

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

DENISE GUBITOSI,

Plaintiff,

v.

BAYER CORPORATION; BAYER
HEALTHCARE PHARMACEUTICALS,
INC.; BAYER PHARMA AG; BAYER AG;
and MERCK & CO., INC.,

Defendants.

)
) Case No.: _____
)
) **COMPLAINT FOR DAMAGES**
) **AND**
) **DEMAND FOR JURY TRIAL**
)
) **1. Strict Liability**
) **2. Product Liability – Failure to**
) **Warn**
) **3. Negligence**
) **4. Breach of Express Warranty**
) **5. Breach of Implied Warranty**
) **6. Fraud**
) **7. Negligent Misrepresentation**
) **8. Fraudulent Concealment**

NOW COMES Plaintiff, Denise Gubitosi (“Plaintiff”), by and through the undersigned counsel, and hereby brings this Complaint for damages against the Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer AG, Bayer Pharma AG, and Merck & Co., Inc. (collectively, “Defendants”), and alleges the following:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants’ negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Avelox® (also known as moxifloxacin). Avelox® in any of its forms shall herein be referred to as “Avelox.”

2. Plaintiff maintains that Avelox is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

PARTIES

3. Plaintiff, Denise Gubitosi, is a natural person and a resident and citizen of Suffolk County, New York. Plaintiff brings this action for personal injuries sustained by the use of Avelox. As a direct and proximate result of being prescribed and ingesting Avelox, Plaintiff developed irreversible peripheral neuropathy.

4. Defendant Bayer Corporation ("Bayer Corp.") is an Indiana corporation that has its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

5. Defendant Bayer Corp. has transacted and conducted business within the State of Pennsylvania.

6. Defendant Bayer Corp. has derived substantial revenue from goods and products used in the State of Pennsylvania.

7. Defendant Bayer Corp. expected or should have expected its acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

8. Defendant Bayer Corp. was engaged in the business of designing, developing, manufacturing, testing, packaging, marketing, distributing, labeling, and/or selling Avelox.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer Healthcare") is a Delaware corporation that has its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045.

10. In January 2008, Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare.

11. Defendant Bayer Healthcare has transacted and conducted business within the State of Pennsylvania.

12. Defendant Bayer Healthcare has derived substantial revenue from goods and products used in the State of Pennsylvania.

13. Defendant Bayer Healthcare expected, or should have expected, its acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

14. Defendant Bayer Healthcare was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

15. Bayer AG (“Bayer AG”) is a pharmaceutical company domiciled in Germany.

16. Bayer AG is one of the largest pharmaceutical companies in the world and is the researcher, developer, producer, and/or manufacturer of Cipro and Avelox.

17. Bayer Pharma AG (“Bayer Pharma AG”) is a pharmaceutical company domiciled in Germany.

18. Bayer Pharma AG is formerly known as Bayer Schering Pharma AG and is the same corporate entity as Bayer Schering Pharma AG. Bayer Schering Pharma AG was formerly known as Schering AG and is the same corporate entity as Schering AG.

19. Upon information and belief, Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

20. Upon information and belief, Bayer Schering Pharma AG was renamed Bayer Pharma AG effective July 1, 2011.

21. Bayer Pharma AG is involved in the research, development, manufacturer, sale, and/or marketing of pharmaceutical products, including Cipro and Avelox.

22. Upon information and belief, and at all relevant times, Defendant Bayer Pharma AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Cipro and Avelox.

23. Defendant Merck & Co., Inc. (“Merck”) is New Jersey corporation that has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

24. Defendant Merck has transacted and conducted business within the State of Pennsylvania.

25. Defendant Merck has derived substantial revenue from goods and products used in the State of Pennsylvania.

26. Defendant Merck expected, or should have expected, their acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

27. At all times material hereto, Defendant Merck was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

28. Defendants are authorized to do business in Pennsylvania and derive substantial income from doing business in this state.

29. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the State of Pennsylvania, thus invoking the benefits and protections of its laws.

30. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and/or distribute Avelox, with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

31. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and because Defendants are all either incorporated and/or have their principal place outside of the state in which the Plaintiff resides.

32. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

33. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market and/or distribute Avelox within Pennsylvania and this District.

FACTUAL ALLEGATIONS

34. At all relevant times, Defendants were in the business of, and did, design,

research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Avelox.

35. Plaintiff was prescribed Avelox in April 2013 and used it as directed.

36. Avelox is a broad-spectrum synthetic antibacterial agent marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

37. Avelox is a member of the quinolone class of antibiotics. Quinolones are divided into four generations based on their spectrum of antimicrobial activity.

38. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

39. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

40. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

41. Avelox was approved by the United States Food and Drug Administration (hereinafter, the “FDA”) on December 10, 1999 for use in the United States, and is the brand name for the antibiotic moxifloxacin.

42. With the patent for Cipro® (Defendants’ other blockbuster fluoroquinolone) set to expire in 2003, Defendants set out to develop and effectively market Avelox in order to be more competitive with 3rd and 4th generation fluoroquinolones, including Levaquin®. Avelox quickly became Defendants’ heir apparent and successor to Cipro®.

43. Similar to Cipro®, Avelox has proven to be a blockbuster drug for Bayer. In 2007 alone, Avelox generated international sales of \$697.3 million dollars.

44. Defendant Bayer Healthcare has indicated on its website that Avelox is “safe and effective” and “has a well-characterized safety profile, which has been studied in over 14,000 patients in clinical trials and 92,000 patients in post marketing surveillance studies.”

45. However, the scientific evidence has established a clear association between Avelox and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

46. Defendants knew or should have known that Avelox is associated with an increased risk of developing irreversible peripheral neuropathy.

47. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff’s prescribing physicians of the serious and dangerous risks associated with the use of Avelox concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

48. The warning label for Avelox during the period from September 2004 through August 2013 misled Plaintiff and Plaintiff’s treating physicians by incorrectly advising patients and physicians that peripheral neuropathy associated with Avelox was “rare” and failing to mention the possibility that it could result in irreversible nerve damage.

49. Though this injury can be significant and debilitating, the language regarding the

“rare” risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Avelox label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

50. Additionally, Defendants failed to disseminate a “Dear Doctor” letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Avelox to physicians.

51. Despite their knowledge that Avelox was associated with an elevated risk of permanent nerve damage, Defendants’ promotional campaign was focused on Avelox’s purported “safety profile.”

52. As early as 1992, there was evidence of the association between fluoroquinolones and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.¹

53. Four years later, Karin Hedenmalm and Olav Spigset published “Peripheral sensory disturbances related to treatment with fluoroquinolones” based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.²

54. In 2001, Jay S. Cohen published a research study in the United States entitled “Peripheral Neuropathy Associated with Fluoroquinolones.”

55. The Cohen paper studied forty-five (45) patients and expressed concerns over a

¹ Aoun M., Jacqy C, Debusscher L, Bron D, Lehert M, Neol P, et al. Peripheral neuropathy associated with fluoroquinolones (letter). Lancet. 1992;340:127.

² Hedenmalm, K. and Spigset, O. Peripheral sensory disturbances related to treatment with fluoroquinolones. J Antimicrob Chemother 1996;37(4):831-7.

link between permanent peripheral neuropathy and fluoroquinolones.³

56. In 2002 and 2003, Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

57. A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning Avelox and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

58. In 2004, the Avelox label was amended to include the following statement regarding peripheral neuropathy in the Warnings section:

Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.

59. Thus, rather than warning patients and physicians that the use of Avelox may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and failed to make any mention of the risk of permanent nerve damage.

60. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Avelox instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which Plaintiff presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with Avelox.

61. The failure of Defendants to include appropriate warnings in the label as published to the medical community also resulted in an absence of adequate warnings in patient

³ Cohen, JS. Peripheral neuropathy associated with fluoroquinolones. *Ann Pharmacother* 2001;35:1540. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy, and concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information." *Id.*

information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

62. Despite Defendants' knowledge and failure to adequately warn Plaintiff and Plaintiff's physicians of the above, Defendants continue to market Avelox as a first-line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.

63. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warnings regarding peripheral nerve damage were inadequate. On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in labels of all fluoroquinolones, including Avelox, and which removed the statement that nerve damage occurred only in "rare" cases:

Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including Avelox. Symptoms may occur soon after initiation of Avelox and may be irreversible. Avelox should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

64. According to a study conducted by Ayad Ali, RPh, PhD, and published in *Annals of Epidemiology* in January 2014, between 1997 and 2012, there were 539 reports of peripheral neuropathy among 46,257 adverse event reports submitted for fluoroquinolone antibiotics to the FDA's Adverse Event Reporting System.⁴ A pharmacovigilance analysis of this data further underscored the link between systemic exposure to fluoroquinolones and peripheral neuropathy, and showed a potential association with more severe forms of nerve damage.⁵ The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential

⁴ Ali, A.K. Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis. *Annals Epidemiol.* 2014;24(4):279-85.

⁵ *Id.*

for Avelox and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

65. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.⁶ The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1.56-2.74).

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

66. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

67. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Avelox in an attempt not only to encourage sales of Avelox, but also to avoid potential legal claims by injured users of Avelox. Defendants' affirmative misrepresentations did, in fact, deter Plaintiff from filing suit by causing Plaintiff and, upon information and belief, Plaintiffs' physicians to fail to recognize that Plaintiff was suffering from permanent neuropathy due to the use of Avelox.

68. As a result of Defendants' affirmative misrepresentations that continued at least through mid-August of 2013, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and should not reasonably have learned through the exercise of due diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions including Defendants' fraud and misrepresentations regarding the true nature of the risks of Avelox.

69. Furthermore, Defendants are estopped from relying on any statute of limitations

⁶ Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. *Neurology* 2014; Epub 2014 Aug 22.

because of their misrepresentations concerning the true character, quality and nature of Avelox that dissuaded Plaintiff from investigating and pursuing any possible claim. Defendants were under a duty to disclose the true character, quality, and nature of Avelox because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. Plaintiff and, upon information and belief, Plaintiff's physicians, relied upon the misrepresentations disseminated by Defendants about Avelox, which misled Plaintiff regarding the true cause of Plaintiff's permanent peripheral neuropathy and induced Plaintiff not to investigate and pursue potential claims against Avelox within the limitations period. Plaintiff acted with reasonable diligence in investigating and pursuing Plaintiff's claims after learning of Defendants' misrepresentations subsequent to Defendants' mid-August 2013 label change. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

70. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule and/or the doctrines of fraudulent concealment and equitable estoppel from relying upon any statute of limitations.

COUNT I

[Strict Liability]

71. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

72. The Avelox drugs manufactured, marketed, supplied and/or distributed by Defendants were defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying such labels failed to warn of the dangerous risks they posed, including the risk of developing irreversible peripheral neuropathy.

73. At all times alleged herein, the Avelox drugs manufactured, marketed, supplied, and/or distributed by Defendants were defective, and Defendants knew that their Avelox drugs were to be used by consumers without inspection for defects. Moreover, Plaintiff, Plaintiff's prescribing physicians, and Plaintiff's healthcare providers neither knew nor had reason to know at the time of Plaintiff's use of Avelox of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

74. At all times alleged herein, the Defendants' Avelox drugs were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

75. The design of Defendants' Avelox drugs were defective in that the risks associated with using the drugs as a first-line therapy for infections that did not dictate the use of Avelox outweighed any benefits of their design. Any benefits associated with the use of the Avelox in such situations were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

76. The defect in design existed when the products left Defendants' possession.

77. At the time Avelox left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting their drug.

78. As a result of the defective condition of Defendants' Avelox, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT II

[Product Liability - Failure to Warn]

79. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

80. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Avelox, and through that conduct have knowingly and intentionally placed Avelox into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

81. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Avelox to Plaintiff and to Plaintiff's prescribing physicians. Additionally, Defendants expected the Avelox that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Avelox did in fact reach – prescribing physicians and consumers, including Plaintiff and Plaintiff's prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

82. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Avelox was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

83. This defect caused serious injury to Plaintiff, who used Avelox in its intended and foreseeable manner.

84. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain

supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

85. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

86. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Avelox, namely irreversible peripheral neuropathy.

87. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Avelox caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Avelox use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

88. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

89. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

90. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

91. Had Defendants properly disclosed the risks associated with Avelox, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Avelox.

92. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT III

[Negligence]

93. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

94. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Avelox.

95. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled Avelox.

96. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

- a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Avelox;
- b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiffs herein, of the dangerous and defective characteristics of Avelox;
- c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Avelox;
- d) In promoting Avelox in an overly aggressive, deceitful, and fraudulent manner, including as a first-line therapy to treat infections for which it was not required despite evidence as to the drug's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;
- e) In representing that Avelox was safe for their intended use when, in fact, the products were unsafe for their intended use;

- f) In failing to perform appropriate pre-market testing of Avelox;
- g) In failing to perform appropriate post-market surveillance of Avelox;
- h) In failing to adequately and properly test Avelox before and after placing them on the market;
- i) In failing to conduct sufficient testing on Avelox which, if properly performed, would have shown that it had the serious side effect of causing irreversible peripheral neuropathy;
- j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Avelox carried a risk of developing irreversible peripheral neuropathy.
- k) In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Avelox; and
- l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from Avelox ingestion as described herein.

97. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

98. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, physical impairment, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT IV

[Breach of Express Warranty]

99. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

100. Before Plaintiff was first prescribed Avelox and during the period in which Plaintiff used Avelox, Defendants expressly warranted that Avelox was safe.

101. Avelox did not conform to these express representations because Avelox was not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

102. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V

[Breach of Implied Warranty]

103. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

104. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Avelox, and before such drugs were prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that Avelox was of merchantable quality and safe and fit for the use for which it was intended.

105. Plaintiff, individually and through Plaintiff's prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

106. Plaintiff was prescribed, purchased, and used Avelox for its intended purpose.

107. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with Avelox until after Plaintiff

used it.

108. Contrary to the implied warranty for the subject products, Defendants' Avelox is not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

109. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VI

[Fraud]

110. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

111. Defendants made misrepresentations to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry regarding the safety and effectiveness of Avelox and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Avelox.

112. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Avelox had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

- (a) Since at least 1996, Defendant Bayer and/or its predecessors were in possession of data demonstrating that Avelox increases the risk of irreversible peripheral neuropathy;
- (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Avelox before and after their product launch;
- (c) Avelox was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and
- (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Avelox increases the risk of irreversible peripheral neuropathy.

113. The misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants.

114. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

115. Defendants made these false representations with the intent or purpose that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the use of Avelox by Plaintiff as well as the general public.

116. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken the subject product.

117. Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Avelox that Defendants did

suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Avelox. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

118. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with Avelox in a timely manner.

119. Defendants made the representations and actively concealed information about the defects and dangers of Avelox with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Avelox as a treatment.

120. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Avelox and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VII

[Negligent Misrepresentation]

121. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

122. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of Avelox and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Avelox.

123. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that

Avelox had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

- (a) Since at least 1996, Defendant Bayer and/or its predecessors were in possession of data demonstrating that Avelox increases the risk of irreversible peripheral neuropathy;
- (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Avelox before and after their product launch;
- (c) Avelox was not fully and adequately tested by Defendants and/or their predecessors for the risk of developing irreversible peripheral neuropathy; and
- (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Avelox increases the risk of irreversible peripheral neuropathy.

124. The negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

125. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

126. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the use of Avelox by Plaintiff as well as the general public.

127. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, Plaintiff's physicians would not have prescribed and Plaintiff would not have taken the subject product.

128. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Avelox and relied on the absence of information regarding the dangers of Avelox which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

129. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with Avelox in a timely manner.

130. Defendants made the representations and actively concealed information about the defects and dangers of Avelox with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Avelox as a treatment.

131. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Avelox and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VIII

[Fraudulent Concealment]

132. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

133. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for

the truth or falsity of such material representations with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on such material representations.

134. Plaintiff and Plaintiff's prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

135. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, Plaintiff's prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and Plaintiff's prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

136. At all times herein mentioned, Defendants had a duty to Plaintiff, Plaintiff's prescribing physicians, and the general public to accurately inform them of risks associated with Avelox because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Avelox.

137. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Avelox at issue in this lawsuit, said breach or breaches constituting fraud because of the propensity to deceive others or constitute an injury to public interests or public policy.

138. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Avelox to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Avelox, Plaintiff was placed at a significantly-increased risk of developing irreversible peripheral neuropathy.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

PUNITIVE DAMAGES

139. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

140. At all times material hereto, Defendants knew or should have known that Avelox was inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

141. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Avelox.

142. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.

143. At all times material hereto, Defendants knew and recklessly disregarded the fact that Avelox causes the chronic illness irreversible peripheral neuropathy.

144. Notwithstanding the foregoing, Defendants continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

145. Defendants knew of their subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Avelox without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Avelox.

146. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable Plaintiff to weigh the true risks of using Avelox against its benefits.

147. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff

suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

148. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

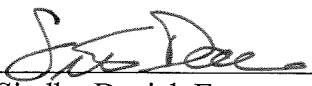
PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

- (a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
- (b) For medical, incidental, and hospital expenses according to proof;
- (c) For pre-judgment and post-judgment interest as provided by law;
- (d) For full refund of all purchase costs Plaintiff paid for Avelox;
- (e) For compensatory damages in excess of the jurisdictional minimum of this Court;
- (f) For consequential damages in excess of the jurisdictional minimum of this Court;
- (g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
- (h) For attorneys' fees, expenses, and costs of this action; and
- (i) For such further relief as this Court deems necessary, just, and proper.

DATED this 4th day of August, 2016

Respectfully submitted,

By: 
Sindhu Daniel, Esq.
Attorney ID No. 77466
Baron & Budd, P.C.
3102 Oak Lawn Ave., Ste. 1100
Dallas, Texas 75219-4281
(214) 521-3605
(214) 520-1181 (fax)
sdaniel@baronbudd.com

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

DATED this 4th day of August, 2016

Respectfully submitted,

By: 
Sindhu Daniel, Esq.
Attorney ID No. 77466
Baron & Budd, P.C.
3102 Oak Lawn Ave., Ste. 1100
Dallas, Texas 75219-4281
(214) 521-3605
(214) 520-1181 (fax)
sdaniel@baronbudd.com

Attorneys for Plaintiff

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

DENISE GUBITOSI

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

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

Sindhu Daniel, Baron & Budd, P.C.
3102 Oak Lawn Avenue, Suite 1100, Dallas, TX 75219
(214) 521-3605

DEFENDANTS

BAYER CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER AG, BAYER PHARMA AG; and MERCK & CO., INC.

County of Residence of First Listed Defendant ALLEGHENY COUNTY, PA
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (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)

- | | PTF | DEF |
|---------------------------------------------------------------|---------------------------------------|---------------------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 |
| Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act (Excludes Veterans) <input type="checkbox"/> 152 Recovery of Defaulted Student Loans <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1332(a)

Brief description of cause:

Personal injury from plaintiffs use of pharmaceutical product manufactured or distributed by defendants

VII. REQUESTED IN COMPLAINT:

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

DEMAND \$

In excess of \$75,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND:

☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE
08/04/2016

SIGNATURE OF ATTORNEY OF RECORD

Sindhu Daniel AUG - 5 2016

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 102 Maple St., Medford, NY 11763

Address of Defendant: Bayer Corporation, 100 Bayer Road, Pittsburgh, PA 15205

Place of Accident, Incident or Transaction: New York

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐ No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☒ No ☐

RELATED CASE, IF ANY: MDL No. 2642; IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION.

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
Yes ☐ No ☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?
Yes ☒ No ☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?
Yes ☐ No ☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
Yes ☐ No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
(Please specify) _____

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify) _____

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Sindhu Daniel, counsel of record do hereby certify:
☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
☐ Relief other than monetary damages is sought.

DATE: August 4, 2016

Sindhu Daniel

Attorney-at-Law

I. D. #77466

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

AUG - 5 2016

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: August 4, 2016

Sindhu Daniel

Attorney-at-Law

I.D. #77466

Attorney I.D.#

PD

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CASE MANAGEMENT TRACK DESIGNATION FORM

DENISE GUBITOSI

CIVIL ACTION

v.

16 4254BAYER CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS,
INC.; BAYER AG; BAYER PHARMA AG; and MERCK & CO., INC.

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.)
- (f) Standard Management – Cases that do not fall into any one of the other tracks.

August 4, 2016
Date

Sindhu Daniel
Attorney-at-law

Plaintiff
Attorney for

214-521-3605

214-520-1181

sdaniel@baronbudd.com

Telephone**FAX Number****E-Mail Address**

AUG - 5 2016