

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
JAN 04 2013
JAMES W. McCORMACK, CLERK
By: SMD DEP CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

SUSAN HARP, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS INC., Defendant.	Civil Action No.: <u>4:13 cv 04 JMM</u> Judge: <u>COMPLAINT WITH JURY DEMAND</u>
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Plaintiff Susan Harp, by and through the undersigned attorneys, hereby brings this cause of action for personal injuries suffered as a proximate result of Plaintiff Susan Harp being prescribed and using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Bayer Healthcare Pharmaceuticals, Inc. ("Bayer").

This case assigned to District Judge Mary
and to Magistrate Judge Ray

PARTIES AND CITIZENSHIP

1. At all relevant times hereto, Plaintiff Susan Harp (the "Plaintiff") was a resident and citizen of Bald Knob, Arkansas in White County.
2. Defendant Bayer Healthcare Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West

Belt Road, Wayne, New Jersey 07470. Defendant Bayer Healthcare Pharmaceuticals, Inc., can be served with process through its registered agent for service of process in Arkansas, Corporation Service Company, Spring Building, Suite 900, 300 South Spring Street, Little Rock, Arkansas 72201.

3. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

4. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

5. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application (“NDA”) for contraceptive device Mirena®.

6. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women’s healthcare products, including the intrauterine contraceptive system, Mirena®.

7. Bayer does business in Arkansas through the sale of Mirena® and other prescription drugs in the state.

8. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

10. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in the Eastern District of Arkansas, Western Division.

FACTS

12. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

13. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as a contraceptive.

14. The federal Food and Drug Administration ("FDA") approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

15. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendant admits "[i]t is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

16. The Mirena® intrauterine system (“IUS”) is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

17. The package labeling recommends that Mirena® be used in women who have had at least one child.

18. Mirena®’s label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

19. Mirena®’s label also describes perforation as an “uncommon” event, despite the numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

20. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

21. In or around December 2009, Defendant was contacted by the Department of Health and Human Services’ Division of Drug Marketing, Advertising, and Communications (“DDMAC”) regarding a consumer-directed program entitled “Mirena Simple Style Statements Program,” a live presentation designed for “busy moms.” The Simple Style program was presented in a consumer’s home or other private setting by a representative from “Mom Central”, a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendant.

22. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined

these claims were unsubstantiated and, in fact, pointed out that Mirena®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

23. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

24. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage is a woman becomes pregnant on Mirena®.

25. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

26. Plaintiff Susan Harp is currently 29 years-old.

27. Plaintiff had the Mirena® IUS inserted in January, 2006 by Dr. Tim Killough of the Westside Family Medical Clinic. The Mirena® IUS insertion was uncomplicated and was properly placed.

28. On January 6, 2010, Plaintiff presented to White County Medical Center with complaints of severe abdominal pain and vomiting. A CT scan with contrast was performed and revealed that Plaintiff's IUD was no longer within her uterus, but rather, was free within her pelvis. Plaintiff was admitted to the hospital.

29. On January 7, 2010, Plaintiff underwent a laparoscopy under general anesthesia and the Mirena IUD was removed from the right adnexal tissue.

30. Plaintiff's recovery was complicated by an episode of Acute Pyelonephritis, which was diagnosed on January 13, 2010.

FIRST CAUSE OF ACTION:
DEFECTIVE MANUFACTURING

31. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

32. Defendant was and is engaged in the business of selling Mirena® in the State of Arkansas.

33. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant was expected to, and did, reach Plaintiff Susan Harp without substantial change in the condition in which it was sold.

34. Defendant introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena® outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena® caused serious harm to Plaintiff Susan Harp.

35. Defendant manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff Susan Harp.

36. As a direct and proximate result of Plaintiff Susan Harp' use of Mirena®, she was forced to undergo surgical removal of the IUS, developed severe pain from the device, developed an infection, and had to undergo numerous procedures.

37. Defendant placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

38. Defendant knew and, in fact, advertised and promoted the use of Mirena® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and

proximate result of the Defendant's advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

39. Despite the fact that evidence existed that the use of Mirena® was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with the Mirena® and in fact acted to deceive the medical community and public at large, including all potential users of Mirena® by promoting it as safe and effective.

40. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

41. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

42. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION:
DESIGN DEFECT

43. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

44. Defendant was and is engaged in the business of selling Mirena® in the State of Arkansas.

45. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant was expected to, and did, reach Plaintiff Susan Harp without substantial change in the condition in which it was sold.

46. The foreseeable risks associated with the design or formulation of the Mirena® include, but are not limited to, the fact that the design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

47. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff Susan Harp.

48. As a direct and proximate cause of Plaintiff Susan Harp's use of Mirena®, she was forced to undergo surgical removal of the Mirena®, developed severe pain, suffered from infection, and underwent numerous procedures.

49. Defendant placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

50. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

51. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

52. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required and medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION:
NEGLIGENCE

53. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

54. Upon information and belief, Defendant failed to use reasonable care in designing Mirena® in that they:

- a. failed to properly and thoroughly test Mirena® before releasing the drug to market;
- b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;
- c. failed to conduct sufficient post-market testing and surveillance of Mirena®;
- d. designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. failed to exercise due care when advertising and promoting Mirena®; and
- f. negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendant knew or should have known of its adverse effects.

55. A reasonable manufacturer would or should have known that its risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

56. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION:
FAILURE TO WARN

57. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

58. Mirena® is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, uterine perforation post-insertion, or the possibility that device complications such as migration and perforation may cause abscesses, infections, require surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

59. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold and otherwise released into the stream of commerce the pharmaceutical, Mirena®, and in the course

of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

60. Mirena® was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

61. Defendant downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendant placed its profits above its customers' safety.

62. Mirena® was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert Plaintiff and her physician to the dangerous risks and reactions associated with it. Even though Defendant knew or should have known of the risks associated with Mirena, Defendant failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

63. Plaintiff Susan Harp used Mirena® as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

64. Plaintiff could not have discovered any defect in Mirena® through the exercise of reasonable care.

65. Defendant, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendant had knowledge of the dangerous risks and side effects of Mirena®.

66. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her physician(s).

67. Defendant had a continuing duty to warn consumers, including Plaintiff Susan Harp and her physicians, and the medical community of the dangers associated with Mirena®, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendant breached their duty.

68. Although Defendant knew, or were reckless in not knowing, of the defective nature of Mirena®, they continued to manufacture, design, formulate, test, package, label, produce, create, made, construct, assemble, market, advertise, distribute and sell Mirena® without providing adequate warnings and instructions concerning the use of Mirena® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena®.

69. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common *law* and statutory law.

FIFTH CAUSE OF ACTION:
STRICT LIABILITY

70. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

71. Defendant are manufacturers and/or suppliers of Mirena® and are strictly liable to Plaintiff for manufacturing, designing, formulating, testing, packaging, labeling, producing,

creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Mirena® into the stream of commerce.

72. Mirena®, manufactured and/or supplied by Defendant, was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

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

74. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendant failed to adequately warn of these risks.

75. Mirena® was defective due to inadequate pre-marketing testing.

76. Defendant failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the extreme risks associated with Mirena® and continues to promote Mirena® in the absence of those adequate warnings.

77. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and. all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

78. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

79. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® as safe for use by the public at large, including Plaintiff, who purchased Mirena®. Defendant knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

80. Plaintiff Susan Harp reasonably relied on the skill and judgment of the Defendant, and as such their implied warranty, in using Mirena®.

81. Contrary to same, Mirena® was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

82. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SEVENTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

83. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

84. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® were expressly warranted to be safe by Defendant for Plaintiff Susan Harp and members of the public generally. At the time of the making of these express warranties, Defendant had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendant warranted Mirena® to be in all respects safe, effective and proper for such purposes.

85. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects.

86. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

EIGHTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION

87. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

88. Defendant, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling,

advertising, and distributing of Mirena® described herein, owed a. duty to provide accurate and complete information regarding Mirena®.

89. Defendant fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

90. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiff Susan Harp was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

91. Defendant knew this information to be false, incomplete and misleading.

92. Defendant intended to deceive and mislead Plaintiff Susan Harp so that she might rely on these fraudulent misrepresentations.

93. Plaintiff Susan Harp had a right to rely on and did reasonably rely upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

94. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

NINTH CAUSE OF ACTION:
FRAUD BY CONCEALMENT

95. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

96. Defendant had a duty and obligation to disclose to Plaintiff Susan Harp that Mirena® was dangerous and likely to cause serious health consequences to users when used as prescribed.

97. Defendant intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff Susan Harp with the intent to defraud her as herein alleged.

98. Neither Plaintiff Susan Harp nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

99. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff Susan Harp has proximately sustained damage, as set forth herein.

100. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

101. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

102. At all times relevant herein, Defendant:

a. knew that Mirena® was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff Susan Harp, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff Susan Harp, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Mirena®; and

d. with full knowledge of the health risks associated with Mirena® and without adequate warnings of the same, manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® for routine use.

103. Defendant, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff Susan Harp and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff Susan Harp and the general public.

104. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Susan Harp suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

WHEREFORE, Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

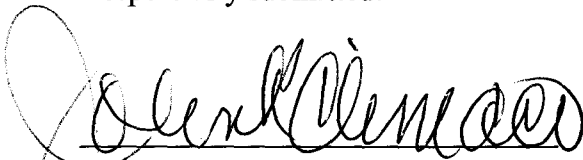
PRAYER FOR RELIEF

Plaintiff demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

JURY DEMAND

A jury trial is requested.

Respectfully submitted:

A large, stylized handwritten signature in black ink, which appears to read "John R. Climaco". The signature is written over a horizontal line.

John R. Climaco (OH#0011456) *Admitted*

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Counsel for the Plaintiff

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil coversheet 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

Susan Harp

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

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

John R. Climaco, Climaco Wilcox Peca Tarantino & Garofoli Co., LPA,
55 Public Square, #1950, Cleveland, OH 44113 216.621.8484

DEFENDANTS

Bayer Healthcare Pharmaceuticals, Inc.,

County of Residence of First Listed Defendant

(IN U.S. PLAINTIFF CASES ONLY)

NOTE:

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

Attorneys (If Known)

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (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 | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

- | | | | | | |
|--|---|---|--|---|--|
| <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
<input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans)
<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 - Med. 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 | <input type="checkbox"/> 422 Appeal 28 USC 158
<input type="checkbox"/> 423 Withdrawal 28 USC 157
<input type="checkbox"/> 820 Copyrights
<input type="checkbox"/> 830 Patent
<input type="checkbox"/> 840 Trademark | <input type="checkbox"/> 375 False Claims Act
<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 |
| <input type="checkbox"/> 210 Land Condemnation
<input type="checkbox"/> 220 Foreclosure
<input type="checkbox"/> 230 Rent Lease & Ejectment
<input type="checkbox"/> 240 Torts to Land
<input type="checkbox"/> 245 Tort Product Liability
<input type="checkbox"/> 290 All Other Real Property | <input type="checkbox"/> 440 Other Civil Rights
<input type="checkbox"/> 441 Voting
<input type="checkbox"/> 442 Employment
<input type="checkbox"/> 443 Housing/Accommodations
<input type="checkbox"/> 445 Amer. w/Disabilities - Employment
<input type="checkbox"/> 446 Amer. w/Disabilities - Other
<input type="checkbox"/> 448 Education | <input type="checkbox"/> 510 Motions to Vacate Sentence
Habeas Corpus:
<input type="checkbox"/> 530 General
<input type="checkbox"/> 535 Death Penalty
<input type="checkbox"/> 540 Mandamus & Other
<input type="checkbox"/> 550 Civil Rights
<input type="checkbox"/> 555 Prison Condition
<input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement | <input type="checkbox"/> 710 Fair Labor Standards Act
<input type="checkbox"/> 720 Labor/Mgmt. 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 Empl. Ret. Inc. Security Act | <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)) | |
| | | | <input type="checkbox"/> 462 Naturalization Application
<input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
<input type="checkbox"/> 465 Other Immigration Actions | <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)
<input type="checkbox"/> 871 IRS—Third Party 26 USC 7609 | |

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

Brief description of cause:

Defective Manufacturing

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

01/03/2013

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE