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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

NILES MONNIN Plaintiff, vs. JANSSEN PHARMACEUTICALS, INC., JANSSEN RESEARCH AND DEVELOPMENT, LLC, JOHNSON & JOHNSON, JANSSEN ORTHO, LLC, MITSUBISHI TANABE PHARMA HOLDINGS AMERICA, INC., MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC., TANABE RESEARCH LABORATORIES U.S.A., INC., and MITSUBISHI TANABE PHARMA CORP. Defendants.	Civil Action No._____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Niles Monnin ("Plaintiff"), tenders the following as his Complaint and Jury Demand against Defendants, Janssen Pharmaceuticals, Inc., Janssen Research and Development, LLC, Johnson & Johnson, Janssen Ortho, LLC, Mitsubishi Tanabe Pharma Holdings America, Inc., Mitsubishi Tanabe Pharma Development America, Inc., Tanabe Research Laboratories U.S.A., Inc., and Mitsubishi Tanabe Pharma Corp. (collectively "Defendants"), for personal

injuries suffered as a proximate result of Plaintiff being prescribed and properly using the Defendants' defective and unreasonably dangerous product Invokana (also known as canagliflozin).

PARTIES

1. At all relevant times hereto, Plaintiff Niles Monnin was a citizen and resident of Violet, St. Bernard Parish, Louisiana. Plaintiff is currently a citizen of and resides in Violet, St. Bernard Parish, Louisiana.

2. Defendant Janssen Research & Development LLC ("Janssen R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at 920 Route 202, Raritan, NJ 08869. Janssen R&D's sole member is Janssen Pharmaceuticals, Inc.

3. At all relevant times, Defendant Janssen R&D transacted business in the State of Louisiana, and it has derived substantial revenue from interstate commerce in this district.

4. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with a principal place of business at 800 Ridgeview Drive, Horsham, PA 19044. Both Janssen, and its wholly owned LLC, Janssen R&D, are subsidiaries of Johnson & Johnson.

5. At all relevant times, Defendant Janssen transacted business in the State of Louisiana, and it has derived substantial revenue from interstate commerce in this district.

6. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

7. At all relevant times, Defendant J&J transacted business in the State of Louisiana, and it has derived substantial revenue from interstate commerce in this district.

8. Defendant Janssen Ortho, LLC, (Janssen Ortho) is a Delaware company with a principal place of business at State Road 933 Km 01, Gurabo, Puerto Rico 00778.

9. At all relevant times, Janssen Ortho manufactured Invokana.

10. At all relevant times, Defendant Janssen Ortho transacted business in the State of Louisiana, and it has derived substantial revenue from interstate commerce in this district.

11. Defendant Mitsubishi Tanabe Pharma Corp. (Tanabe) is a Japanese corporation with its principal place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan. Tanabe is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana.

12. Defendant Mitsubishi Tanabe Pharma Holdings America, Inc. ("Tanabe Holdings") is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, NJ 07310.

13. Tanabe Holdings is a subsidiary of Tanabe and a holding company for U.S. subsidiaries.

14. Defendant Mitsubishi Tanabe Pharma Development America, Inc. ("Tanabe Development") is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, New Jersey 07310.

15. Tanabe Development licenses pharmaceuticals and drug therapies including Invokana for its parent corporation, Tanabe, conducts clinical development activity for obtaining marketing approval of drugs in the U.S., including Invokana, and provides administration support for the U.S. affiliates.

16. Defendant Tanabe Research Laboratories U.S.A., Inc. ("Tanabe Research") is a California corporation, with a principal place of business 4540 Towne Centre Court, San Diego, California 92121

17. Tanabe Research conducts pharmaceutical research, including research related to Invokana.

18. At all times herein mentioned, Defendants advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, Invokana.

19. At all relevant times, Defendants derived substantial revenue from interstate commerce in this district.

A. JURISDICTION AND VENUE

20. This Court has subject matter 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 Plaintiff is a citizen of a different state than all Defendants.

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

22. This Court has personal jurisdiction over the Defendants because they have done business in the State of Louisiana, have committed a tort in whole or in part in the State of Louisiana, have substantial and continuing contact with the State of Louisiana, and derive substantial revenue from goods used and consumed within the State of Louisiana. The Defendants actively sell, market, and promote their pharmaceutical product Invokana to physicians and consumers in this state and district on a regular and consistent basis.

23. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including Invokana, within Louisiana, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

24. At all times relevant to this action, Defendants were engaged in substantial business activities in Louisiana, including disseminating inaccurate, false, and misleading information about Invokana to health care professionals in Louisiana, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout Louisiana and throughout the United States.

25. Venue is proper within this district and division pursuant to 28 U.S.C. § 1391(a) because the Defendants are subject to this Court's personal jurisdiction.

B. FACTUAL ALLEGATIONS

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

27. Invokana is a member of the gliflozin class of pharmaceuticals, also known as sodium-glucose co-transporter 2 ("SGLT2") inhibitors.

28. SGLT2 inhibitors, including Invokana, inhibit renal glucose reabsorption through the SGLT2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract. This puts additional stress on the kidneys in patients already at risk for kidney disease.

29. SGLT2 inhibitors, including Invokana, are designed to target primarily the SGLT2 receptor, but have varying selectivity for this receptor, and block other sodium-glucose co-transporter receptors, including SGLT1.

30. The SGLT2 and SGLT1 receptors are located throughout the body, including in the kidney, intestines, and brain.

31. Invokana has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States.

32. SGLT2 inhibitors, including Invokana, are currently approved only for improvement of glycemic control in adults with type 2 diabetes.

33. At all times herein mentioned, the Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Invokana for the use and application by patients with diabetes, including, but not limited to, Plaintiff.

34. On information and belief, Defendants Tanabe, Tanabe Holdings, Tanabe Development, and Tanabe Research, in collaboration with the other Defendants, designed, developed, and marketed the diabetes drug, Invokana in the United States, and have made misrepresentations regarding the safety of the drug.

35. Defendant J&J, the parent company of Janssen, is involved in the marketing and branding of Invokana, and publishes marketing and warnings regarding the product.

36. Indeed, Defendants have published advertisements on their company websites and issued press releases announcing favorable information about Invokana. For example, the FDA's approval of Invokana on March 29, 2013 was announced on the J&J web site. On April 1, 2013, Tanabe announced the approval of Invokana in the United States as a new treatment option for Type 2 diabetes. On March 14, 2016, the J&J issued a press release announcing "First Real-World Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Shows Adults with Type 2

Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (canagliflozin)". The former announcements did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions.

37. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities at residents of Louisiana.

38. The Invokana-related pages on the Defendants' web sites are accessible from within Louisiana, and have been indexed by search engines so that they are located through searches that are conducted from within Louisiana.

39. Defendant J&J also published information touting the strong sales of Invokana in its corporate reports and in earnings calls.

40. Further, J&J employees had responsibility for overseeing promotion strategies for the drug Invokana.

41. All marketing materials, advertisements, press releases, web site publications, dear doctor letters, and other communications regarding Invokana are part of the design and labeling of the drug, and could be altered without prior FDA approval.

42. Defendant J&J had the ability and the duty to independently alter the design and labeling of Invokana. Specifically, it could independently publish additional warnings regarding Invokana, particularly the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infection, bone fracture, etc.

43. Defendant J&J so substantially dominates and controls the operations of Janssen, Janssen R&D, and Janssen Ortho, that it could have required them to make changes to the safety label of the drug Invokana.

44. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokana and direct these activities on behalf of J&J, Janssen, Janssen R&D, and Janssen Ortho.

45. In fact, J&J so substantially dominates and controls the operations of Janssen, Janssen R&D, and Janssen Ortho, that the entities are indistinct for purposes of this litigation such that Janssen, Janssen R&D, and Janssen Ortho should be considered agents or departments of J&J, and J&J is their alter-ego.

46. Employees of Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokana and direct these activities on behalf of J&J, Janssen, Janssen R&D, and Janssen Ortho.

47. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing rights to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in the United States, including in Louisiana.

48. In May 2012, Janssen R&D submitted a New Drug Application to the FDA for approval to market Invokana in the United States.

49. In March 2013, the FDA approved Invokana as an adjunct to diet and exercise for the improvement of glycemic control in adults with the treatment of type 2 diabetes.

50. As part of its marketing approval of Invokana, the FDA required the defendants to conduct five post-marketing studies: a cardiovascular outcomes trial; an enhanced pharmacovigilance program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy

outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamic study and a safety and efficacy study.

51. In an effort to increase sales and market share, Defendants have aggressively marketed and continue to aggressively market Invokana to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in type 1 diabetics.

52. Defendants also, through their marketing materials, misrepresented and exaggerated the effectiveness of Invokana, both as to its ability to lower glucose, and its benefit for non-surrogate measures of health, such as reducing adverse cardiovascular outcomes.

53. Defendants' marketing campaign willfully and intentionally misrepresented the risks of Invokana and failed to warn about the risks of diabetic ketoacidosis and kidney failure.

54. Defendants' misrepresentations and off-label advertising campaigns have led to Invokana being prescribed for off-label uses, in people with type 1 diabetes, for weight loss, and reduced blood pressure.

55. Invokana is one of Defendants' top selling drugs, with annual sales exceeding $1 billion.

56. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

57. Defendants, both individually and in concert with one another, misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes

serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, as well as serious cardiovascular problems.

58. Specifically, Defendants knew or should have known of the risks of diabetic ketoacidosis and kidney failure based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports, and regulatory authority investigations, including, but not limited to the following:

a. Invokana selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given Invokana;

c. Studies of phlorizin indicating a propensity to cause ketoacidosis;

d. Reports involving people with familial glycosuria, indicating a propensity to develop ketoacidosis;

e. Clinical studies demonstrating increases in glucagon in people taking Invokana;

f. Clinical studies, adverse event reports, and case reports demonstrating increased ketones in people taking Invokana;

g. Clinical studies, adverse event reports, and case reports demonstrating dehydration and volume depletion in people taking Invokana;

h. Clinical studies, adverse event reports, and case reports demonstrating vomiting in people taking Invokana;

i. Clinical studies, adverse event reports, and case reports demonstrating re-challenge responses in increasing ketones and diabetic ketoacidosis in people taking Invokana; and

j. Adverse event report analysis demonstrating an increased rate of reports for ketoacidosis in people taking Invokana compared to other glucose-lowering medications.

59. Diabetic ketoacidosis may lead to complications such as cerebral edema, pulmonary edema, cerebrovascular accident, myocardial infarction, nonspecific myocardial injury, severe dehydration, and coma.

60. Invokana-induced diabetic ketoacidosis may lead to delayed treatment because in many cases Invokana will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis. This may result in increased progression of the condition and increased injury to the patient.

61. Despite Defendants' knowledge of the risks of ketoacidosis injuries as described above, Invokana's label fails to contain a warning for either event.

62. Along with the above-described injuries, SGLT- 2 inhibitors, and Invokana in particular, also dramatically increase the likelihood of a patient developing kidney failure.

63. Invokana by its very mechanism of action causes dehydration and osmotic diuresis. Osmotic diuresis is the increase of urination rate caused by the presence of certain substances in the small tubes of the kidneys. The excretion occurs when substances such as glucose enter the kidney tubules and cannot be reabsorbed.

64. Because Invokana blocks sugar from being reabsorbed by the kidneys, the kidneys expel the sugar in the patient's urine. A buildup of sugar in the tubes leading from the kidneys leads to acute kidney (or "renal") failure.

65. Osmotic diuresis leads to volume depletion, which is water loss and salt loss.

66. Volume depletion is distinct from dehydration, which relates only to water loss.

67. Volume depletion leads to decreased renal perfusion, meaning the kidneys do not push the fluid through its vessels as well as they should. Unimpeded, decreased renal perfusion leads to acute renal injury, including kidney failure which necessitates dialysis and, unencumbered, may require kidney transplants.

68. Invokana causes osmotic diuresis due to its very mechanism of action, by forcing the kidneys to work harder and push more glucose through their tubules than the kidneys are intended to do. This continued heightened state the kidneys are put in when a patient is on Invokana makes kidney injury a higher likelihood, even for those with normal kidney function at the beginning of Invokana therapy.

69. Defendants were aware of the potential for Invokana to cause kidney failure prior to Invokana's approval. In fact, Invokana's medical review, submitted with Invokana's NDA approval documents, disclosed a nearly three-fold increase (1.7% compared to 0.6%) in acute renal failure for patients taking the higher dose of Invokana compared to those taking placebo, even in patients whose kidney function was normal.

70. Defendants knew that the likelihood of renal adverse effects such as acute renal failure was nearly tripled in patients with near normal kidney function and more than doubled in patients with even moderately impaired kidney function.

71. Defendants were aware that the mechanism of action for Invokana places extraordinary strain on the kidneys and renal system.

72. Despite its knowledge of data indicating that Invokana use is causally related to the development of diabetic ketoacidosis and kidney failure, Defendants promoted and marketed Invokana as safe and effective for persons such as Plaintiff throughout the United States, in Louisiana.

73. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not warn patients but instead continued to defend Invokana, mislead physicians and the public, and minimized unfavorable findings.

74. Defendants failed to adequately warn consumers and physicians about the risks associated with Invokana and the monitoring required to ensure their patients' safety.

75. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not conduct the necessary additional studies to properly evaluate these risks prior to marketing the drug to the general public.

76. Consumers of Invokana and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including diabetic ketoacidosis, kidney failure, cardiovascular problems, and the life-threatening complications thereof.

77. Consumers, including Plaintiff, have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents including treatment with Glucophage (Metformin)

78. Plaintiff was prescribed Invokana by his treating physician and used it as directed.

79. Plaintiff was prescribed Invokana to improve glycemic control as an adjunct to diet and exercise on or about September 10, 2014.

80. While taking Invokana, Plaintiff was diagnosed with diabetic ketoacidosis on or about November 7, 2014, as a result of treatment with Invokana and required continued treatment.

81. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment, which will continue in the future. Plaintiff seeks actual and compensatory damages from Defendants.

82. Defendants' wrongful acts, omissions, fraudulent misrepresentations, inadequate warnings, and unreasonably dangerous design of Invokana caused Plaintiff's injuries and damages.

83. Defendants, both individually and in concert with one another, misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems, which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae.

84. Plaintiff's injuries were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana. This conduct and the product defects complained of were substantial factors in bringing about and exacerbating Plaintiff's injuries.

85. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking Invokana.

86. On information and belief, Defendants, both individually and in concert with one another, withheld material information from the FDA and misrepresented material information regarding the risks and benefits of Invokana in its communications with the FDA. These omissions and misrepresentations included failing to report instances of diabetic ketoacidosis to the FDA, failure to properly categorize adverse events in clinical trials, post-marketing trials, and obtained through its adverse event reporting system, and withholding of relevant information from pre-clinical and clinical trials.

87. On May 15, 2015, the FDA announced that SGLT2 inhibitors may lead to diabetic ketoacidosis.

88. On September 10, 2015, the FDA announced that Invokana causes premature bone loss and fractures.

89. On October 16, 2015, Health Canada, the Canadian drug regulatory authority, announced that Invokana can cause acute kidney injury.

90. On December 4, 2015, the FDA announced a label change for SGLT2 inhibitors, requiring that the label of SGLT2 inhibitors include a warning of ketoacidosis, the risk of too much acid in the blood, while taking SGLT2 inhibitors.

91. Prior to the FDA's December 4, 2015, safety announcement, Invokana's label continued to fail to warn consumers of the serious risk of developing diabetic ketoacidosis.

92. The Invokana label currently does not warn of the serious risks of developing bone fractures and kidney injury.

93. Despite the FDA's announcements, Defendants continue to engage in aggressive direct-to-consumer and physician marketing and advertising campaigns for Invokana.

94. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied Invokana to the purchaser.

95. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that Invokana was unreasonably dangerous because it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with adequate and proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

96. Defendants had a duty to warn Plaintiff's prescribing physicians about the risks of Invokana use, including the risk of diabetic ketoacidosis, kidney failure, and resulting complications.

97. Had Plaintiff and his physicians known the true risks associated with the use of SGLT2 inhibitors, including Invokana, Plaintiff would not have been prescribed Invokana, and Plaintiff would not have taken Invokana or Plaintiff would have been adequately monitored for its side effects, and as a result, would not have suffered injuries and damages from using Invokana.

98. Plaintiff's prescribing and treating physicians relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff's prescribing and treating physicians directly, through print and television advertising, articles and study reports funded and promoted by Defendants, and indirectly, through other healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

99. Plaintiff relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff directly, through print and television advertising, and indirectly, through Plaintiff's healthcare

providers and others who have been exposed to Defendants' claims through their comprehensive marketing campaigns.

100. Based on Defendants' direct-to-consumer advertising and Defendants' misrepresentations and omissions, Plaintiff made an independent decision to use Invokana based on the overall benefits and risks communicated by Defendants.

101. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokana's defects, and were not reasonably foreseeable to Plaintiff or Plaintiff's physicians.

102. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injury. In addition, Plaintiff requires and will continue to require healthcare and medical services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

103. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff has reason to suspect, that they had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable prescriptive period prior to the filing of this action.

104. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that the drug Invokana is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

105. The Defendants are liable under the theory of product liability as set forth in the Louisiana Products Liability Act. See La. Rev. Stat. Ann. § 9:2800.51 et seq.

I. CAUSES OF ACTION

COUNT ONE
UNREASONABLY DANGEROUS IN DESIGN
(including violation of the Louisiana Products Liability Act; La. Rev. Stat. Ann. § 9:2800.51 et seq.)

106. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

107. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in an unreasonably dangerous and defective manner, including the Invokana used by Plaintiff.

108. The unreasonably dangerous design was caused by Defendants' failure to:

a. Adequately test Invokana;

b. Develop and provide a product label and marketing materials that accurately describes the risks of and does not overstate the benefits of using Invokana;

c. Provide full, complete, and accurate information to the FDA about Invokana;

d. Adequately test and study Invokana;

e. Ensure that the benefits of Invokana outweighed the risks for people susceptible to diabetic ketoacidosis, kidney failure or other adverse effects;

f. Conduct adequate post-market surveillance; and

g. Use a safer alternative formulation.

109. The unreasonably dangerous design made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

110. The unreasonably dangerous design was such that the risks of Invokana outweighed its utility.

111. This unreasonable danger was unknowable to Plaintiff and would be considered unacceptable to the average consumer.

112. There were practical and technically feasible alternative designs that would not have reduced the utility of Invokana and would not have cost substantially more to develop, including, but not limited to providing a better warning with Invokana, using an alternative diabetes treatment such as Glucophage (Metformin), or developing an SLGT2 inhibitor with a different safety profile.

113. The label is part of the design of Invokana, and therefore the design can be changed. Specifically, the label could have included a contraindication for people whose ketones increase, which would have alerted doctors and patients that the drug Invokana is not suitable for that population because the risks outweigh the benefits.

114. Defendants' unreasonably dangerous design of Invokana was reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Intentionally valuing profits over the safety and well-being of the consumers of

Invokana, Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting users.

115. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

116. Defendants expected and intended Invokana to reach, and it did in fact reach, Plaintiff without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

117. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known of Invokana's unreasonably dangerous design.

118. Plaintiff and Plaintiff's physicians did not have the same knowledge or expertise as Defendants and could not have discovered any unreasonably dangerous design defect in Invokana through the exercise of reasonable care.

119. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the unreasonably dangerous design of Invokana, Plaintiff sustained permanent injury.

120. The defects in Invokana were substantial contributing factors in causing Plaintiff's injuries.

Count Two
UNREASONABLY DANGEROUS DUE TO INADEQUATE WARNING
(including violation of the Louisiana Products Liability Act; La. Rev. Stat. Ann. § 9:2800.51 et seq.)

121. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

122. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in an unreasonably dangerous manner, including the Invokana used by Plaintiff. The unreasonably dangerous design made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

123. Invokana's inadequate warnings rendered Invokana unreasonably dangerous.

124. Defendants' defective warnings for Invokana were reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Intentionally valuing profits over the safety and well-being of the consumers of Invokana, Defendants made conscious decisions not to adequately warn about risks they know or should have known about.

125. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

126. Defendants expected and intended Invokana to reach, and it did in fact reach, Plaintiff without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

127. Plaintiff could not have discovered the inadequate warning and unwarned of risks of using Invokana through the exercise of reasonable care.

128. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Invokana were inadequate and thus made Invokana unreasonably dangerous.

129. Plaintiff did not have the same knowledge as Defendants, and Defendants did not communicate adequate warnings or other clinically relevant information and data to Plaintiff or to Plaintiff's treating physicians. The warnings that were given by the Defendants were inaccurate, inadequate, and incomplete.

130. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take other such steps as necessary to ensure that Invokana did not cause users to suffer from unreasonable and dangerous risks.

131. Defendants knew or should have known that the limited warnings disseminated with Invokana were inadequate, but they failed to communicate adequate information on the dangers and safe use of their product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

132. At all times material hereto, Defendants knew or should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Invokana to cause or increase the harm of diabetic ketoacidosis, kidney failure, and the life threatening complications of those conditions.

133. Defendants had a duty to adequately warn physicians, healthcare providers, and patients the causal relationship or association of Invokana to diabetic ketoacidosis, kidney failure, and the life threatening complications of those conditions.

134. As a result of the Defendants' aggressive marketing campaigns promoting off-label uses, including for type 1 diabetes, weight loss, and to improve blood pressure and kidney function, Defendants knew or should have known and expected that consumers would use Invokana for such off-label uses and did not adequately warn physicians, healthcare providers, or patients of the dangers associated with such use.

135. Defendants knew or should have known that some patients would develop serious injuries, including diabetic ketoacidosis, kidney failure, and cardiovascular injury, and did not adequately warn physicians, healthcare providers, or patients about these injuries, which were foreseeable following Invokana use.

136. Despite the fact that Defendants knew or should have known that Invokana was unreasonably dangerous, Defendants continued to market Invokana to consumers including Plaintiff, when there were safer alternative methods available, and did not adequately warn Plaintiff or his healthcare providers about the unreasonably dangerous nature of Invokana.

137. Neither Plaintiff nor his healthcare providers knew or could have known the nature and extent of the injuries that could result from Invokana when it was prescribed to Plaintiff, and they were misinformed about the benefits of Invokana and could not have discovered this information independently.

138. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, and failure to adequately warn Plaintiff and his physicians about the significant risks inherent in Invokana therapy, Plaintiff sustained permanent injury.

Count Three
UNREASONABLY DANGEROUS DUE TO NONCONFORMITY TO AN EXPRESS WARRANTY
(including violation of Louisiana Products Liability Act; La. Rev. Stat. Ann. § 9:2800.51 et seq.)

139. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

140. At all relevant times, Defendants expressly represented and warranted to Plaintiff and Plaintiff's physicians and health care providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians, medical patients and the general public, that Invokana was safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was efficacious.

141. In particular, the "Warnings and Precautions" section of the Invokana prescribing information purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about.

142. In particular, the Consumer Medication Guide expressly indicates "What is the most important information I should know about INVOKANA?" and "What are the possible side effects of INVOKANA?" and "General information about the safe and effective use of INVOKANA" and does not mention that Invokana has been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events.

143. Furthermore, Defendants J&J, Janssen, Janssen R&D, Janssen Ortho, Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug

Invokana was generally well tolerated and safe for use, and was not likely to cause side effects other than the ones listed—these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, bone fractures, etc.

144. Plaintiff's physician prescribed Invokana and Plaintiff purchased and consumed Invokana reasonably relying upon these warranties; Plaintiff and Plaintiff's physicians did not know and could not have learned independently that Defendants' representations were false and misleading.

145. Defendants knew and expected or should have known and expected, and intended Plaintiff to rely on their warranties.

146. The representations contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

147. In utilizing Invokana, Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of Defendants.

148. These warranties and representations were false in that Invokana is not safe, effective, fit and proper for its intended use because of its propensity to cause, among other conditions, diabetic ketoacidosis, kidney failure, and cardiovascular problems.

149. Because Invokana did not conform to Defendants' express representation, Defendants breached the warranties.

150. Invokana's nonconformity to an express warranty was reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Intentionally valuing profits over the safety and well-being of the consumers of

Invokana, Defendants made conscious decisions not to adequately warn about risks they know or should have known about.

151. As a foreseeable, direct, and proximate result of the breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

PRESERVATION CLAIMS

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

173. Many States have enacted tort reform statutes with "exclusive remedy" provisions. Courts have yet to determine whether these exclusive remedy provisions eliminate or supersede, to any extent, state common law claims. If during the pendency of this action this court makes any such determination, Plaintiffs hereby specifically make claim to and preserve any State claim based upon any exclusive remedy provision, under any state law this court may apply, to the extent not already alleged above.

174. To the extent that Defendants may claim that one or more of Plaintiff's claims are barred by any applicable prescriptive period, Plaintiff asserts that the prescriptive period has been tolled by Plaintiff's delayed discovery that his injuries were caused by Defendants' defective product and failure to properly and adequately warn of the products' risks, all as more fully set forth in this Complaint.

175. Specifically, Plaintiff could not reasonably have discovered, and in fact did not discover, that his injuries were caused by the Defendants unreasonably dangerous product and/or the wrongful conduct of the Defendants until he learned that many other patients had also suffered similar injuries after being prescribed Invokana.

DEMAND FOR JUDGMENT AGAINST DEFENDANTS

152. **WHEREFORE,** Plaintiff demands judgment against the Defendants and requests:

a. General damages in an amount that will conform to proof at time of trial;

b. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

c. Loss of earnings and impaired earning capacity according to proof at the time of trial;

d. Medical expenses, past and future, according to proof at the time of trial;

e. Past and future mental and emotional distress, according to proof at the time of trial;

f. Restitution, disgorgement of profits, and other equitable relief;

g. Punitive damages;

h. Attorney's fees;

i. Costs of suit incurred herein;

j. Pre-judgment interest as provided by law; and

k. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

153. Plaintiff hereby demands a jury trial on all claims so triable in this action.

Date: February 10, 2017.

/s/ Gerald Waltman III
Gerald Waltman III
Louisiana Bar No. 37347
DAVIS & CRUMP, P.C.
2601 14th Street
Gulfport, MS 39501
Telephone: (228) 863-6000
Facsimile: (228) 864-0907
jess.waltman@daviscrump.com

Attorney for Plaintiff

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Niles Monnin

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Gerald Waltman III, Davis & Crump, P.C.
2601 14th Street, Gulfport, MS 39501
228-863-6000

DEFENDANTS

JANSSEN PHARMACEUTICALS, INC., et al.

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS
☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/ Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	**Habeas Corpus:** ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty **Other:** ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Niles Monnin was injured by the unreasonably dangerous Invokana, manufactured by Defendants

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
02/10/2017

SIGNATURE OF ATTORNEY OF RECORD
s/ Gerald Waltman III

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

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

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

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

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

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

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Pharmaceuticals, Inc.
800 Ridgeview Drive
Horsham, PA 19044

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Research and Development, LLC
920 Route 202
Raritan, NJ 08869

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Ortho, LLC
State Road 933 Km 01
Gurabo, Puerto Rico 00778.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

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

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Janssen Ortho, LLC
State Road 933 Km 01
Gurabo, Puerto Rico 00778.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

This summons for *(name of individual and title, if any)* Mitsubishi Tanabe Pharma Holdings America, Inc.
was received by me on *(date)* _____ .

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Tanabe Research Laboratories U.S.A., Inc.
4540 Towne Centre Court
San Diego, CA 92121

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

This summons for *(name of individual and title, if any)* Tanabe Research Laboratories U.S.A., Inc.
was received by me on *(date)* _____ .

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

NILES MONNIN

Plaintiff(s)

v.

JANSSEN PHARMACEUTICALS, INC., ET AL.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Mitsubishi Tanabe Pharma Development America, Inc.
525 Washington Boulevard
Suite 400
Jersey City, NJ 07310

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Gerald Waltman, III
Davis & Crump, P.C.
2601 14th Street
Gulfport, MS 39501

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

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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

This summons for *(name of individual and title, if any)* Mitsubishi Tanabe Pharma Development America, Inc.
was received by me on *(date)* _____ .

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

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

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

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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

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

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset