Administrative Agency**) from the list below. Enter this information in the designated spaces on the Case Information Statement.

<p>APPEALS AADM - Administrative Agency ACER - Certiorari ACCP - Court of Common Pleas AIAB - Industrial Accident Board APSC - Public Service Commission AUIB - Unemployment Insurance Appeal Board</p> <p>COMPLAINTS CABT - Abatement CASB - Asbestos CAAA - Auto Arb Appeal CMIS - Civil Miscellaneous CACT - Class Action CCON - Condemnation CCLD - Complex Commercial Litigation Division (NCC ONLY) CDBT - Debt/Breach of Contract CDEJ - Declaratory Judgment CDEF - Defamation CEJM - Ejectment CATT - Foreign & Domestic Attachment CFJG - Foreign Judgment CFRD - Fraud Enforcement CINT - Interpleader CLEM - Lemon Law CLIB - Libel CMAL - Malpractice CMED - Medical Malpractice CPIN - Personal Injury CPIA - Personal Injury Auto CPRL - Products Liability CPRD - Property Damage CRPV - Replevin CSPD - Summary Proceedings Dispute CCCP - Transfer from CCP CCHA - Transfer from Chancery</p> <p>MASS TORT CBEN - Benzene Cases CPEL - Pelvic Mesh Cases CPLX - Plavix Cases CXAR - Xarelto Cases</p> <p>INVOLUNTARY COMMITMENTS INVC - Involuntary Commitment</p>	<p>MISCELLANEOUS MAGM - AG Motion - Civil/Criminal Investigations * MADB - Appeal from Disability Board * MAFF - Application for Forfeiture MAAT - Appointment of Attorney MGAR - Appointment of Guardianship MCED - Cease and Desist Order MCON - Civil Contempt/Capias MCVP - Civil Penalty MSOJ - Compel Satisfaction of Judgment MSAM - Compel Satisfaction of Mortgage MCTO - Consent Order MIND - Destruction of Indicia of Arrest * MESP - Excess Sheriff Proceeds MHAC - Habeas Corpus MTOX - Hazardous Substance Cleanup MFOR - Intercept of Forfeited Money MISS - Issuance of Subpoena MLEX - Lien Extension MMAN - Mandamus MWIT - Material Witness * MWOT - Material Witness - Out of State MRAT - Motion for Risk Assessment MROP - Petition for Return of Property MCRO - Petition Requesting Order MROD - Road Resolution MSEL - Sell Real Estate for Property Tax MSEM - Set Aside Satisfaction of Mortgage MSSS - Set Aside Sheriff's Sale MSET - Structured Settlement MTAX - Tax Ditches MREF - Tax Intercept MLAG - Tax Lagoons MVAC - Vacate Public Road MPOS - Writ of Possession MPRO - Writ of Prohibition</p> <p>MORTGAGES MCOM - Mortgage Commercial MMED - Mortgage Mediation MORT - Mortgage Non-Mediation (Res.)</p> <p>MECHANICS LIENS LIEN - Mechanics Lien</p>
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*** Not eFiled**

DUTY OF THE PLAINTIFF

Each plaintiff/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the complaint.

DUTY OF THE DEFENDANT

Each defendant/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the answer and/or first responsive pleading.



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)

C.A. NO.:

Plaintiffs,)

JURY TRIAL DEMANDED

v.)

SANOFI U.S. SERVICES INC., formerly known as)
SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS U.S.)
LLC, separately and doing business as WINTHROP U.S.;)
HOSPIRA WORLDWIDE, INC.; SUN PHARMA)
GLOBAL INC.; McKESSON CORPORATION doing)
business as McKESSON PACKAGING; SANDOZ INC.;)
ACCORD HEALTHCARE LTD.; ACCORD)
HEALTHCARE, INC.; INTAS PHARMACEUTICALS)
LIMITED; SANOFI S.A., AVENTIS PHARMA S.A.; and)
DOES, INC)

Defendants)

PLAINTIFF’S ANSWERS TO FORM 30 INTERROGATORIES

- 1. Give the name and present or last-known residential and employment address and telephone number of each eyewitness to the incident which is the subject of the litigation.

ANSWER:

To be supplemented, if applicable.

- 2. Give the name and present or last-known residential and employment address and telephone number of each person who has knowledge of the facts relating to the litigation.

ANSWER:

Plaintiffs may be contacted only through the undersigned counsel. Plaintiff’s treating physicians. The names and contact information of said treating physicians will be supplied by plaintiff. To be supplemented, if applicable.

- 3. Give the names of all persons who have been interviewed in connection with the above litigation, including the names and present or last-known residential and employment

addresses and telephone numbers of the persons who made said interviews and the names and present or last-known residential and employment addresses and telephone numbers of persons who have the original and copies of the interview.

ANSWER: None.

4. Identify all photographs, diagrams, or other representations made in connection with the matter in litigation, giving the name and present or last-known residential and employment address and telephone number of the person having the original and copies thereof. (In lieu thereof, a copy can be attached.)

ANSWER: None currently in possession.

5. Give the name, professional address, and telephone number of all expert witnesses presently retained by the party together with the dates of any written opinions prepared by said expert. If an expert is not presently retained, describe by type the experts whom the party expects to retain in connection with the litigation.

ANSWER: Experts in epidemiology, Experts in blood clotting, FDA Regulatory Experts, Causation Experts, Damages Experts and other experts will be retained.

6. Give a brief description of any insurance policy, including excess coverage, that is or may be applicable to the litigation, including:
 - a. The name and address of all companies insuring the risk;
 - b. The policy number(s);
 - c. The type of insurance;
 - d. The amounts of primary, secondary, and excess coverage.

ANSWER: Not Applicable

7. Give the name, professional address, and telephone number of all physicians, chiropractors, psychologists, and physical therapists who have examined or treated you at any time during the ten year period immediately prior to the date of the incident at issue in this litigation.

ANSWER: To be supplemented.

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman

James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiffs

DATED: December 19, 2016



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)

Plaintiffs,)

v.)

SANOFI U.S. SERVICES INC., formerly known as)
SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS)
U.S. LLC, separately and doing business as)
WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.;)
SUN PHARMA GLOBAL INC.; McKESSON)
CORPORATION doing business as McKESSON)
PACKAGING; SANDOZ INC.; ACCORD)
HEALTHCARE LTD.; ACCORD HEALTHCARE,)
INC.; INTAS PHARMACEUTICALS LIMITED;)
SANOFI S.A., AVENTIS PHARMA S.A.; and)
DOES, INC)

Defendants)

C.A. No.:

Jury Trial Demanded

PRAECIPE

PLEASE ISSUE Summons and Complaint through the Sheriff of New Castle County to the defendants at the addresses indicated herein:

SANOFI U.S. SERVICES INC.,

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

SANOFI-AVENTIS U.S. LLC

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

HOSPIRA WORLDWIDE INC.

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

MCKESSON CORPORATION

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

PLEASE ISSUE Summons and Complaint through Plaintiffs' Attorneys to the defendants listed below at the addresses indicated herein pursuant to 10 Del. C. § 3104.

SANDOZ INC.

100 College Road West
Princeton, NJ 08540

ACCORD HEALTHCARE INC.

1009 Slater Road
Suite 210B
Durham, NC 27703

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiffs

DATED: December 19, 2016



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)

Plaintiffs,)

v.)

SANOFI U.S. SERVICES INC., formerly known as)
SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS)
U.S. LLC, separately and doing business as)
WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.;)
SUN PHARMA GLOBAL INC.; McKESSON)
CORPORATION doing business as McKESSON)
PACKAGING; SANDOZ INC.; ACCORD)
HEALTHCARE LTD.; ACCORD HEALTHCARE,)
INC.; INTAS PHARMACEUTICALS LIMITED;)
SANOFI S.A., AVENTIS PHARMA S.A.; and)
DOES, INC)

Defendants.)

C.A. No.:

Jury Trial Demanded

SUMMONS

**THE STATE OF DELAWARE,
TO THE SHERIFF OF NEW CASTLE COUNTY:**

YOU ARE COMMANDED:

To summon the above defendant so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiffs' attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiffs).

Dated:

SUSAN HEARN

Prothonotary

Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiffs' attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN HEARN

Prothonotary

Per Deputy



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)
)
) C.A. No.
 Plaintiffs,) Jury Trial Demanded
)
)
 v.)
)
 SANOFI U.S. SERVICES INC., formerly known as)
 SANOFI-AVENTIS U.S. INC.; SANOFI-AVENTIS)
 U.S. LLC, separately and doing business as)
 WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.;)
 SUN PHARMA GLOBAL INC.; McKESSON)
 CORPORATION doing business as McKESSON)
 PACKAGING; SANDOZ INC.; ACCORD)
 HEALTHCARE LTD.; ACCORD HEALTHCARE,)
 INC.; INTAS PHARMACEUTICALS LIMITED;)
 SANOFI S.A.; AVENTIS PHARMA S.A.; and)
 DOES, INC.)
 Defendants)
)

SUMMONS PURSUANT TO 10 DEL. C. § 3104

**THE STATE OF DELAWARE,
PLAINTIFFS' COUNSEL
YOU ARE COMMANDED:**

To summon the above-named defendant so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiffs' attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiffs).

Dated:

SUSAN HEARN
Prothonotary

Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiffs' attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN HEARN

Prothonotary

Per Deputy



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)
)
Plaintiffs,) C.A. No.:
)
v.) Jury Trial Demanded
)
)
SANOFI U.S. SERVICES INC., formerly known as)
SANOFI-AVENTIS U.S. INC.; SANOFI-AVENTIS)
U.S. LLC, separately and doing business as)
WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.;)
SUN PHARMA GLOBAL INC.; McKESSON)
CORPORATION doing business as McKESSON)
PACKAGING; SANDOZ INC.; ACCORD)
HEALTHCARE LTD.; ACCORD HEALTHCARE,)
INC.; INTAS PHARMACEUTICALS LIMITED;)
SANOFI S.A., AVENTIS PHARMA S.A.; and)
DOES, INC)
Defendants)

HAGUE CONVENTION PRAECIPE

PLEASE ISSUE Summons and Complaint through Plaintiffs' Attorneys to the defendants listed below at the addresses indicated herein pursuant to the Article 5 of the Hague Convention:

SANOFI S.A.
54 rue La Boétie
75008 Paris
FRANCE

AVENTIS PHARMA S.A.
20 avenue Raymond Aron
92160 Antony
FRANCE

SUN PHARMA GLOBAL INC.
P.O. Box 659
Road Town
British Virgin Islands

ACCORD HEALTHCARE LTD.

Sage House
319 Pinner Road
North Harrow HA1 4HF
United Kingdom

INTAS PHARMACEUTICALS LTD.

Chinubhai Cetre,
Off. Nehru Bridge
Ashram Road
Ahmebadad, 380009
Gujarat, India

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman

James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiffs

DATED: December 19, 2016



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)

Plaintiffs,)

v.)

SANOFI U.S. SERVICES INC., formerly known as)
SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS)
U.S. LLC, separately and doing business as)
WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.;)
SUN PHARMA GLOBAL INC.; McKESSON)
CORPORATION doing business as McKESSON)
PACKAGING; SANDOZ INC.; ACCORD)
HEALTHCARE LTD.; ACCORD HEALTHCARE,)
INC.; INTAS PHARMACEUTICALS LIMITED;)
SANOFI S.A., AVENTIS PHARMA S.A.; and)
DOES, INC)

Defendants)

C.A. No.:

Jury Trial Demanded

SUMMONS PURSUANT TO ARTICLE 5 OF THE HAGUE CONVENTION

**THE STATE OF DELAWARE,
PLAINTIFFS' COUNSEL
YOU ARE COMMANDED:**

To summon the above-named defendant so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiffs' attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiffs).

Dated:

SHARON AGNEW
Prothonotary

Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiffs' attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SHARON AGNEW
Prothonotary

Per Deputy



REQUEST FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

DEMANDE
AUX FINS DE SIGNIFICATION OU DE NOTIFICATION À L'ÉTRANGER
D'UN ACTE JUDICIAIRE OU EXTRAJUDICIAIRE

Convention on the service abroad of judicial and extrajudicial documents in civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

Identity and address of the applicant
Identité et adresse du requérant

JAMES D. HEISMAN, ESQUIRE
NAPOLI SHKOLNIK, LLC
919 N. MARKET STREET
SUITE 1801
WILMINGTON, DE 19801

Address of receiving authority
Adresse de l'autorité destinataire

The Senior Master,
For the attention of the Foreign Process
Section,
Room E16, Royal Courts of Justice
Strand,
LONDON WC2A 2LL

The undersigned applicant has the honour to transmit -- in duplicate-- the documents listed below and, in conformity with article 5 of the above-mentioned Convention, requests prompt service of one copy thereof on the addressee, i.e., (identity and address)

Le requérant soussigné a l'honneur de faire parvenir--en double exemplaire--à l'autorité destinataire les documents ci-dessous énumérés, en la priant, conformément à l'article 5 de la Convention précitée, d'en faire remettre sans retard un exemplaire au destinataire, à savoir:

(identité et adresse)

ACCORD HEALTHCARE LTD. Sage House 319 Pinner Road North Harrow HA1 4HF United Kingdom

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention.*

a) selon les formes légales (article 5 alinéa premier, lettre a).

(b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of article 5)*:

b) selon la forme particulière suivante (article 5, alinéa premier, lettre b) :

(c) by delivery to the addressee, if he accepts it voluntarily (second paragraph of article 5)*:

c) le cas échéant, par remise simple (article 5, alinéa 2).

The authority is requested to return or to have returned to the applicant a copy of the documents and of the annexes with a certificate as provided on the reverse side.

Cette autorité est priée de renvoyer ou de faire renvoyer au requérant un exemplaire de l'acte - et de ses annexes - avec l'attestation figurant au verso.

List of documents
Énumération des pièces

Summons to initiate Lawsuit
Complaint for Lawsuit
Form 30 Interrogatories
Order Appointing Special Process Server

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

*Delete if inappropriate
Rayer les mentions inutiles.

**CERTIFICATE
ATTESTATION**

The undersigned authority has the honour to certify, in conformity with article 6 of the Convention,
L'autorité soussignée a l'honneur d'attester conformément à l'article 6 de ladite Convention,

1) that the document has been served *

1) *que la demande a été exécutée*

-- the (date) -- *le (date)* _____

-- at (place, street, number) - *à (localité, rue, numéro)* _____

-- in one of the following methods authorized by article 5:

-- *dans une des formes suivantes prévues à l'article 5:*

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention*.
a) selon les formes légales (article 5. alinéa premier, lettre a)

(b) in accordance with the following particular method:
b) selon la forme particulière suivante: _____

(c) by delivery to the addressee, who accepted it voluntarily.*
c) par remise simple.

The documents referred to in the request have been delivered to:

Les documents mentionnés dans la demande ont été remis à:

- *(identity and description of person)*

- *(Identité et qualité de la personne)*

- relationship to the addressee family, business or other

- *liens de parenté de subordination ou autres avec le destinataire de l'acte:*

2) that the document has not been served, by reason of the following facts*:

2) *que la demande n'a pas été exécutée, en raison des faits suivants:*

In conformity with the second paragraph of article 12 of the Convention, the applicant is requested to pay or reimburse the expenses detailed in the attached statement*

Conformément à l'article 12, alinéa 2, de ladite Convention, le requérant est prié de payer ou de rembourser les frais dont le détail figure au mémoire ci-joint.

ANNEXES

Annexes

Documents returned:

Pieces renvoyées

In appropriate cases, documents establishing the service:

Le cas échéant, les documents justificatifs de l'exécution:

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

SUMMARY OF THE DOCUMENT TO BE SERVED
ÉLÉMENTS ESSENTIELS DE L'ACTE

Convention on the service abroad of judicial and extrajudicial documents In civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

(article 5, fourth paragraph)
(article 5, alinéa quatre)

Name and address of the requesting authority:

Nom et adresse de l'autorité requérante:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, WILMINGTON, DELAWARE, USA 19801

Particulars of the parties:

Identité des parties:

DENA STROTHER AND CHRISTOPHER STROTHER (Plaintiffs) V. SANOFI U.S. Services Inc., ET AL (Accord Healthcare LTD.) (Defendants)

JUDICIAL DOCUMENT
ACTE JUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

LAWSUIT-COMPLAINT AND SUMMONS TO INITIATE LAWSUIT IN DELAWARE USA

Nature and purpose of the proceedings and, where appropriate, the amount in dispute:

Nature et objet de l'instance, le cas échéant, le montant du litige:

PRODUCT LIABILITY CIVIL LAWSUIT

Date and place for entering appearance:

Date et lieu de la comparution:

NAPOLI SHKOLNIK, LLC, 919 N. MARKET ST., STE. 1801, WILMINGTON, DE 19801 USA

Court which has given judgment:**

Jurisdiction qui a rendu la décision:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, USA

Dale of judgment:**

Date de la décision:

n/a-CASE HAS JUST BEGUN

Time limits stated in the document:**

Indication des délais figurant dans l'acte:

120 DAYS OF RECEIPT OF SUMMONS AND COMPLAINT

EXTRAJUDICIAL DOCUMENT
ACTE EXTRAJUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

Time limits stated in the document:**

Indication des délais figurant dans l'acte:



REQUEST FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

DEMANDE
AUX FINS DE SIGNIFICATION OU DE NOTIFICATION À L'ETRANGER
D'UN ACTE JUDICIAIRE OU EXTRAJUDICIAIRE

Convention on the service abroad of judicial and extrajudicial documents in civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

Identity and address of the applicant
Identité et adresse du requérant

JAMES D. HEISMAN, ESQUIRE
NAPOLI SHKOLNIK, LLC
919 N. MARKET STREET
SUITE 1801
WILMINGTON, DE 19801

Address of receiving authority
Adresse de l'autorité destinataire

Ministère de la Justice
Bureau de l'Entraide Judiciaire Internationale
13, place Vendôme
75042 Paris Cedex 01
France

The undersigned applicant has the honour to transmit -- in duplicate-- the documents listed below and, in conformity with article 5 of the above-mentioned Convention, requests prompt service of one copy thereof on the addressee, i.e., (identity and address)

Le requérant soussignée a l'honneur de faire parvenir--en double exemplaire--à l'autorité destinataire les documents ci-dessous énumérés, en la priant, conformément à l'article 5 de la Convention précitée, d'en faire remettre sans retard un exemplaire au destinataire, à savoir:

(identité et adresse)

AVENTIS PHARMA S.A., 20 avenue Raymond Aron, 92160, Antony, FRANCE

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention.*

a) selon les formes légales (article 5 alinéa premier, lettre a).

(b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of article 5)*:

b) selon la forme particulière suivante (article 5, alinéa premier, lettre b) :

(c) by delivery to the addressee, if he accepts it voluntarily (second paragraph of article 5)*:

c) le cas échéant, par remise simple (article 5, alinéa 2).

The authority is requested to return or to have returned to the applicant a copy of the documents and of the annexes with a certificate as provided on the reverse side.

Cette autorité est priée de renvoyer ou de faire renvoyer au requérant un exemplaire de l'acte - et de ses annexes - avec l'attestation figurant au verso.

List of documents
Énumération des pièces

Summons to initiate Lawsuit
Complaint for Lawsuit
Form 30 Interrogatories
Order Appointing Special Process Server

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

*Delete if inappropriate
Rayer les mentions inutiles.

**CERTIFICATE
ATTESTATION**

The undersigned authority has the honour to certify, in conformity with article 6 of the Convention,
L'autorité soussignée a l'honneur d'attester conformément à l'article 6 de ladite Convention,

1) that the document has been served *

1) *que la demande a été exécutée*

-- the (date) -- *le (date)* _____
-- at (place, street, number) - *à (localité, rue, numéro)* _____

-- in one of the following methods authorized by article 5:
-- *dans une des formes suivantes prévues à l'article 5:*

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention*.
a) selon les formes légales (article 5. alinéa premier, lettre a)

(b) in accordance with the following particular method:
b) selon la forme particulière suivante: _____

(c) by delivery to the addressee, who accepted it voluntarily.*
c) par remise simple.

The documents referred to in the request have been delivered to:
Les documents mentionnés dans la demande ont été remis à:

- *(identity and description of person)*
- *(Identité et qualité de la personne)*

- relationship to the addressee family, business or other
- *liens de parenté de subordination ou autres avec le destinataire de l'acte:*

2) that the document has not been served, by reason of the following facts*:
2) *que la demande n'a pas été exécutée, en raison des faits suivants:*

In conformity with the second paragraph of article 12 of the Convention, the applicant is requested to pay or reimburse the expenses detailed in the attached statement*

Conformément à l'article 12, alinéa 2, de ladite Convention, le requérant est prié de payer ou de rembourser les frais dont le détail figure au mémoire ci-joint.

ANNEXES

Annexes

Documents returned:

Pieces renvoyées

In appropriate cases, documents establishing the service:
Le cas échéant, les documents justificatifs de l'exécution:

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

SUMMARY OF THE DOCUMENT TO BE SERVED
ÉLÉMENTS ESSENTIELS DE L'ACTE

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(article 5, fourth paragraph)
(article 5, alinéa quatre)

Name and address of the requesting authority:

Nom et adresse de l'autorité requérante:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, WILMINGTON, DELAWARE, USA 19801

Particulars of the parties:

Identité des parties:

DENA STROTHER AND CHRISTOPHER STROTHER (Plaintiffs) V. SANOFI U.S. Services Inc., ET AL (AVI)

JUDICIAL DOCUMENT
ACTE JUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

LAWSUIT-COMPLAINT AND SUMMONS TO INITIATE LAWSUIT IN DELAWARE USA

Nature and purpose of the proceedings and, where appropriate, the amount in dispute:

Nature et objet de l'instance, le cas échéant, le montant du litige:

PRODUCT LIABILITY CIVIL LAWSUIT

Date and place for entering appearance:

Date et lieu de la comparution:

NAPOLI SHKOLNIK, LLC, 919 N. MARKET ST., STE. 1801, WILMINGTON, DE 19801 USA

Court which has given judgment:**

Jurisdiction qui a rendu la décision:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, USA

Dale of judgment:**

Date de la décision:

n/a-CASE HAS JUST BEGUN

Time limits stated in the document:**

Indication des délais figurant dans l'acte:

120 DAYS OF RECEIPT OF SUMMONS AND COMPLAINT

EXTRAJUDICIAL DOCUMENT
ACTE EXTRAJUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

Time limits stated in the document:**

Indication des délais figurant dans l'acte:



REQUEST FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

DEMANDE
AUX FINS DE SIGNIFICATION OU DE NOTIFICATION À L'ETRANGER
D'UN ACTE JUDICIAIRE OU EXTRAJUDICIAIRE

Convention on the service abroad of judicial and extrajudicial documents in civil or commercial matters, signed at The Hague, November 15, 1965.

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Identity and address of the applicant
Identité et adresse du requérant

JAMES D. HEISMAN, ESQUIRE
NAPOLI SHKOLNIK, LLC
919 N. MARKET STREET
SUITE 1801
WILMINGTON, DE 19801

Address of receiving authority
Adresse de l'autorité destinataire

Joint Secretary (Legal & Treaties)
Ministry of External Affairs
Legal & Treaties Division
ISIL Building
9 Bhagwandass Road
NEW DELHI 110 001
India

The undersigned applicant has the honour to transmit -- in duplicate-- the documents listed below and, in conformity with article 5 of the above-mentioned Convention, requests prompt service of one copy thereof on the addressee, i.e., (identity and address)

Le requérant soussignée a l'honneur de faire parvenir--en double exemplaire--à l'autorité destinataire les documents ci-dessous énumérés, en la priant, conformément à l'article 5 de la Convention précitée, d'en faire remettre sans retard un exemplaire au destinataire, à savoir:

(identité et adresse)

INTAS PHARMACEUTICALS LTD. Chinubhai Cetre, Off. Nehru Bridge Ashram Road Ahmebadad, 380009 Gujarat, India

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention.*

a) selon les formes légales (article 5 alinéa premier, lettre a).

(b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of article 5)*:

b) selon la forme particulière suivante (article 5, alinéa premier, lettre b) :

(c) by delivery to the addressee, if he accepts it voluntarily (second paragraph of article 5)*:

c) le cas échéant, par remise simple (article 5, alinéa 2).

The authority is requested to return or to have returned to the applicant a copy of the documents and of the annexes with a certificate as provided on the reverse side.

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List of documents
Énumération des pièces

Summons to initiate Lawsuit
Complaint for Lawsuit
Form 30 Interrogatories
Order Appointing Special Process Server

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

*Delete if inappropriate
Rayer les mentions inutiles.

**CERTIFICATE
ATTESTATION**

The undersigned authority has the honour to certify, in conformity with article 6 of the Convention,
L'autorité soussignée a l'honneur d'attester conformément à l'article 6 de ladite Convention,

1) that the document has been served *

1) *que la demande a été exécutée*

-- the (date) -- *le (date)* _____

-- at (place, street, number) - *à (localité, rue, numéro)* _____

-- in one of the following methods authorized by article 5:

-- *dans une des formes suivantes prévues à l'article 5:*

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention*.
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The documents referred to in the request have been delivered to:

Les documents mentionnés dans la demande ont été remis à:

- *(identity and description of person)*

- *(Identité et qualité de la personne)*

- relationship to the addressee family, business or other

- *liens de parenté de subordination ou autres avec le destinataire de l'acte:*

2) that the document has not been served, by reason of the following facts*:

2) *que la demande n'a pas été exécutée, en raison des faits suivants:*

In conformity with the second paragraph of article 12 of the Convention, the applicant is requested to pay or reimburse the expenses detailed in the attached statement*

Conformément à l'article 12, alinéa 2, de ladite Convention, le requérant est prié de payer ou de rembourser les frais dont le détail figure au mémoire ci-joint.

ANNEXES

Annexes

Documents returned:

Pieces renvoyées

In appropriate cases, documents establishing the service:

Le cas échéant, les documents justificatifs de l'exécution:

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

SUMMARY OF THE DOCUMENT TO BE SERVED
ÉLÉMENTS ESSENTIELS DE L'ACTE

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(article 5, fourth paragraph)
(article 5, alinéa quatre)

Name and address of the requesting authority:

Nom et adresse de l'autorité requérante:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, WILMINGTON, DELAWARE, USA 19801

Particulars of the parties:

Identité des parties:

DENA STROTHER AND CHRISTOPHER STROTHER (Plaintiffs) V. SANOFI U.S. Services Inc., ET AL (INTAS PHARMACEUTICALS LTD) (Defendants)

JUDICIAL DOCUMENT
ACTE JUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

LAWSUIT-COMPLAINT AND SUMMONS TO INITIATE LAWSUIT IN DELAWARE USA

Nature and purpose of the proceedings and, where appropriate, the amount in dispute:

Nature et objet de l'instance, le cas échéant, le montant du litige:

PRODUCT LIABILITY CIVIL LAWSUIT

Date and place for entering appearance:

Date et lieu de la comparution:

NAPOLI SHKOLNIK, LLC, 919 N. MARKET ST., STE. 1801, WILMINGTON, DE 19801 USA

Court which has given judgment:**

Jurisdiction qui a rendu la décision:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, USA

Dale of judgment:**

Date de la décision:

n/a-CASE HAS JUST BEGUN

Time limits stated in the document:**

Indication des délais figurant dans l'acte:

120 DAYS OF RECEIPT OF SUMMONS AND COMPLAINT

EXTRAJUDICIAL DOCUMENT
ACTE EXTRAJUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

Time limits stated in the document:**

Indication des délais figurant dans l'acte:



REQUEST FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

DEMANDE
AUX FINS DE SIGNIFICATION OU DE NOTIFICATION À L'ETRANGER
D'UN ACTE JUDICIAIRE OU EXTRAJUDICIAIRE

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Identity and address of the applicant
Identité et adresse du requérant

JAMES D. HEISMAN, ESQUIRE
NAPOLI SHKOLNIK, LLC
919 N. MARKET STREET
SUITE 1801
WILMINGTON, DE 19801

Address of receiving authority
Adresse de l'autorité destinataire

Ministère de la Justice
Bureau de l'Entraide Judiciaire Internationale
13, place Vendôme
75042 Paris Cedex 01
France

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Le requérant soussigné a l'honneur de faire parvenir--en double exemplaire--à l'autorité destinataire les documents ci-dessous énumérés, en la priant, conformément à l'article 5 de la Convention précitée, d'en faire remettre sans retard un exemplaire au destinataire, à savoir:

(identité et adresse)

SANOFI S.A., 54 rue La Boétie, 75008, Paris, FRANCE

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention.*

a) selon les formes légales (article 5 alinéa premier, lettre a).

(b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of article 5)*:

b) selon la forme particulière suivante (article 5, alinéa premier, lettre b) :

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c) le cas échéant, par remise simple (article 5, alinéa 2).

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List of documents
Énumération des pièces

Summons to Initiate lawsuit
Complaint initiating lawsuit
Form 30 Interrogatories
Order Appointing Special Process Server

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

*Delete if inappropriate
Rayer les mentions inutiles.

**CERTIFICATE
ATTESTATION**

The undersigned authority has the honour to certify, in conformity with article 6 of the Convention,
L'autorité soussignée a l'honneur d'attester conformément à l'article 6 de ladite Convention,

1) that the document has been served *

1) *que la demande a été exécutée*

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a) selon les formes légales (article 5. alinéa premier, lettre a)

(b) in accordance with the following particular method:
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- *(Identité et qualité de la personne)*

- relationship to the addressee family, business or other

- *liens de parenté de subordination ou autres avec le destinataire de l'acte:*

2) that the document has not been served, by reason of the following facts*:

2) *que la demande n'a pas été exécutée, en raison des faits suivants:*

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Conformément à l'article 12, alinéa 2, de ladite Convention, le requérant est prié de payer ou de rembourser les frais dont le détail figure au mémoire ci-joint.

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Documents returned:

Pieces renvoyées

In appropriate cases, documents establishing the service:

Le cas échéant, les documents justificatifs de l'exécution:

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

SUMMARY OF THE DOCUMENT TO BE SERVED
ÉLÉMENTS ESSENTIELS DE L'ACTE

Convention on the service abroad of judicial and extrajudicial documents In civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

(article 5, fourth paragraph)
(article 5, alinéa quatre)

Name and address of the requesting authority:

Nom et adresse de l'autorité requérante:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, WILMINGTON, DELAWARE, USA 19801

Particulars of the parties:

Identité des parties:

DENA STROTHER AND CHRISTOPHER STROTHER (Plaintiffs) V. SANOFI S.A., ET AL (Sanofi S.A.) (Def

JUDICIAL DOCUMENT
ACTE JUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

LAWSUIT-COMPLAINT AND SUMMONS TO INITIATE LAWSUIT IN DELAWARE USA

Nature and purpose of the proceedings and, where appropriate, the amount in dispute:

Nature et objet de l'instance, le cas échéant, le montant du litige:

PRODUCT LIABILITY CIVIL LAWSUIT

Date and place for entering appearance:

Date et lieu de la comparution:

NAPOLI SHKOLNIK, LLC, 919 N. MARKET ST., STE. 1801, WILMINGTON, DE 19801 USA

Court which has given judgment:**

Jurisdiction qui a rendu la décision:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, USA

Dale of judgment:**

Date de la décision:

n/a-CASE HAS JUST BEGUN

Time limits stated in the document:**

Indication des délais figurant dans l'acte:

120 DAYS OF RECEIPT OF SUMMONS AND COMPLAINT

EXTRAJUDICIAL DOCUMENT
ACTE EXTRAJUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

Time limits stated in the document:**

Indication des délais figurant dans l'acte:



REQUEST FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

DEMANDE
AUX FINS DE SIGNIFICATION OU DE NOTIFICATION À L'ÉTRANGER
D'UN ACTE JUDICIAIRE OU EXTRAJUDICIAIRE

Convention on the service abroad of judicial and extrajudicial documents in civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

Identity and address of the applicant
Identité et adresse du requérant

JAMES D. HEISMAN, ESQUIRE
NAPOLI SHKOLNIK, LLC
919 N. MARKET STREET
SUITE 1801
WILMINGTON, DE 19801

Address of receiving authority
Adresse de l'autorité destinataire

Registrar of the Supreme Court
Supreme Court Registry
No. 84 Main Street
P.O. Box 418
Road Town, Tortola,
British Virgin Islands VG1110

The undersigned applicant has the honour to transmit -- in duplicate-- the documents listed below and, in conformity with article 5 of the above-mentioned Convention, requests prompt service of one copy thereof on the addressee, i.e., (identity and address)

Le requérant soussigné a l'honneur de faire parvenir--en double exemplaire--à l'autorité destinataire les documents ci-dessous énumérés, en la priant, conformément à l'article 5 de la Convention précitée, d'en faire remettre sans retard un exemplaire au destinataire, à savoir:

(identité et adresse)

Sun Pharma Global Inc., P.O. Box 659, Road Town, British Virgin Islands

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention.*

a) selon les formes légales (article 5 alinéa premier, lettre a).

(b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of article 5)*:

b) selon la forme particulière suivante (article 5, alinéa premier, lettre b) :

(c) by delivery to the addressee, if he accepts it voluntarily (second paragraph of article 5)*:

c) le cas échéant, par remise simple (article 5, alinéa 2).

The authority is requested to return or to have returned to the applicant a copy of the documents and of the annexes with a certificate as provided on the reverse side.

Cette autorité est priée de renvoyer ou de faire renvoyer au requérant un exemplaire de l'acte - et de ses annexes - avec l'attestation figurant au verso.

List of documents
Énumération des pièces

Summons to initiate Lawsuit
Complaint for Lawsuit
Form 30 Interrogatories
Order Appointing Special Process Server

Done at _____, the
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

*Delete if inappropriate
Rayer les mentions inutiles.

**CERTIFICATE
ATTESTATION**

The undersigned authority has the honour to certify, in conformity with article 6 of the Convention,
L'autorité soussignée a l'honneur d'attester conformément à l'article 6 de ladite Convention,

1) that the document has been served *

1) *que la demande a été exécutée*

-- the (date) -- *le (date)* _____

-- at (place, street, number) - *à (localité, rue, numéro)* _____

-- in one of the following methods authorized by article 5:

-- *dans une des formes suivantes prévues à l'article 5:*

(a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention*.
a) selon les formes légales (article 5. alinéa premier, lettre a)

(b) in accordance with the following particular method:
b) selon la forme particulière suivante: _____

(c) by delivery to the addressee, who accepted it voluntarily.*
c) par remise simple.

The documents referred to in the request have been delivered to:

Les documents mentionnés dans la demande ont été remis à:

- *(identity and description of person)*

- *(Identité et qualité de la personne)*

- relationship to the addressee family, business or other

- *liens de parenté de subordination ou autres avec le destinataire de l'acte:*

2) that the document has not been served, by reason of the following facts*:

2) *que la demande n'a pas été exécutée, en raison des faits suivants:*

In conformity with the second paragraph of article 12 of the Convention, the applicant is requested to pay or reimburse the expenses detailed in the attached statement*

Conformément à l'article 12, alinéa 2, de ladite Convention, le requérant est prié de payer ou de rembourser les frais dont le détail figure au mémoire ci-joint.

ANNEXES

Annexes

Documents returned:

Pieces renvoyées

In appropriate cases, documents establishing the service:

Le cas échéant, les documents justificatifs de l'exécution:

Done at _____, the _____
Fait à _____, le _____

Signature and/or stamp
Signature et/ou cachet

SUMMARY OF THE DOCUMENT TO BE SERVED
ÉLÉMENTS ESSENTIELS DE L'ACTE

Convention on the service abroad of judicial and extrajudicial documents In civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

(article 5, fourth paragraph)
(article 5, alinéa quatre)

Name and address of the requesting authority:

Nom et adresse de l'autorité requérante:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, WILMINGTON, DELAWARE, USA 19801

Particulars of the parties:

Identité des parties:

DENA STROTHER AND CHRISTOPHER STROTHER (Plaintiffs) V. SANOFI U.S. Services Inc., ET AL (Sur

JUDICIAL DOCUMENT
ACTE JUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

LAWSUIT-COMPLAINT AND SUMMONS TO INITIATE LAWSUIT IN DELAWARE USA

Nature and purpose of the proceedings and, where appropriate, the amount in dispute:

Nature et objet de l'instance, le cas échéant, le montant du litige:

PRODUCT LIABILITY CIVIL LAWSUIT

Date and place for entering appearance:

Date et lieu de la comparution:

NAPOLI SHKOLNIK, LLC, 919 N. MARKET ST., STE. 1801, WILMINGTON, DE 19801 USA

Court which has given judgment:**

Jurisdiction qui a rendu la décision:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, USA

Dale of judgment:**

Date de la décision:

n/a-CASE HAS JUST BEGUN

Time limits stated in the document:**

Indication des délais figurant dans l'acte:

120 DAYS OF RECEIPT OF SUMMONS AND COMPLAINT

EXTRAJUDICIAL DOCUMENT
ACTE EXTRAJUDICIAIRE

Nature and purpose of the document:

Nature et objet de l'acte:

Time limits stated in the document:**

Indication des délais figurant dans l'acte:



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER and CHRISTOPHER STROTHER,

Plaintiffs,

v.

C.A. No. N16C-12-422 VLM

SANOFI U.S. SERVICES INC., formerly known as SANOFI-AVENTIS U.S., INC.; SANOFI-AVENTIS U.S. LLC, separately and doing business as WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.; SUN PHARMA GLOBAL INC.; McKESSON CORPORATION doing business as McKESSON PACKAGING; SANDOZ INC.; ACCORD HEALTHCARE LTD.; ACCORD HEALTHCARE, INC.; INTAS PHARMACEUTICALS LIMITED; SANOFI S.A.; AVENTIS PHARMA S.A.; and DOES, INC.,

Defendants.

NOTICE OF FILING OF NOTICE OF REMOVAL

**TO: Clerk of the Court,
Superior Court of the State of Delaware**

PLEASE TAKE NOTICE that, on January 5, 2017, Defendant sanofi-aventis U.S. LLC filed in the United States District Court for the District of Delaware a Notice of Removal in the above-captioned action, a copy of which is attached hereto as Exhibit 1 and which was served contemporaneously with this Notice.

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
Attorneys for Defendant
sanofi-aventis U.S. LLC

Dated: January 5, 2017

OF COUNSEL:

SHOOK, HARDY & BACON L.L.P.
Harley V. Ratliff, Esq.
2555 Grand Blvd.
Kansas City, Missouri 64108
Tel.: (816) 474-6550
Fax: (816) 421-5547
hratliff@shb.com

CERTIFICATE OF SERVICE

I, Christopher Viceconte, hereby certify that, on this 5th day of January 2017, a true and correct copy of Defendant sanofi-aventis U.S. LLC's Notice of Filing of Notice of Removal was served via File and ServeXpress upon Plaintiffs' counsel of record as follows:

James D. Heisman, Esq.
NAPOLI SHKOLNIK LLC
919 North Market Street, Suite 1801
Wilmington, Delaware 19801
Attorneys for Plaintiffs

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte, Esq. (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
*Attorneys for Defendant
sanofi-aventis U.S. LLC*

Dated: January 5, 2017

EFiled: Jan 05 2017 11:55AM EST
Transaction ID 60024568
Case No. N16C-12-422 VLM



EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

DENA STROTHER and CHRISTOPHER STROTHER,

Plaintiffs,

v.

C.A. No. _____

SANOFI U.S. SERVICES INC., formerly known as SANOFI-AVENTIS U.S., INC; SANOFI-AVENTIS U.S. LLC, separately and doing business as WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.; SUN PHARMA GLOBAL INC.; McKESSON CORPORATION doing business as McKESSON PACKAGING; SANDOZ INC.; ACCORD HEALTHCARE LTD.; ACCORD HEALTHCARE, INC.; INTAS PHARMACEUTICALS LIMITED; SANOFI S.A.; AVENTIS PHARMA S.A.; and DOES, INC.,

Defendants.

DEFENDANT SANOFI-AVENTIS U.S. LLC'S NOTICE OF REMOVAL

Defendant sanofi-aventis U.S. LLC¹ hereby files this Notice of Removal pursuant to 28 U.S.C. §§ 1332, 1441, and 1446 and states as follows:

THE REMOVED ACTION

1. On December 30, 2016, Plaintiffs Dena Strother and Christopher Strother ("Plaintiffs") filed a Complaint and Demand for Jury Trial in the Superior Court of the State of Delaware, which was assigned Civil Action No. N16C-12-422 VLM. Pursuant to 28 U.S.C. §

¹ No Defendant has been served in this matter. Regardless, this Notice of Removal is solely on sanofi-aventis U.S. LLC's behalf and not on behalf of Sanofi U.S. Services Inc., Sanofi S.A., or Aventis Pharma S.A. This Notice of Removal does not waive the rights of Sanofi U.S. Services Inc., Sanofi S.A. or Aventis Pharma S.A.

1446(a), a true and legible copy of Plaintiffs' Civil Action Complaint is attached hereto as "Exhibit A."

2. This action is a pharmaceutical product liability case in which Ms. Strother alleges that she sustained injuries as a result of receiving Taxotere. *See* Complaint ("Ex. A") ¶ 42. Mr. Strother alleges the loss of Ms. Strother's "companionship and society." *Id.* ¶ 145.

3. Neither sanofi-aventis U.S. LLC nor any other Defendant has been served yet in this matter. This Removal is thus timely pursuant to 28 U.S.C. § 1446(b). Sanofi-aventis U.S. LLC has not previously filed a Notice of Removal of this matter in this Court.

4. No further pleadings have been filed, and no proceedings have yet occurred in the state court action.

GROUND FOR REMOVAL

5. Under 28 U.S.C. § 1332, this Court has original jurisdiction over Plaintiffs' action. As explained below, there is complete diversity between the parties and the amount in controversy exceeds \$75,000.00. Thus, removal is proper pursuant to 28 U.S.C. § 1441.

DIVERSITY OF CITIZENSHIP EXISTS

6. Diversity of citizenship exists when a suit is between citizens of different states or citizens of a state and citizens of a foreign state. 28 U.S.C. § 1332 (a)(1)-(2).

7. There is complete diversity of citizenship between Plaintiffs and all Defendants:

a) Plaintiffs are citizens of the State of South Carolina. *See* Ex. A ¶¶ 1-2.

b) Under 28 U.S.C. § 1332(c)(1), "a corporation shall be deemed to be a citizen of any State by which it has been incorporated and of the State where it has its principal place of business. . . ." For purposes of diversity jurisdiction, the citizenship of an LLC is that of its members. *Zambelli Fireworks Mfg. Co., Inc. v. Wood*, 592

F.3d 412, 420 (3d Cir. 2010) (stating that every circuit court to have considered the issue has held that the citizenship of an LLC is determined by the citizenship of its members, and joining in that holding).

c) Defendants are all alleged to be citizens of states other than South Carolina. *See* Ex. A ¶¶ 3, 12, 16, 22, 24, 34-35, 37-41.

d) Defendant sanofi-aventis U.S. LLC is a Delaware limited liability company with its principal place of business in New Jersey. Ex. A ¶ 12. Sanofi U.S. Services Inc. is the sole member of sanofi-aventis U.S. LLC. Sanofi U.S. Services Inc. is a Delaware corporation with its principal place of business in New Jersey. Ex. A ¶ 3.

e) Sanofi S.A. is a French corporation with its principal place of business in France. Ex. A ¶ 16.

f) Aventis Pharma S.A. is a French corporation with its principal place of business in France. Ex. A ¶ 22.

g) Hospira Worldwide, Inc. is alleged to be a Delaware corporation with its principal place of business in Illinois. Ex. A ¶ 34.

h) Sun Pharma Global Inc. is alleged to be a British Virgin Islands corporation with its principal place of business in the British Virgin Islands. Ex. A ¶ 35.

i) McKesson Corporation is alleged to be a Delaware corporation with its principal place of business in California. Ex. A ¶ 37.

j) Sandoz, Inc. is alleged to be a Colorado corporation with its principal place of business in New Jersey. Ex. A ¶ 38.

k) Accord Healthcare LTD. is alleged to be an English and Wales company with its principal place of business in the United Kingdom. Ex. A ¶ 39.

l) Accord Healthcare Inc. is alleged to be a North Carolina corporation with its principal place of business in North Carolina. Ex. A ¶ 40.

m) Intas Pharmaceuticals Ltd. is alleged to be an Indian company with its principal place of business in India. Ex. A ¶ 41.

8. Because Plaintiffs and Defendants are citizens of different states, there is complete diversity of citizenship for jurisdiction purposes.

9. Further, as stated above, no Defendant has been served at the time of the filing of this Notice. Therefore, consent from the other above named Defendants is unnecessary. *Lewis v. Rego Co.*, 757 F.2d 66, 68-69 (3d Cir. 1985) (finding that defendant who has not been served need not consent to removal).

THE AMOUNT IN CONTROVERSY EXCEEDS \$75,000

10. Although the Complaint seeks unspecified compensatory and punitive damages, it is apparent that the amount in controversy exceeds \$75,000.00. *See Angus v. Shiley, Inc.*, 989 F.2d 142, 146 (3d Cir. 1993) (“[T]he amount in controversy is not measured by the low end of an open-ended claim, but rather by a reasonable reading of the value of the rights being litigated.”). Ms. Strother alleges that she suffered various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of her use of Taxotere. Mr. Strother alleges the loss of Ms. Strother’s “companionship and society,” and that he has been caused great mental anguish. Plaintiffs seek both compensatory and punitive damages. *See Ex. A.*

11. Given the nature and extent of Plaintiffs’ alleged injuries and damages, Plaintiffs’ Complaint places at issue more than \$75,000, exclusive of interest and costs. *See Aloise v. Giant*

of *Md., LLC*, No. CIV. 12-00897-LPS, 2013 WL 1222776, at *2 (D. Del. Mar. 26, 2013) (although plaintiff sought “an indeterminate amount of damages,” amount in controversy satisfied when plaintiff alleged “painful, permanent, and disabling injuries . . . [and] substantial medical expenses”).

12. Plaintiffs’ claim for damages therefore exceeds the requisite amount in controversy for purposes of diversity jurisdiction under 28 U.S.C. § 1332(a).

**REMOVAL IS PROPER BECAUSE NO FORUM
DEFENDANT HAS BEEN SERVED WITH PROCESS**

13. Pursuant to 28 U.S.C. § 1441(b), this action is removable because no party in interest properly joined and served as a defendant is a citizen of the State of Delaware, the state in which this action was brought (a “forum defendant”). *See* 28 U.S.C. § 1441(b) (providing that non-federal question cases “shall be removable only if none of the parties in interest properly joined *and served* as defendants is a citizen of the State in which the action is brought”) (emphasis added).

14. No Defendant, including any forum defendant, has been served. Removal is proper where there is complete diversity, but no forum defendant has been served. Certain decisions from this Court and other District Courts in this Circuit have applied the plain language of the removal statute to permit removal of an action before a forum defendant is served. *See Munchel v. Wyeth LLC*, No. CIV.A. 12-906-LPS, 2012 WL 4050072, at *4 (D. Del. Sept. 11, 2012) (denying plaintiff’s motion to remand when forum defendant removed case prior to being served); *Hutchins v. Bayer Corp.*, No. 08-640-LPS, 2009 WL 192468, at *11 (D. Del. Jan. 23, 2009) (denying plaintiffs’ motion to remand when non-forum defendant removed case prior to forum defendant being served stating “the language of § 1441(b) is plain and unambiguous: a case involving diversity jurisdiction ‘shall be removable’ if none of the forum defendants have

been ‘properly joined and served.’”); *see also Valido-Shade v. Wyeth, LLC*, No. 12-2003, 2012 WL 2861113, at *2 (E.D. Pa. Jul. 11, 2012); *Boyer v. Wyeth Pharm., Inc.*, No. 12-739, 2012 WL 1449246, at *2 (E.D. Pa. Apr. 26, 2012). *But see Stefan v. Bristol-Myers Squibb Co.*, No. 13-1662-RGA, 2013 WL 6354588, at *3-5 & n.2 (D. Del. Dec. 6, 2013); *Laugelle v. Bell Helicopter Textron*, No. 10-1080-GMS, 2012 WL 368220, at *2-3 (D. Del. Feb. 2, 2012) (both remanding upon holding that removal prior to service on forum defendants was improper).

15. Congress has enacted legislation reaffirming that an action may be removed on the basis of diversity jurisdiction when a forum defendant is not properly joined or served at the time of removal. The Federal Courts Jurisdiction and Venue Clarification Act of 2011 amended the removal and remand procedures in 28 U.S.C. § 1441, but retained the language in section 1441(b) that bars removal only if any “of the parties in interest *properly joined and served* as defendants is a citizen of the State in which such action is brought.” *See* Federal Courts Jurisdiction and Venue Clarification Act of 2011, Pub. L. No. 112-63 § 103, 125 Stat. 758, 760 (2011) (emphasis added).

16. Relying on the language of Section 1441(b), in *Hutchins v. Bayer Corp.*, the District of Delaware denied plaintiffs’ motion for remand where a properly joined and served non-forum defendant removed the action before the alleged forum defendant had been properly joined and served. 2009 WL 192468, at *11; *see also Valido-Shade*, 2012 WL 2861113, at *4; *Vanderwerf v. GlaxoSmithKline, PLC*, No. 05-1315, 2005 WL 6151369, at *1 (E.D. Pa. May 5, 2005); *Thomson v. Novartis Pharms. Corp.*, No. 06-6280, 2007 WL 1521138, at *4 (D.N.J. May 22, 2007). The *Hutchins* court found that “nothing about permitting removal in the circumstances presented here disrupts [the purpose of § 1441(b)]” or “conflict[s] with Congressional intent.” 2009 WL 192468, at *7.

17. In *Munchel v. Wyeth LLC*, this District Court considered whether removal was proper when a forum defendant removed the action before any forum defendant had been properly joined and served. Relying on the plain language of Section 1441(b) and Congress's amendment of the removal statute, the court denied the plaintiff's motion for remand. 2012 WL 4050072, at *3-4 ("The undersigned judge continues to adhere to the views expressed in *Hutchins* [on the plain language of Section 1441(b)] [T]he amendment reinforces the conclusion that Congress intended for the plain language of the statute to be followed.").

18. Here, because Plaintiffs have not served any Defendant, any such Defendant's alleged citizenship in Delaware is not an impediment to removal under 28 U.S.C. § 1441(b).

REMOVAL IS OTHERWISE PROPER

19. Removal to this District is proper because the Superior Court of the State of Delaware is within the District of Delaware. 28 U.S.C. §§ 1441(a), 1446(a).

20. Pursuant to 28 U.S.C. § 1446(d), sanofi-aventis U.S. LLC shall give Plaintiffs written notice of the filing of this Notice of Removal.

21. Pursuant to 28 U.S.C. § 1446(d), sanofi-aventis U.S. LLC shall file the written notice of the filing of this Notice of Removal with the Superior Court of the State of Delaware, attaching as Exhibit A thereto a copy of this Notice of Removal and the documents attached to this Notice of Removal.

WHEREFORE, sanofi-aventis U.S. LLC hereby gives notice that the above entitled state court action, formerly pending in the Superior Court of the State of Delaware, has been removed to the United States District Court for the District of Delaware.

Dated: January 5, 2017

Respectfully submitted,

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
Attorneys for Defendant
sanofi-aventis U.S. LLC

OF COUNSEL:

SHOOK, HARDY & BACON L.L.P.
Harley V. Ratliff, Esq.
2555 Grand Blvd.
Kansas City, Missouri 64108
Tel.: (816) 474-6550
Fax: (816) 421-5547
hratliff@shb.com

CERTIFICATION OF FILING AND SERVICE

I, Christopher Viceconte, hereby certify that, on this 5th day of January 2017, two (2) true and correct copies of Defendant's Notice of Removal, along with a Notice to Adversary of Filing of Notice of Removal and a Notice of Filing of Notice of Removal in the forms attached to the Notice of Removal as Exhibit B, and Copies of All Process, Pleadings and Orders in State Court, as attached to the Notice of Removal as Exhibit A, were served via hand delivery or Federal Express overnight delivery upon counsel of record for Plaintiffs as follows:

James D. Heisman (#2746)
NAPOLI SHKOLNIK LLC
919 North Market Street, Suite 1801
Wilmington, Delaware 19801
Attorneys for Plaintiffs

I further certify that a true and correct courtesy copy of the foregoing Notice of Removal, and its attached Exhibits, will be filed with the Clerk of the United States District Court for the District of Delaware in accordance with Local Civil Rule 5.3.

I further certify that a copy of the foregoing Notice of Removal, and its attached Exhibits, will be filed with the Clerk of the Superior Court of the State of Delaware upon receipt of the same from the United States District Court for the District of Delaware.

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
Attorneys for Defendant
sanofi-aventis U.S. LLC

Dated: January 5, 2017

EXHIBIT A

EFiled: Dec 30 2016 07:54AM EST
Transaction ID 60007313
Case No. N16C-12-422 VLM



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER AND CHRISTOPHER STROTHER,)

Plaintiffs,)

v.)

SANOFI U.S. SERVICES INC., formerly known as)
SANOFI-AVENTIS U.S. INC; SANOFI-AVENTIS U.S.)
LLC, separately and doing business as WINTHROP U.S.;)
HOSPIRA WORLDWIDE, INC.; SUN PHARMA)
GLOBAL INC.; McKESSON CORPORATION doing)
business as McKESSON PACKAGING; SANDOZ INC.;)
ACCORD HEALTHCARE LTD.; ACCORD)
HEALTHCARE, INC.; INTAS PHARMACEUTICALS)
LIMITED; SANOFI S.A.; AVENTIS PHARMA S.A.; and)
DOES, INC.)

Defendants.)

C.A. No.
Jury Trial Demanded

COMPLAINT

COMMON ALLEGATIONS

A. PARTIES

1. At all times relevant hereto, Plaintiff Dena Strother (“Plaintiff” or “Dena Strother”) was a resident of the state of South Carolina.

2. At all times relevant hereto, Plaintiff Christopher Strother (“Spousal Plaintiff”), was a resident of the state of South Carolina and the spouse of Plaintiff.

3. Sanofi U.S. Services Inc., f/k/a Sanofi-Aventis U.S. Inc., is incorporated under the laws of the State of Delaware, with its principal place of business located at 55 Corporate Dr., Bridgewater, NJ 08807.

4. Upon information and belief, Sanofi U.S. Services Inc., is a wholly owned

subsidiary of Sanofi-Aventis, and is one of the largest pharmaceutical companies in the United States.

5. Sanofi U.S. Services Inc. develops products in therapeutic areas including cardiovascular disease, central nervous systems, internal medicine, metabolic disorder, oncology, ophthalmology, and thrombosis.

6. The predecessor to Sanofi U.S. Services Inc. was founded in 1950 and until 2006, was known as Sanofi-Aventis U.S. Inc.

7. Sanofi U.S. Services Inc. develops, manufactures, markets, and distributes pharmaceutical products in the United States.

8. Sanofi U.S. Services Inc. operates pharmaceutical research sites in Bridgewater, NJ, Malvern, PA, Cambridge MA, and Tucson, AZ.

9. Sanofi U.S. Services Inc. has a distribution center in Forest Park, GA, a manufacturing facility in Kansas City, MO, and a packaging services facility in St. Louis, MO.

10. Sanofi U.S. Services Inc. markets its parent's products in the U.S. through its substantial number of field sales professionals.

11. One of Sanofi U.S. Services Inc.'s key products is the cancer treatment drug, Taxotere (docetaxel).

12. Sanofi-Aventis U.S. LLC is a limited liability company, formed under the laws of the State of Delaware, with its principal place of business located at 55 Corporate Dr., Bridgewater, NJ 08807.

13. Sanofi-Aventis U.S. LLC is a healthcare company that was founded in 1999 and discovers, develops, produces, and markets therapeutic solutions focused on patients' needs in the United States.

14. Upon information and belief, Sanofi-Aventis U.S. LLC is one of the current holders of the approved New Drug Application (“NDA”) and supplemental NDAs for Taxotere.

15. Upon information and belief, Defendant Sanofi-Aventis U.S. LLC sometimes operates, promotes, markets, sells, distributes pharmaceutical products, and does business under the name Winthrop U.S., which is a division within Sanofi-Aventis U.S. LLC.

16. Defendant Sanofi S.A. is a corporation, or “Société Anonyme,” under the laws of France, with its principal place of business located at 54 rue La Boétie, 75008 Paris, France.

17. Upon information and belief, Sanofi S.A. is a global pharmaceutical parent company that operates in the United States, through an intricate network of approximately 400 wholly owned subsidiaries, including Aventis Pharma S.A. and Sanofi-Aventis U.S.

18. Upon information and belief, Sanofi S.A.’s predecessor was from a subsidiary of a French oil company that acquired the Labaz Group Pharmaceutical Company. This entity, in or about May of 1999, merged with a Delaware incorporated pharmaceutical company named Synthélabo Inc.

19. Upon information and belief, at all relevant times hereto, Synthélabo had its principal place of business located at 90 Park Avenue, New York, New York 10016.

20. Upon information and belief, Aventis was formed when a French company, Rhone-Poulenc S.A., merged with a German corporation Hoechst Marion Roussel.

21. Upon information and belief, Aventis merged with Sanofi-Synthélabo, to become Sanofi-Aventis S.A. which later changed its name to Sanofi S.A. on or about May 6, 2011.

22. Defendant Aventis Pharma S.A. is a corporation, or “Société Anonyme,” under the laws of France, with its principal place of business located at 20 avenue Raymond Aron, 92160 Antony, France.

23. Upon information and belief, on or about March of 1989, Sanofi S.A. acquired 100% of the shares and/or financial interest of Aventis Pharma S.A. and has directed and controlled the operations and activities of Aventis Pharma S.A. and since March of 1989, Aventis Pharma S.A. has been a wholly owned subsidiary of Sanofi S.A.

24. Defendant Sanofi-Aventis U.S. LLC is a limited liability company formed under the laws of the State of Delaware, with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

25. Upon information and belief, Sanofi-Aventis U.S. LLC was formed on or about June 28, 2000 under the laws of the State of Delaware.

26. At all times relevant hereto, according to Sanofi S.A.’s Form 20-F filed with the U.S. Securities and Exchange Commission for the fiscal year ending on December 31, 2014, Defendant Sanofi-Aventis U.S. was a wholly owned subsidiary of Defendant Sanofi S.A. and was the only member and owned 100% of the membership interest of Sanofi-Aventis U.S.

27. Upon information and belief, Taxotere (docetaxel) was invented and developed by the predecessor to Aventis Pharma S.A. and also was the holder of the initial patent disclosing the formulation and computation of Taxotere (docetaxel).

28. At all times relevant hereto, Defendants Sanofi S.A., Aventis Pharma S.A., and/or Sanofi-Aventis U.S. LLC were engaged in transactions and conducted business within the State of Delaware and has derived substantial revenue from goods and products disseminated and used in the State of Delaware. At all times relevant hereto, as part of its

business, Sanofi S.A., Aventis Pharma S.A., and/or Sanofi-Aventis U.S. LLC were involved in researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel) to the public, including the Plaintiff.

29. At all times relevant hereto, Defendants worked in conjunction with each other and they were affiliated, related, jointly owned, and/or controlled entities or subsidiaries during the researching, analyzing, licensing, designing, testing, formulating, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling the prescription drug known as Taxotere (docetaxel).

30. Defendants Sanofi S.A., Aventis Pharma S.A. and Sanofi-Aventis U.S. LLC, shall be referred to herein individually by name or jointly as “Defendants.”

31. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

32. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

33. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into

interstate commerce throughout the United States, which necessarily includes Delaware, either directly or indirectly through third parties, subsidiaries or related entities, the drug Taxotere.

34. Upon information and belief, Defendant Hospira Worldwide, Inc., (“Hospira”), is incorporated under the laws of the State of Delaware, with its principal place of business located at 275 N. Field Drive, Lake Forest, Illinois 60045.

35. Sun Pharma Global Inc. (“Sun Pharma”), is a foreign company formed under the International Business Companies Act, Cap. 291 of British Virgin Islands with its principal place of business at International Trust Building, Road Town, British Virgin Islands and has the mailing address of P.O. Box 659, Road Town, British Virgin Islands.

36. Upon information and belief, Sun Pharmaceuticals Industries LTD. is the parent company of Sun Pharma Global Inc.

37. Defendant McKesson Corporation, doing business as McKesson Packaging, (“McKesson”) is a corporation formed under the laws of the State of Delaware with its principal place of business located at One Post Street, San Francisco, California 94104.

38. Defendant Sandoz, Inc. (“Sandoz”) is incorporated under the laws of the State of Colorado, with its principal place of business located at 100 College Road West, Princeton, New Jersey 08540.

39. Upon information and belief, Defendant Accord Healthcare LTD., is a company through the Registrar of Companies for England and Wales with its principal place of business located at Sage House, 319 Pinner Road, North Harrow HA1 4HF, United Kingdom.

40. Accord Healthcare, Inc. (“Accord”) is a corporation formed under the laws of the State of North Carolina with its principal place of business located at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

41. Upon information and belief, Defendant Intas Pharmaceuticals LTD. was formed under the laws of India and has its principal place of business located at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmebadad, 380009, Gujarat, India.

B. NATURE OF THE CASE

42. Plaintiffs brings this case against Sanofi U.S. Services Inc., Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi S.A. (herein collectively referred to as the “Sanofi Defendants”) and/or Winthrop U.S. LLC., and/or Hospira Worldwide Inc., and/or Sun Pharma Global Inc., and/or McKesson Corporation doing business as McKesson Packaging, and/or Sandoz Inc., and/or Accord Healthcare LTD., and/or Accord Healthcare Inc., and/or Intas Pharmaceuticals Limited (herein collectively referred to as “Generic non-bioequivalent Defendants”), for damages associated with the Plaintiff’s infusion of the pharmaceutical drug Taxotere (docetaxel), which was designed, manufactured, marketed, sold and/or distributed by Defendants. Specifically, Plaintiff suffered various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of Plaintiff’s use of Taxotere (docetaxel) and/or its generic non-bioequivalent.

43. At all relevant times, all Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and/or distribute Taxotere (docetaxel) to treat various forms of cancer, including but not limited to breast cancer.

44. Taxotere (docetaxel) was developed, manufactured, researched, marketed, tested, advertised, promoted, and sold by Sanofi Defendants and began enrolling test patients in or about 1990 in the Phase 1 clinical trial also known as “TAX 001” study.

45. Taxotere is a part of the chemotherapy family of drugs known as “Taxanes.” Taxanes are a type of chemicals called “diterpenoids,” which specifically contain a taxadiene core within the molecule, which is produced by yew trees.

46. Taxanes are widely used as chemotherapy agents, and several taxanes are available for cancer treatment, including but not limited to Taxol, generically known as paclitaxel, Jevtana, generically known as cabazitaxel, and of course Taxotere, generically known as docetaxel.

47. Upon information and belief, the TAX 001 study concluded in or about May 1992 and subsequently reported in or about May 1994.

48. Taxol (paclitaxel) was developed, manufactured, distributed, and marketed by Bristol Meyers Squibb (BMS) and was first approved by the U.S. Food and Drug Administration (FDA) in December of 1992.

49. Upon information and belief, Aventis Pharma S.A., sought FDA approval for Taxotere in or about December of 1994 and the FDA’s Oncologic Drugs Advisory Committee Panel had unanimously recommended the rejection of the approval for Taxotere because the Taxotere was more toxic than Taxol, and recommended more testing and studies for Taxotere’s side effects.

50. On or about May 14, 1996, Sanofi Defendants obtained FDA approval for the “treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.”

51. Sanofi Defendants continued to seek additional indications for Taxotere and based on self-sponsored clinical trials, Sanofi Defendants alleged superiority over other

chemotherapy products approved for the treatment of breast cancer. Sanofi Defendants' marketing claims included superior efficacy over the lower potency Taxanes, including Taxol.

52. Despite Sanofi Defendants' claims of superior efficacy, post market surveillance demonstrated that the more potent and more toxic Taxotere, in fact, did not have higher efficacy or benefits compared to the other Taxanes and Defendants concealed the existence of studies from the FDA, physicians, patients, and the public that refuted Sanofi Defendants' claims and advertisements of superior efficacy.

53. In or about August of 2007, the journal, *Cancer Treatment Review*, published a comparison of the relative efficacy of Taxanes in the treatment of breast cancer. This study concluded that there were no significant differences between the efficacy and outcomes obtained from Taxotere treatment and Taxol treatment.

54. In or about April of 2008, the *New England Journal of Medicine* published a study titled, *Weekly Paclitaxel in the Adjuvant Treatment of Breast Cancer*, which concluded that Taxol was more effective than Taxotere for patients undergoing the standard adjuvant chemotherapy with doxorubicin and cyclophosphamide.

55. Sanofi Defendants continued to make false and misleading statements, promoting the "superior efficacy" of Taxotere over the competing product Taxol, despite the studies that concluded otherwise. Specifically, in or about June 2008, Sanofi-Aventis used a "reprint carrier" citing a clinical study published in August of 2005 from the *Journal of Clinical Oncology* that concluded Taxotere had superior efficacy compared to Taxol "providing significant clinical benefit in terms of survival and time to disease progression, with a numerically higher response rate and manageable toxicities" in the marketing and promotional materials for Taxotere.

56. Sanofi Defendants' statements in the "reprint carrier" materials highlighting the conclusions of the 2005 study were false and/or misleading due to the 2007 and 2008 studies finding Taxotere was not more effective than Taxol in the treatment of breast cancer.

57. Consequently, on or about April 16, 2009, Keith Olin, from the FDA Division of Drug Marketing, Advertising, and Communications (DDMAC), issued a warning letter to MaryRose Salvacion, the Director of US Regulatory Affairs Marketed Products for Sanofi-Aventis, regarding the NDA #20-449, Taxotere (docetaxel). In this letter, the DDMAC stated:

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)

58. In addition, a Qui Tam lawsuit was filed against Sanofi-Aventis and its affiliates in the U.S. District Court for the Eastern District of Pennsylvania, by a former employee stating Sanofi-Aventis and its affiliates engaged in fraudulent marketing schemes, paid kickbacks, and provided other unlawful incentives to entice physicians to use docetaxel. *See U.S. dx rel. Ghoil v. Sanofi-Aventis U.S. Inc.*, CA No. 02-2964 (E.D. Pa. 2015).

59. Beginning in or around 1996, Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S., LLC, Sanofi U.S. Services, Inc., and their predecessors and affiliates, designed, directed, and/or engaged in a marketing plot that promoted Taxotere for indications not approved by the

FDA, also known as off label promotion. The plot had two prongs. The first prong was training and directing employees to misrepresent the safety and effectiveness of the off-label use of Taxotere, to get a foothold in other types of cancer treatment markets. The other prong was paying healthcare providers illegal kickbacks in the form of grants, speaker fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free reimbursement assistance to incentivize healthcare providers to prescribe Taxotere for off label treatment.

60. The Sanofi Defendants fraudulent marketing and illegal kickback scheme increased the Taxotere the revenue of sales by approximately one billion dollars from 2000's \$424 million to 2004's \$1.4 billion. *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 508 (E.D. Pa. 2015).

61. Sanofi Defendants' fraudulent and illegal conduct drastically increased the number of victims to be exposed to a more toxic chemotherapy treatment with no better efficacy than less toxic chemotherapy treatments already available.

62. Sanofi Defendants' fraudulent and illegal conduct caused thousands of individuals to be exposed to more frequent and/or more severe side effects, including but not limited to disfiguring and permanent alopecia (hair loss).

C. SANOFI DEFENDANTS' COVER UP OF THE KNOWN RISK OF PERMANENT HAIR LOSS

63. It is well known that cancer treatments like radiation and chemotherapy can cause temporary hair loss during treatment. However, permanent alopecia is not common place. Sanofi Defendants, through their marketing and promotional materials, misled the medical community, the public, and the Plaintiff, to believe Taxotere, as with other chemotherapy treatment, would cause temporary hair loss, but that the hair would grow back.

64. Sanofi Defendants knew, or should have known, that the rate of permanent alopecia related to Taxotere (docetaxel) was far greater than with other chemotherapy treatments for the same conditions as Taxotere (docetaxel).

65. Permanent alopecia, hair loss, is disfiguring, especially for women. Women who experienced this disfigurement as a result of the use of Taxotere suffered and continue to suffer great mental anguish, as well as economic damage, including but not limited to, loss of work or inability due to work due to significant psychological damage.

66. Women might have accepted the possibility of permanent baldness as a result of exposure to Taxotere if no other treatment were available for their cancer. However, this is not the case.

67. There were similar products on the market that were at least as effective as Taxotere and did not subject the female users to the same risk of disfiguring levels of alopecia.

68. Plaintiff would not have agreed to Taxotere treatment if the true risk of permanent alopecia was made available to her.

69. Beginning in the late 1990's, Sanofi Defendants sponsored, and/or were aware of the GEICAM 9805 study. By 2005, Sanofi Defendants' knew that the GEICAM 9805 study demonstrated that 9.2% of patients who were administered Taxotere, had persistent alopecia for up to 10 years and 5 months and in some cases even longer. Despite this knowledge, Sanofi Defendants purposefully and unjustly withheld these results contained in the GEICAM 9805 study from the physicians, healthcare providers, and patients in the U.S., including Plaintiff.

70. By 2006, Sanofi Defendants knew, or should have known, that a Denver based oncologist in the U.S. had observed that an increased percentage, 6.3% specifically, of his

patients who had Taxotere treatment suffered from permanent and disfiguring hair loss for years after the patient had ended their Taxotere treatment.

71. Sanofi Defendants knew of relevant findings from GEICAM 9805 and knew of the patient reports from the Denver oncologist, and failed, to date, to provide accurate information and proper warnings to the physicians, healthcare providers, and patients in the U.S., including Plaintiff, that Taxotere has a significantly increased risk of experiencing permanent and disfiguring alopecia.

72. Sanofi Defendants chose to withhold this information from the U.S. market despite physicians, patients, and regulatory agencies in other countries, including, but not limited to, the European Union and Canada, that Taxotere caused an increased risk of permanent and disfiguring alopecia. Sanofi Defendants continued to tell the U.S. physicians, healthcare providers, patients, and Plaintiff, that “hair generally grows back” after taking Taxotere.

73. Taxotere consumers were not given the opportunity to make an informed decision because they were unable to perform a risk benefit analysis due to the systematic and continuous deception perpetrated by Sanofi Defendants by overstating and/or misrepresenting the benefits and failing to warn of the true risks of permanent and disfiguring alopecia while other less potent but equally effective alternatives were available.

74. It is notable that Sanofi Defendants publish information in other countries to individual patients, as well as regulatory agencies, informing patients of a risk of permanent alopecia relating to Taxotere use, however despite the numerous U.S. label changes and safety warnings issued by Sanofi Defendants during the near, two decades Taxotere has been on the U.S. market, the words “permanent alopecia” or “permanent hair loss” did not appear in any published information from Sanofi Defendants until December 2015.

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

76. Sanofi Defendants' failure to warn patients of the true risk of disfiguring and permanent alopecia in the U.S., to healthcare providers, physicians, and patients, including Plaintiff, deprived them of the chance to make an informed decision as to exposing oneself to Taxotere (docetaxel) when other comparably effective products were available.

77. Sanofi Defendants took advantage of vulnerable groups of individuals during one of the most difficult times of their lives. Sanofi Defendants made billions of dollars in increased revenues at the expense of unwary cancer victims who wanted a chance at a normal life again.

78. Taxotere was defective in its design. Taxotere was designed as a more potent Taxane. This increased potency resulted in increased toxicity, which can be directly related to the increased adverse events. The most likely reason Sanofi Defendants designed a more potent Taxane was to enable them to obtain a patent, and grab the current market, on a patent that was, in fact, not novel, but only more dangerous.

79. Sanofi Defendants' reckless, willful, and wanton conduct permanently disfigured Plaintiff, as well as many other innocent victims to satisfy the Sanofi Defendants' avarice.

D. GENERIC NON-BIOEQUIVALENT DEFENDANTS' CONDUCT

80. Defendant Hospira filed for a NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel anhydrous. The FDA granted Hospira's NDA on or about March 8, 2011 and Hospira put the docetaxel anhydrous on the market on or about March 8, 2011.

81. Defendant Sun Pharma filed for an NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docefrez. The FDA granted Sun Pharma's NDA on or about May 2, 2011 and Sun Pharma put docefrez on the market on or about May 2, 2011.

82. Defendant McKesson filed an NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel anhydrous. The FDA granted McKesson's NDA on or about June 8, 2011, and McKesson put docetaxel anhydrous on the market on or about June 8, 2011.

83. Defendant Sandoz filed an NDA with the FDA for a generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel. The FDA granted Sandoz's NDA on or about July 22, 2015 and Sandoz put docetaxel on the market on or about July 22, 2015.

84. Upon information and belief, Defendant Accord filed for two (3) NDAs with the FDA for generic non-bioequivalents of Taxotere (docetaxel).

85. Upon information and belief, Defendant Accord was approved by the FDA for the first generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel on or about June 30, 2011 and Accord put docetaxel on the market on or about June 30, 2011.

86. Defendant Accord was approved by the FDA for the second generic non-bioequivalent of Taxotere (docetaxel) in the form of docetaxel anhydrous (20 mg/0.5 mL and 80 mg/2 mL) on or about July 1, 2012 and Accord put docetaxel anhydrous on the market on or about July 1, 2012.

87. Upon information and belief, Defendant Accord was approved by the FDA for the third generic non-bioequivalent of Taxotere (docetaxel) in another form of docetaxel

anhydrous in a more concentrated form, on or about May 15, 2013 and Accord put the more concentrated docetaxel anhydrous on the market on or about May 15, 2013.

E. THE PLAINTIFF'S USE OF TAXOTERE AND RESULTING INJURIES

88. By reason of the foregoing acts and omissions, the Plaintiff suffered permanent alopecia, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and medical treatment.

89. Upon information and belief, despite the permanent alopecia findings in studies and other clinical evidence, all Defendants failed to adequately conduct complete and proper testing of Taxotere prior to filing their New Drug Application for Taxotere.

90. Upon information and belief, from the date all Defendants received FDA approval to market Taxotere (docetaxel) and/or its generic non-bioequivalent forms, all Defendants made, distributed, marketed, and sold Taxotere (docetaxel) and/or its generic non-bioequivalent form, without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Taxotere (docetaxel), and/or its generic non-bioequivalent form, was associated with and/or could cause permanent hair loss in patients who used it, and that all Defendants had not adequately conducted complete and proper testing and studies of Taxotere (docetaxel), and/or its generic non-bioequivalent form, with regard to permanent nature of the alopecia.

91. Upon information and belief, Taxotere (docetaxel), and/or its generic non-bioequivalent form, concealed and failed to completely disclose their knowledge that Taxotere (docetaxel), and/or its generic non-bioequivalent form, was associated with or could cause permanent alopecia as well as their knowledge that they had failed to fully test or study said risk.

92. Upon information and belief, all Defendants ignored the association between the

use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, and the risk of developing permanent and disfiguring alopecia.

93. Upon information and belief, all Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of permanent hair loss of Taxotere (docetaxel), and/or its generic non-bioequivalent form, but similar efficacy compared to less potent products.

94. All of the Defendants' failures to disclose information that they possessed regarding the failure to adequately test and study Taxotere (docetaxel), and/or its generic non-bioequivalent form, for permanent hair loss risk further rendered warnings for this medication inadequate.

95. By reason of the forgoing acts and omissions, Plaintiffs have suffered damages and harm, including, but not limited to, emotional distress, medical expenses, other economic harm, as well as a loss of consortium, services, society, companionship, love and comfort.

FACTUAL ALLEGATIONS

96. On or about November 1, 2008, Plaintiff was first prescribed and began taking Taxotere (docetaxel), and/or its generic non-bioequivalent form, upon the direction of her physician for the treatment of breast cancer. Subsequently, as a direct result of being exposed to Taxotere (docetaxel), and/or its generic non-bioequivalent form, on or about January 1, 2016, Plaintiff was diagnosed with permanent and severe alopecia at Spring Valley Family Medicine located in Columbia, South Carolina.

97. As a direct result of being prescribed Taxotere for this period of time, Plaintiff suffered significant injuries, such as those described above.

98. As a proximate result of all of the Defendants' acts and omissions, Plaintiff

suffered the injuries described hereinabove due to Plaintiff's exposure to Taxotere (docetaxel), and/or its generic non-bioequivalent form,. Plaintiff accordingly seeks damages associated with these injuries.

99. Plaintiff would not have used Taxotere (docetaxel), and/or its generic non-bioequivalent form, had all of the Defendants properly disclosed the risks associated with its use.

COUNT I: STRICT LIABILITY

100. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

101. At all times relevant times hereto, Defendants were engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Taxotere (docetaxel), and/or its generic non-bioequivalent form, at issue in this lawsuit. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, manufactured by Defendants reached Plaintiff without substantial change and was infused as directed. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.

102. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of permanent alopecia and other injuries associated with the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, were inadequate.

103. Plaintiffs did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

104. Defendants had a continuing duty to provide consumers, including Plaintiff, and Plaintiff's physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with Taxotere (docetaxel), and/or its generic non-bioequivalent form,, as it became or could have become available to Defendants.

105. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Taxotere (docetaxel), and/or its generic non-bioequivalent form, to health care providers empowered to prescribe and dispense Taxotere to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Taxotere (docetaxel), and/or its generic non-bioequivalent form, which resulted in injury to Plaintiff.

106. Despite the fact that Defendants knew or should have known that Taxotere (docetaxel), and/or its generic non-bioequivalent form, caused unreasonable and permanent side effects, they continued to promote and market Taxotere (docetaxel), and/or its generic non-bioequivalent form, without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

107. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

108. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the

following ways:

- a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Taxotere (docetaxel), and/or its generic non-bioequivalent form, including, among other things, permanent alopecia;
- b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, permanent alopecia;
- c. Defendants continued to aggressively promote and sell Taxotere (docetaxel), and/or its generic non-bioequivalent form, even after they knew or should have known of the unreasonable risks of permanent alopecia from this drug.

109. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Taxotere (docetaxel), and/or its generic non-bioequivalent form, and/or that there existed safer and more or equally effective alternative drug products.

110. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Taxotere (docetaxel), and/or its generic non-bioequivalent form, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

111. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

112. As a direct and proximate result of the actions and inactions of the Defendants as

set forth above, Plaintiff was exposed to Taxotere (docetaxel), and/or its generic non-bioequivalent form, and suffered the injuries and damages set forth hereinabove.

COUNT II: STRICT LIABILITY – DESIGN DEFECT,

MARKETING DEFECT AND MANUFACTURING DEFECT

113. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

114. Taxotere (docetaxel), and/or its generic non-bioequivalent form, was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Taxotere (docetaxel), and/or its generic non-bioequivalent form, could cause injuries such as those suffered by Plaintiff during foreseeable use. This fact was known to Defendants at the time Taxotere (docetaxel), and/or its generic non-bioequivalent form, was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including Plaintiff. Nonetheless, Defendants failed to warn that Taxotere (docetaxel), and/or its generic non-bioequivalent form, as designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Such a failure to warn rendered the Taxotere (docetaxel), and/or its generic non-bioequivalent form, unreasonably dangerously defective as designed and marketed.

115. At all times material to these allegations, Defendants manufactured, distributed, tested, packaged, promoted, marketed, labeled, designed and sold Taxotere (docetaxel), and/or its generic non-bioequivalent form, as alleged herein.

116. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field.

117. The Taxotere (docetaxel), and/or its generic non-bioequivalent form,

administered to Plaintiff was defective in design or formulation in the following respects:

- a. When it left the hands of Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;
- b. Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as Defendants intended;
- c. The dosages and/or formulation of Taxotere (docetaxel), and/or its generic non-bioequivalent form, sold by Defendants was unreasonably dangerous;
- d. There are no patients for whom the benefits of Taxotere (docetaxel), and/or its generic non-bioequivalent form, outweighed the risks;
- e. The subject product was not made in accordance with Defendants' specifications or performance standards;
- f. There are no patients for whom Taxotere (docetaxel), and/or its generic non-bioequivalent form, is a safer and more efficacious drug than other drug products in its class; and/or
- g. There were safer alternatives that did not carry the same risks and dangers that Defendants' Taxotere (docetaxel), and/or its generic non-bioequivalent form, had.

118. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, administered to Plaintiff was defective at the time it was distributed by Defendants or left their control.

119. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, administered to Plaintiff was expected to reach the user without substantial change in the

condition in which it was sold.

120. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, administered to Plaintiff reached Plaintiff without substantial change in the condition in which it was sold.

121. There were safer alternative methods and designs for Defendants' Taxotere (docetaxel), and/or its generic non-bioequivalent form.

122. Plaintiff was a patient who Defendants reasonably expected would be administered Taxotere (docetaxel), and/or its generic non-bioequivalent form.

123. Defendants were at liberty to withdraw Taxotere (docetaxel), and/or its generic non-bioequivalent form, from the market at any time, but failed to do so.

124. The defective and unreasonably dangerous design and marketing of Taxotere (docetaxel), and/or its generic non-bioequivalent form, was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case, including punitive damages.

125. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff was injured as described herein. All of said injuries caused Plaintiff's damages, for which Plaintiff is entitled to damages.

126. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff was required to obtain reasonable and necessary healthcare treatment and services and incurred expenses for which Plaintiff is entitled to damages.

127. As a direct and proximate result of the design, marketing and manufacturing defects of Defendants' product, Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff suffered the injuries as previously alleged herein.

COUNT III: NEGLIGENCE

128. Plaintiffs incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

129. Defendants owed a duty to the general public and specifically to the Plaintiff to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Taxotere (docetaxel), and/or its generic non-bioequivalent form, at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Taxotere (docetaxel), and/or its generic non-bioequivalent form, because as designed, it was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Taxotere (docetaxel), and/or its generic non-bioequivalent form, because they failed to warn, that as designed, Taxotere (docetaxel), and/or its generic non-bioequivalent form, was capable of causing serious and permanent personal injuries such as those suffered by Plaintiff during foreseeable use.

130. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

- a. Failing to use due care in developing, testing, designing and manufacturing Taxotere so as to avoid the aforementioned risks to individuals when Taxotere was being used for treatment;
- b. Failing to accompany their product with proper or adequate warnings or labeling

regarding adverse side effects and health risks associated with the use of Taxotere and the comparative severity and duration of such adverse effects;

- c. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;
- d. Failing to accompany their products with proper or adequate rate of incidence or prevalence of permanent hair loss;
- e. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;
- f. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Taxotere (docetaxel), and/or its generic non-bioequivalent form;
- g. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;
- h. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Taxotere (docetaxel), and/or its generic non-bioequivalent form, and patients taking Taxotere (docetaxel), and/or its generic non-bioequivalent form;
- i. Failing to adequately test and/or warn about the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, including, without limitations, the possible adverse side effects and health risks caused by the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form;

- j. Failing to design and/or manufacture a product that could be used safely;
- k. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff;
- l. Failing to remove Taxotere (docetaxel), and/or its generic non-bioequivalent form, from the market when Defendants' knew or should have known of the likelihood of serious and permanent side effects and injury to its users;
- m. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of permanent hair loss and related conditions to individuals taking Taxotere (docetaxel), and/or its generic non-bioequivalent form; and
- n. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

131. The Taxotere (docetaxel), and/or its generic non-bioequivalent form, that injured Plaintiff was in substantially the same condition when Plaintiff was infused with it as it was when it left the control of Defendants. Taxotere's (docetaxel), and/or its generic non-bioequivalent form's, ability to cause serious and permanent personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff was infused the Taxotere (docetaxel), and/or its generic non-bioequivalent form, as directed and without change in its form or substance.

132. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Taxotere (docetaxel), and/or its generic non-bioequivalent form, was a proximate cause of Plaintiff's injuries and damages.

133. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

COUNT IV: BREACH OF WARRANTY - BREACH OF EXPRESS WARRANTY

134. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

135. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Taxotere (docetaxel), and/or its generic non-bioequivalent form, in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Plaintiff, or persons responsible for consumer.

136. Taxotere (docetaxel), and/or its generic non-bioequivalent form, materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of Taxotere (docetaxel), and/or its generic non-bioequivalent form, respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and was infused with in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Taxotere (docetaxel), and/or its generic non-bioequivalent form, sold to Plaintiff.

137. As a direct, foreseeable and proximate result of Defendants' breaches of express warranties, Plaintiff suffered permanent and grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Taxotere (docetaxel), and/or its generic non-bioequivalent form, Plaintiff purchased and was infused with Taxotere (docetaxel), and/or its generic non-bioequivalent form, as prescribed and instructed by Plaintiff's physician, leading to Plaintiff's injuries.

COUNT V: BREACH OF WARRANTY – BREACH OF IMPLIED WARRANTY

138. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

139. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Taxotere (docetaxel), and/or its generic non-bioequivalent form, in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

140. Defendants impliedly warranted their Taxotere (docetaxel), and/or its generic non-bioequivalent form, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

141. Defendants breached their implied warranties of the Taxotere (docetaxel), and/or its generic non-bioequivalent form, sold to Plaintiff because this product was not fit for its common, ordinary, and intended use.

142. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiff suffered permanent and grievous bodily injury and consequential economic and other losses, as described above, when Plaintiff was infused with Taxotere (docetaxel), and/or its generic non-bioequivalent form, in reasonable reliance upon the implied warranties.

COUNT VI: LOSS OF CONSORTIUM

143. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth and further alleges as follows:

144. Christopher Strother, was at all times relevant hereto the spouse of Dena Strother

145. For the reasons set forth herein, Christopher Strother has been caused presently and in the future, to suffer the loss of Dena Strother's companionship and society, and accordingly, Christopher Strother has been caused great mental anguish.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiffs for the injuries Plaintiffs have suffered and or will suffer. Plaintiffs further demand judgment against each of the Defendants for punitive damages. Plaintiffs further demand payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiffs further demand payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

NAPOLI SHKOLNIK LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiffs

Dated: December 19, 2016

EXHIBIT B

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DENA STROTHER and CHRISTOPHER STROTHER,

Plaintiffs,

v.

C.A. No. N16C-12-422 VLM

SANOFI U.S. SERVICES INC., formerly known as SANOFI-AVENTIS U.S., INC.; SANOFI-AVENTIS U.S. LLC, separately and doing business as WINTHROP U.S.; HOSPIRA WORLDWIDE, INC.; SUN PHARMA GLOBAL INC.; McKESSON CORPORATION doing business as McKESSON PACKAGING; SANDOZ INC.; ACCORD HEALTHCARE LTD.; ACCORD HEALTHCARE, INC.; INTAS PHARMACEUTICALS LIMITED; SANOFI S.A.; AVENTIS PHARMA S.A.; and DOES, INC.,

Defendants.

NOTICE OF FILING OF NOTICE OF REMOVAL

**TO: Clerk of the Court,
Superior Court of the State of Delaware**

PLEASE TAKE NOTICE that, on January 5, 2017, Defendant sanofi-aventis U.S. LLC filed in the United States District Court for the District of Delaware a Notice of Removal in the above-captioned action, a copy of which is attached hereto as Exhibit 1 and which was served contemporaneously with this Notice.

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
Attorneys for Defendant
sanofi-aventis U.S. LLC

Dated: January 5, 2017

OF COUNSEL:

SHOOK, HARDY & BACON L.L.P.
Harley V. Ratliff, Esq.
2555 Grand Blvd.
Kansas City, Missouri 64108
Tel.: (816) 474-6550
Fax: (816) 421-5547
hratliff@shb.com

CERTIFICATE OF SERVICE

I, Christopher Viceconte, hereby certify that, on this 5th day of January 2017, a true and correct copy of Defendant sanofi-aventis U.S. LLC's Notice of Filing of Notice of Removal was served via File and ServeXpress upon Plaintiffs' counsel of record as follows:

James D. Heisman, Esq.
NAPOLI SHKOLNIK LLC
919 North Market Street, Suite 1801
Wilmington, Delaware 19801
Attorneys for Plaintiffs

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte, Esq. (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
*Attorneys for Defendant
sanofi-aventis U.S. LLC*

Dated: January 5, 2017

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

DENA STROTHER and CHRISTOPHER STROTHER

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

(c) Attorneys (Firm Name, Address, and Telephone Number) James D. Heisman, Esq. - Napoli Shkolnik LLC 919 North Market Street, Suite 1801 Wilmington, DE 19801 (302) 330-8025

DEFENDANTS

SANOFI U.S. SERVICES INC., et al.

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known) Christopher Viceconte, Esq. - Gibbons P.C. 300 Delaware Avenue, Suite 1015 Wilmington, DE 19801 (302) 518-6322

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

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

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

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location options.

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

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. 1332, 1441, 1446
Brief description of cause: Product liability causes of action (strict liability, negligence, warranty, etc.)

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): Hon. Kurt D. Engelhardt MDL 2740
Hon. Sue L. Robinson DOCKET NUMBER See Schedule A, attached.

DATE 01/05/2017 SIGNATURE OF ATTORNEY OF RECORD /s/ Christopher Viceconte (#5568)

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Buttons: Print, Save As..., Reset

VIII. RELATED CASES – SCHEDULE A

<u>JUDGE</u>	<u>DOCKET NUMBER</u>
Hon. Sue L. Robinson	D. Del. 16-cv-01067
Hon. Sue L. Robinson	D. Del. 16-cv-01179
Hon. Sue L. Robinson	D. Del. 16-cv-01180
Hon. Sue L. Robinson	D. Del. 16-cv-01183
Hon. Sue L. Robinson	D. Del. 16-cv-01187
Hon. Sue L. Robinson	D. Del. 16-cv-01188
Hon. Sue L. Robinson	D. Del. 16-cv-01189
Hon. Sue L. Robinson	D. Del. 16-cv-01190
Hon. Sue L. Robinson	D. Del. 16-cv-01191
Hon. Sue L. Robinson	D. Del. 16-cv-01192
Hon. Sue L. Robinson	D. Del. 16-cv-01193
Hon. Sue L. Robinson	D. Del. 16-cv-01195
Hon. Sue L. Robinson	D. Del. 16-cv-01197
Hon. Sue L. Robinson	D. Del. 16-cv-01198
Hon. Sue L. Robinson	D. Del. 16-cv-01199
Hon. Sue L. Robinson	D. Del. 16-cv-01200
Hon. Sue L. Robinson	D. Del. 16-cv-01201
Hon. Sue L. Robinson	D. Del. 16-cv-01202
Hon. Sue L. Robinson	D. Del. 16-cv-01207
Hon. Sue L. Robinson	D. Del. 16-cv-01208
Hon. Sue L. Robinson	D. Del. 16-cv-01209
Hon. Sue L. Robinson	D. Del. 16-cv-01210
Hon. Sue L. Robinson	D. Del. 16-cv-01211

VIII. RELATED CASES – SCHEDULE A

<u>JUDGE</u>	<u>DOCKET NUMBER</u>
Hon. Sue L. Robinson	D. Del. 16-cv-01212
Hon. Sue L. Robinson	D. Del. 16-cv-01213
Hon. Sue L. Robinson	D. Del. 16-cv-01214
Hon. Sue L. Robinson	D. Del. 16-cv-01215
Hon. Sue L. Robinson	D. Del. 16-cv-01216
Hon. Sue L. Robinson	D. Del. 16-cv-01219
Hon. Sue L. Robinson	D. Del. 16-cv-01223
Hon. Sue L. Robinson	D. Del. 16-cv-01225
Hon. Sue L. Robinson	D. Del. 16-cv-01226
Hon. Sue L. Robinson	D. Del. 16-cv-01227
Hon. Sue L. Robinson	D. Del. 16-cv-01230
Hon. Sue L. Robinson	D. Del. 16-cv-01231
Hon. Sue L. Robinson	D. Del. 16-cv-01234
Hon. Sue L. Robinson	D. Del. 16-cv-01235
Hon. Sue L. Robinson	D. Del. 16-cv-01237
Hon. Sue L. Robinson	D. Del. 16-cv-01238
Hon. Sue L. Robinson	D. Del. 16-cv-01241
Hon. Sue L. Robinson	D. Del. 16-cv-01242
Hon. Sue L. Robinson	D. Del. 16-cv-01244
Hon. Sue L. Robinson	D. Del. 16-cv-01245
Hon. Sue L. Robinson	D. Del. 16-cv-01246
Hon. Sue L. Robinson	D. Del. 16-cv-01247

VIII. RELATED CASES – SCHEDULE A

<u>JUDGE</u>	<u>DOCKET NUMBER</u>
Hon. Sue L. Robinson	D. Del. 16-cv-01248
Hon. Sue L. Robinson	D. Del. 16-cv-01249
Hon. Sue L. Robinson	D. Del. 16-cv-01250
Hon. Sue L. Robinson	D. Del. 16-cv-01251
Hon. Sue L. Robinson	D. Del. 16-cv-01252
Hon. Sue L. Robinson	D. Del. 16-cv-01253
Hon. Sue L. Robinson	D. Del. 16-cv-01256
Hon. Sue L. Robinson	D. Del. 16-cv-01257
Hon. Sue L. Robinson	D. Del. 16-cv-01258
Hon. Sue L. Robinson	D. Del. 16-cv-01259
Hon. Sue L. Robinson	D. Del. 16-cv-01260
Hon. Sue L. Robinson	D. Del. 16-cv-01261
Hon. Sue L. Robinson	D. Del. 16-cv-01262
Hon. Sue L. Robinson	D. Del. 16-cv-01263
Hon. Sue L. Robinson	D. Del. 16-cv-01264
Hon. Sue L. Robinson	D. Del. 16-cv-01265
Hon. Sue L. Robinson	D. Del. 16-cv-01268
Hon. Sue L. Robinson	D. Del. 16-cv-01269
Hon. Sue L. Robinson	D. Del. 16-cv-01270
Hon. Sue L. Robinson	D. Del. 16-cv-01271
Hon. Sue L. Robinson	D. Del. 16-cv-01272
Hon. Sue L. Robinson	D. Del. 16-cv-01273
Hon. Sue L. Robinson	D. Del. 16-cv-01274

VIII. RELATED CASES – SCHEDULE A

<u>JUDGE</u>	<u>DOCKET NUMBER</u>
Hon. Sue L. Robinson	D. Del. 16-cv-01276
Hon. Sue L. Robinson	D. Del. 16-cv-01277
Hon. Sue L. Robinson	D. Del. 16-cv-01278
Hon. Sue L. Robinson	D. Del. 16-cv-01284
Hon. Sue L. Robinson	D. Del. 16-cv-01286
Hon. Sue L. Robinson	D. Del. 16-cv-01287
Hon. Sue L. Robinson	D. Del. 16-cv-01288
Hon. Sue L. Robinson	D. Del. 16-cv-01289
Hon. Sue L. Robinson	D. Del. 16-cv-01290
Hon. Sue L. Robinson	D. Del. 16-cv-01291
Hon. Sue L. Robinson	D. Del. 16-cv-01292
Hon. Sue L. Robinson	D. Del. 16-cv-01293
Hon. Sue L. Robinson	D. Del. 16-cv-01294
Hon. Sue L. Robinson	D. Del. 16-cv-01295
Hon. Sue L. Robinson	D. Del. 16-cv-01296

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

DENA STROTHER and CHRISTOPHER
STROTHER,

Plaintiffs,

v.

C.A. No. _____

SANOFI U.S. SERVICES INC., formerly
known as SANOFI-AVENTIS U.S., INC;
SANOFI-AVENTIS U.S. LLC, separately
and doing business as WINTHROP U.S.;
HOSPIRA WORLDWIDE, INC.; SUN PHARMA
GLOBAL INC.; McKESSON CORPORATION
doing business as McKESSON PACKAGING;
SANDOZ INC.; ACCORD HEALTHCARE LTD.;
ACCORD HEALTHCARE, INC.; INTAS
PHARMACEUTICALS LIMITED; SANOFI S.A.;
AVENTIS PHARMA S.A.; and DOES, INC.,

Defendants.

SANOFI-AVENTIS U.S. LLC'S RULE 7.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1, Defendant sanofi-aventis U.S. LLC, by
its attorneys, provides the following disclosure:

1. The parent corporation of sanofi-aventis U.S. LLC, and all publicly held corporations
owning 10% or more of the stock of sanofi-aventis U.S. LLC, are listed here:

Owner	% of Shares Owned
Sanofi	100%

2. Sanofi is a French corporation that is publicly traded on the New York and Paris
exchanges.

Respectfully submitted,

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte (#5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
*Attorneys for Defendant
sanofi-aventis U.S. LLC*

Dated: January 5, 2017

OF COUNSEL:

SHOOK, HARDY & BACON L.L.P.
Harley V. Ratliff, Esq.
2555 Grand Blvd.
Kansas City, Missouri 64108
Tel.: (816) 474-6550
Fax: (816) 421-5547
hratliff@shb.com

CERTIFICATE OF SERVICE

I, Christopher Viceconte, hereby certify that, on this 5th day of January 2017, a true and correct copy of Defendant Sanofi-aventis U.S. LLC's Corporate Disclosure Statement Pursuant to Rule 7.1 was served by hand or by Federal Express overnight delivery upon Plaintiffs' counsel of record as follows:

James D. Heisman (#2746)
NAPOLI SHKOLNIK LLC
919 North Market Street, Suite 1801
Wilmington, Delaware 19801
Attorneys for Plaintiffs

GIBBONS P.C.

By: /s/ Christopher Viceconte
Christopher Viceconte (No. 5568)
300 Delaware Avenue, Suite 1015
Wilmington, Delaware 19801
Tel.: (302) 518-6322
Fax: (302) 397-2050
cviceconte@gibbonslaw.com
*Attorneys for Defendant
sanofi-aventis U.S. LLC*

Dated: January 5, 2017