**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION | MDL No. 2750<br>Master Docket No. 3:16-md-2750 |
| Thomas Layton and Jaime Layton,<br><br>Plaintiffs,<br><br>vs.<br><br>Janssen Pharmaceuticals, Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC,<br><br>Defendants. | JUDGE BRIAN R. MARTINOTTI<br>JUDGE LOIS H. GOODMAN<br><br>DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 4<br><br>CIVIL ACTION NO.:_____ |

Plaintiffs Thomas Layton and Jaime Layton file this Complaint pursuant to CMO No. 4 and are to be bound by the rights, protections and privileges and obligations of that CMO. Further, in accordance with CMO No. 4, Plaintiffs hereby designate the United States District Court for the Western District of Texas, as the place of remand as this case may have originally been filed there.

Plaintiffs by and through the undersigned attorney, submit this complaint and jury demand against Defendants JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, JANSSEN ORTHO, LLC, and JANSSEN PHARMACEUTICALS, INC.

As more specifically set forth below, Plaintiffs maintain that the diabetes drug, Invokana, is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper warning to the dangers associated with its use. This case is being filed in accordance with Case Management Order No. 4 of the *In re: Invokana* MDL No. 2750.

## NATURE OF ACTION

1. Defendants are the manufacturers of the prescription drug Invokana, developed and indicated for the treatment of type 2 diabetes. It was initially approved by the FDA in January of 2014 and is in a class of new diabetes drugs called glucose cotransporter-2 ("SGLT-2") inhibitors. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. As the name suggests, SGLT-2 inhibitors decrease sugar in the bloodstream by inhibiting glucose reabsorption. The extra sugar is then eliminated from the body through urine produced by the user's kidneys, putting extra strain on the kidneys of patients that already have increased insult to their kidneys by virtue of having diabetes.

2. In May 2015, the FDA issued a safety communication warning that SGLT-2 inhibitors (including Invokana) can cause life-threatening diabetic ketoacidosis ("DKA"), having discovered more than 20 cases that had been reported to FDA's adverse event reporting system ("FAERS"). Although DKA in Type 1 diabetics occurs with some frequency, it is uncommon in Type 2 diabetics.

3. On May 16, 2017, the FDA issued a safety communication confirming that Invokana use increases the risk of leg and foot amputations, based on data from two large clinical trials. This led to the FDA requiring a black boxed warning to be added to the label of Invokana, Invokamet and Invokamet XR (the latter two being combination drugs of Invokana and metformin, another oral hypoglycemic) regarding the risk of amputation. The risk was not found to be associated with the entire class of SGLT-2 inhibitors, only with Invokana. Therefore, this safety communication and the black box warning was not for the entire class of SGLT-2 inhibitors, but was solely for Invokana, Invokamet and Invokamet XR. On June 12, 2017, results from a large study sponsored by Defendants and examining safety outcomes with

Canagliflozin (CANVAS) was published in the *New England Journal of Medicine* that showed an increased risk of amputations in users of Invokana.

4. The Plaintiff herein, Thomas Layton, had type 2 diabetes, used Invokana and developed an infection that led to amputation of the fifth toe of his left foot. Plaintiff contends that the Defendants knew of this risk with Invokana, but failed to inform him or his doctor regarding this risk, and therefore bring this Complaint against Defendants.

**PARTIES**

5. Plaintiff Thomas Layton ingested and was physically harmed by the Defendants' product. Plaintiff-Spouse Jaime Layton was and is his spouse and sues for derivative claims from loss of consortium herein. "Plaintiff" when used in the singular, refers to plaintiff Thomas Layton, the plaintiff that ingested Invokana and was physically harmed.

6. At all relevant times since Thomas Layton's initial use of Invokana, Plaintiff and his Plaintiff-Spouse Jaime Layton were and are residents and citizens of San Marcos, Texas, located in Hays County.

7. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICIA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("Janssen"), was at all relevant times, a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson and Johnson. At all times relevant and material hereto, Janssen was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Invokana, in New Jersey and Texas and throughout the United States.

8. Janssen is registered to do business throughout the United States, including New Jersey and Texas, where Plaintiffs reside and where Plaintiff was treated for his injuries.

9. Janssen, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

10. Janssen is the wholly owned subsidiary of Johnson & Johnson ("J&J"). J&J and Janssen worked together to achieve the common business purpose of selling and profiting from Invokana.

11. Janssen's President and Chief Executive Officer at all relevant times reports directly to a J&J Company Group Chairman, who in turn reports to J&J's Executive Committee and Board of Directors. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

12. J&J and Janssen executives were also members of a Pharmaceutical Global Operating Committee, through which J&J set overall corporate goals that guided Janssen's strategic and tactical plans for Invokana. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

13. J&J established Janssen's business objectives and sales goals and regularly reviewed and approved Janssen's sales numbers and projections. During the relevant time period, J&J supervised and controlled corporate sales goals; drug research; development, and manufacturing; medical affairs; regulatory affairs and compliance; legal affairs; and public relations. At all relevant times, J&J and Janssen worked together to achieve the common business purpose of selling Invokana.

14. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC, is a limited liability company organized under the laws of New Jersey which has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ. Defendant Janssen Research &

Development, LLC (formerly known as Johnson & Johnson Pharmaceutical Research and Development, LLC, and hereinafter referred to as "Janssen R&D"), is a New Jersey limited liability company. Janssen R&D is a wholly owned subsidiary of Centocor Research & Development, Inc., which is not a publically held corporation. Centocor Research & Development, Inc., a Pennsylvania corporation with its principal place of business in Pennsylvania, Janssen R&D is registered to do business throughout the United States, including in New Jersey and Texas, where Plaintiffs reside and where plaintiff Thomas Layton was treated for his injuries.

15. Janssen R&D is registered to do business throughout the United States, including in New Jersey where the case is filed and Texas where Plaintiffs reside and where plaintiff Thomas Layton was treated for his injuries.

16. Janssen R&D, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

17. Defendant JOHNSON & JOHNSON (hereinafter "J&J"), is a fictitious name adopted by Defendant JOHNSON & JOHNSON COMPANY, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JOHNSON & JOHNSON was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Invokana.

18. J&J, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

19. Defendant, JANSSEN ORTHO, LLC ("Ortho") is a Delaware limited liability company with a principal place of business at State road 933 Km 01, Street Statero, Gurabo, Puerto Rico 00778. Ortho is a wholly-owned subsidiary of Johnson & Johnson. At all times relevant hereto, Defendant Ortho manufactures, and continues to manufacture Invokana. At all times relevant hereto, Defendant Ortho derived, and continues to derive, substantial revenue from goods and products developed, marketed, sold, distributed and disseminated and used in New Jersey, Texas and throughout the United States.

20. Ortho, by its employees or agents attended meetings and/or participated in telephone calls regarding the research, and/or development, and/or FDA approval, and/or marketing of Invokana.

21. At all times alleged herein, Defendants shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

## JURISDICTION AND VENUE

22. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

23. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(b) because, at all times material hereto, a substantial part of the events or omissions giving rise to this claim occurred in this District, and 28 U.S.C. §1391(a) because at all times material hereto, Defendants JANSSEN and JOHNSON & JOHNSON had their principal place of business in this District, and all the defendants conducted substantial business in this District

related to Invokana. Additionally, the Multi-District Litigation was created in and assigned to this District.

## FACTUAL ALLEGATIONS

### A. General Allegation

24. This action seeks, among other relief, general and special damages due to Plaintiff Thomas Layton suffering severe, life threatening and permanently debilitating side effect[s] of an amputation caused by Invokana and claims of his spouse Jaime Layton that are derivative therefrom.

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

26. SGLT2 inhibitors, including Invokana, inhibit renal glucose reabsorption through the SGL2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract instead of reabsorbed into the blood stream thereby putting additional strain on the kidneys.

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

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

29. The active ingredient in Invokana, canagliflozin is contained in both Invokana and Invokamet and has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States. This makes it unique among the class of SGLT2 inhibitors.

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

31. 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, Thomas Layton.

32. 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.

33. Defendants published advertisements on their company websites and issued press releases announcing favorable information about Canagliflozin. For example, the FDA's approval of Canagliflozin (Invokana) on March 29, 2013 was announced on the J&J web site.

34. On April 1, 2013, Defendants announced the approval of Canagliflozin (Invokana) in the United States as a new treatment option for Type 2 diabetes. On March 14, 2016, 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 announcement did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions. Neither announcement contained any warnings about the increased risk of amputations.

35. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities nationally including towards residents of Texas and New Jersey.

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

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

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

39. Materials including advertisements, press releases, web site publications, and other communications regarding Invokana are part of the labeling of the drug, and could be altered without prior FDA approval.

40. Defendant J&J had the ability and the duty to improve the labeling of Invokana to warn of the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infections such as urosepsis as well as gangrene leading to amputations.

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

42. 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, and Janssen R&D.

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

44. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing right to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in Texas and New Jersey and the remainder of the United States.

45. In February, 2014, Janssen R&D submitted an NDA to the FDA for approval to market Invokana in the United States.

46. In August 2014, the FDA approved Invokana as an adjunct to diet and exercise for the improvement of glycemic control in adults with type 2 diabetes.

47. As part of its marketing approval of canagliflozin, 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 pharmacodynamics study and a safety and efficacy study.

48. 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.

49. 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.

50. Defendants' marketing campaign willfully and intentionally misrepresented the risks of Invokana and failed to warn about the risks of diabetic ketoacidosis, kidney failure, sepsis, amputation and other injuries.

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

52. In September 2015, the FDA announced that SGLT2 inhibitors cause premature bone loss and fractures.

53. In December 2015, the FDA announced that SGLT2 inhibitors cause diabetic ketoacidosis, pyelonephritis (kidney infections), and urosepsis.

54. In May 2016, the FDA announced that SGLT2 inhibitors have been linked to an increased risk of amputations.

55. In June 2016, the FDA announced that SGLT2 inhibitors cause severe renal impairment, angioedema, and anaphylaxis.

56. In May of 2017 the FDA confirmed that Invokana and Invokamet increase the risk of leg and foot amputations and required a black box warning, as well as announcing further investigation into this safety issue.

57. 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 Thomas Layton.

58. 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 debilitating and/or life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, sepsis and kidney failure and its sequelae and amputations of the toes, feet and legs.

59. 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. Canagliflozin selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given canagliflozin;

c. Studies of SGLT1 inhibitor phlorizin, and its propensity to cause ketoacidosis;

d. Reports involving people with familial glycosuria, an indication of a propensity to develop ketoacidosis;

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

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

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

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

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

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

k. Clinical studies and adverse event reports demonstrating an increased rate of reports of patients developing gangrene, diabetic foot ulcers, lower limb ischemia and running the risk of and/or actually requiring an amputation.

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

61. Amputations lead to loss of mobility further exacerbating the risks of a sedentary lifestyle, including but not limited to weight gain, cardiovascular risks, pressure ulcers and resulting dangerous infections, as well as the physical and economic requirements of adapting to life in a wheelchair, such as ramps, bathroom and kitchen alterations, the inability to drive or costs needed for vehicle adaptations, cost for prosthetics and impaired earning potential.

62. 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.

63. Defendants were aware that the mechanism of action for Invokana places extraordinary strain on the kidneys and renal system. They were also aware that Invokana use causes volume depletion and that, as with thiazide diuretics, this could lead to increased risk of gangrene, diabetic foot ulcers, lower limb ischemia and eventually amputation of toes, feet and legs below the knee.

64. On June 12, 2017 the *New England Journal of Medicine* published results from the Canagliflozin Cardiovascular Assessment Study ("CANVAS") which integrated data from two trials involving a total of 10,142 patients. CANVAS reported that the risk of lower limb amputations was 5.9 amputations per 1.000 patients per year for canagliflozin compared to 2.8 amputations per 1,000 patients per year for placebo. Defendants, who sponsored and supported CANVAS, received and were aware of this data well before the publication date. Yet, despite this knowledge, they failed to make any changes to their label and failed to alert patients like Plaintiff and their physicians of this serious risk.

65. Despite their knowledge of data indicating that Invokana use is causally related to the development of diabetic ketoacidosis, kidney failure and amputations, Defendants promoted and marketed Invokana as safe and effective for persons such as Thomas Layton throughout the United States, including Texas and New Jersey.

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

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

68. 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.

69. 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, sepsis, amputations, and the life-threatening complications thereof.

70. Consumers, including Thomas Layton, have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents.

**B. Specific Allegations**

71. Thomas Layton had several alternative and safer methods to treat his diabetes, including diet and exercise and other diabetes medications. Thomas Layton was prescribed Invokana in or about May 2015 and used it as directed.

72. In May 2015, Thomas Layton was prescribed Invokana to be taken once by mouth daily improve glycemic control as an adjunct to diet and exercise.

73. In or about approximately October 2015, as a direct result of his treatment with Invokana, Thomas Layton was hospitalized for a severe diabetic ulcer of the left foot.

74. In or about approximately October 2015, as direct result of his use of INVOKANA, Thomas Layton underwent surgery for an amputation to remove the fifth toe of his left foot.

75. Plaintiff was discharged from the hospital in or around approximately October 2015.

76. In or about approximately August 2016, Plaintiff Thomas Layton underwent a subsequent surgery to remove additional bone from the previously infected and amputated left fifth toe area.

77. Plaintiff was discharged from the hospital in or around approximately August 2016.

78. Plaintiff is now limited to the use of crutches and/or a knee scooter in order to be mobile. He requires assistance from his spouse for many daily activities of living and has been unable to return to work as the Assistant Manager of a lumber company.

79. Thomas Layton has endured pain and suffering, and will continue to endure pain and suffering as a result of his permanent disability, as well as emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

80. Defendants' wrongful acts, omissions and fraudulent misrepresentations caused Thomas Layton's permanent injuries and damages.

81. Thomas Layton'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 and debilitating risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana. The conduct and the product defects were a substantial factor in bringing about Plaintiff's injuries.

82. Defendants had a duty to warn Thomas Layton's prescribing physicians about the risks of Invokana use, including the risk of diabetic ketoacidosis, renal failure, sepsis, resulting

complications thereof as well as gangrene, diabetic foot ulcers, lower limb ischemia and amputations.

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

84. Thomas Layton'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 Thomas Layton's prescribing and treating physicians directly, through sales representatives detailing the product, 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 their comprehensive marketing campaigns.

85. Thomas Layton 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 Thomas Layton directly, through print and television advertising, and indirectly, through his healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

86. Based on the Defendants' direct to consumer advertising and Defendants' misrepresentations and omissions, Thomas Layton made an independent decision to use Invokana in reference to the overall benefits and risks communicated by Defendants.

87. Thomas Layton's injuries were a reasonable foreseeable consequence of Defendants' conduct and Invokana's hazards, and were not reasonably foreseeable to Plaintiff or Plaintiff's physicians.

## CLAIMS FOR RELIEF

### COUNT ONE – STRICT PRODUCTS LIABILITY - DESIGN DEFECT

88. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein

89. Defendants had a duty to properly design, manufacture, compound, test, inspect, label, distribute, market, examine, maintain, supply, provide proper warnings, and take such steps as to assure that Invokana did not cause users to suffer from unreasonable and dangerous side effects.

90. The aforesaid product was defective and unsafe in design and manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Thomas Layton.

91. Invokana was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Invokana failed to warn of the dangerous risks posed by Invokana, including the risk of developing diabetic ketoacidosis, kidney damage, sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations.

92. Invokana was defective and Defendants knew that Invokana was to be used by consumers without inspection for defects. Moreover, Thomas Layton's prescribing physicians and other health care providers neither knew nor had reason to know at the time of Thomas Layton's use of Invokana of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

93. Invokana was prescribed to and used by Thomas Layton as intended by Defendants and in a manner reasonably foreseeable to Defendants.

94. The design of Invokana was defective in that the risks associated with using Invokana outweighed any benefits of the design. Any benefits associated with the use of Invokana were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

95. The defect in design existed when the product left Defendants' possession.

96. At the time Invokana left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Invokana.

97. As a result of Invokana's defective condition, Plaintiffs suffered the permanent injuries and damages alleged herein.

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

**COUNT TWO – STRICT PRODUCTS LIABILITY - FAILURE TO WARN**

98. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

99. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by Thomas Layton. The design defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

100. Invokana's inadequate warnings rendered Invokana unreasonably dangerous and defective.

101. 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. Defendants made conscious decisions not to adequately warn about risks they know or should have known about. Defendants' reckless conduct warrants an award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Invokana.

102. Thomas Layton was prescribed and used Invokana for its intended purposes and for purposes that the defendants expected and could foresee.

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

104. Thomas Layton could not have discovered the unwarned risks of using Invokana through the exercise of reasonable care.

105. 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 incomplete and inadequate.

106. Thomas Layton did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Thomas Layton or to his treating physicians. The warnings that were given by the Defendants were not accurate and were incomplete.

107. 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.

108. 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 its 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.

109. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug and failure to warn Thomas Layton and his physicians about the significant risks inherent in Invokana therapy, Thomas Layton sustained severe and permanent injuries.

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

**COUNT THREE – NEGLIGENCE**

110. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

111. At all times relevant times, Defendants had a duty to use reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect,

research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Invokana.

112. At all times material hereto, Defendants had actual knowledge, or in the alternative, 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, sepsis, and the life threatening complications of those conditions in addition to diabetic foot ulcers, gangrene, lower limb ischemia which can lead to amputations of toes, feet and legs below the knee.

113. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others when developing and selling Invokana.

114. Defendants had a duty to disclose to physicians, healthcare providers, and patients the causal relationship or association of Invokana to diabetic ketoacidosis, kidney failure, sepsis, and the life threatening complications of those conditions, in addition to diabetic foot ulcers, gangrene, lower limb ischemia which can lead to amputations of toes, feet and legs below the knee.

115. Defendants had a duty to accurately communicate the risks and benefits of Invokana to physicians, healthcare providers, and patients.

116. 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.

117. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including diabetic ketoacidosis, kidney failure

and sepsis, diabetic foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee; these injuries were foreseeable.

118. Thomas Layton did not know the nature and extent of the injuries that could result from Invokana and were misinformed about the benefits of Invokana and could not have discovered this information independently.

119. At all times herein mentioned, Defendants breached their duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use, and selling Invokana, and failing to adequately test and warn of the risks and dangers of Invokana.

120. Despite the fact that Defendants knew or should have known that Invokana caused unreasonable, dangerous side effects, Defendants continued to market Invokana to consumers, including Thomas Layton, when there were safer alternative methods available.

121. Defendants' negligence was a foreseeable and proximate cause of Thomas Layton's injuries, harm and economic loss which he suffered, as described and prayed for herein.

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

**COUNT FOUR - BREACH OF IMPLIED WARRANTY**

122. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

123. Defendants impliedly warranted to Thomas Layton and his physicians and health care providers that Invokana was of merchantable quality and safe and fit for the use which it was intended.

124. The product did not conform to representations made by the manufacturer.

125. Thomas Layton reasonably relied entirely on the skill, judgment, and implied warranty of the Defendants when using Invokana.

126. As a result, Thomas Layton used the Defendants' product as it was warranted and intended.

127. Invokana was not of merchantable quality, as warranted by Defendants because it was dangerous when used as intended and can cause severe injuries to consumers.

128. As a result of Defendants' breach of implied warranties, Plaintiff suffered permanent injuries and damages.

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

**COUNT FIVE - BREACH OF EXPRESS WARRANTY**

129. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

130. Defendants expressly warranted to Plaintiff's physicians and Plaintiff 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 and the public that Invokana is safe, effective, fit and proper for its intended use, of

merchantable quality, had been adequately tested, contained adequate warnings, and was effective.

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

132. In particular the Consumer Medication Guide did not include any language that would suggest Invokana has been associated with diabetic ketoacidosis, kidney failure, blood infections, kidney infections, diabetic foot ulcers, gangrene, lower limb ischemia and amputations.

133. Thomas Layton's physician prescribed Invokana and Thomas Layton consumed Invokana reasonably relying on these warranties. Thomas Layton and his physician could not have learned independently that Defendants were false and misleading.

134. The product did not conform to representations made by the manufacturer.

135. Defendants knew or should have known Thomas Layton would rely on their warranties.

136. Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of the Defendants.

137. The warranties and representations are false because Invokana can cause diabetic ketoacidosis, kidney failure, blood infections, kidney infections, diabetic foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee.

138. Invokana does not conform to the Defendants' express representations; therefore, Defendants have breached the express warranties.

139. The breach of express warranties by Defendants was a foreseeable, direct, and proximate cause of Thomas Layton's injuries and damages which are permanent.

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

**COUNT SIX - FRAUDULENT MISREPRESENTATION**

140. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

141. Defendants intentionally and fraudulently misrepresented the safety and efficacy of Invokana in the product label.

142. Specifically Defendants intentionally and fraudulently:

a. Provided a "Warnings and Precautions" section of the Invokana prescribing information that purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about, but in which material and relevant information was fraudulently withheld from this section;

b. Provided Consumer Medication Guide that 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 fraudulently omits information that Invokana has been associated with diabetic ketoacidosis, kidney failure, or cardiovascular adverse events;

c. On information and belief, each and every advertisement and marketing channel fraudulently omits information about the risks of Invokana and overstates the benefits;

d. Failed to disclose that Invokana was not as safe and effective as other diabetes drugs;

e. Failed to disclose that Invokana does not result in safe and more effective diabetes treatments than other available drugs;

f. Failed to disclose that the risk of harm associated with Invokana was greater than the risk of harm associated with other diabetes drugs;

g. Failed to disclose that Defendants knew that Invokana was not adequately tested;

h. Failed to disclose that testing had revealed unreasonably high risk of injury;

i. On information and belief, failed to disclose that Defendants intentionally withheld safety information from the FDA; and

j. Affirmatively asserted that Invokana was safe and effective.

143. Defendants knew that their representations were false, yet they willfully, wantonly and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of Invokana to Thomas Layton, other consumers, Thomas Layton's physicians, and the medical community.

144. The representations were made by the Defendants with the intent that doctors and patients, including Thomas Layton and his physicians, rely upon them.

145. Defendants' representations were made with the intent of defrauding and deceiving Thomas Layton, other consumers, Thomas Layton's physicians, and the medical community to induce and encourage the sale of Invokana.

146. Defendants J&J, Janssen, and Janssen R&D, 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, sepsis, or foot ulcers, gangrene, lower limb ischemia and amputations of toes, feet and legs below the knee. Thomas Layton, his doctors, and others relied upon these representations.

147. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations Thomas Layton suffered amputation of the fifth toe of his left foot and other related health complications. Plaintiff has incurred medical and related expenses. 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.

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

**COUNT SEVEN – NEGLIGENT MISREPRESENTATION**

148. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

149. Defendants made misrepresentations to Plaintiff's physicians, Plaintiff, and the general public from the time Invokana was first tested until now. The misrepresentation includes but is not limited to the misrepresentation that Invokana is safe, fit, and effective for human consumption.

150. Defendants owed a duty to Plaintiff to exercise reasonable care and ensure they did not misrepresent the safety or efficacy of Invokana.

151. Defendants failed to exercise that reasonable care and have therefore breached their duty to Plaintiff.

152. Defendants had a duty to correct these material misstatements because they knew or should have known the statements were false and others would reasonable rely on them and suffer injury.

153. These misrepresentations were made directly by the Defendants, by agents of the Defendants, and in written material directed to physicians, medical patients, and the public, with the intention of inducing reliance and the prescription, purchase, and use of the subject product.

154. The representations by the Defendants were in fact false, in that Invokana is not safe, fit, and effective for human consumption, using Invokana is hazardous to health, and Invokana has a serious propensity to cause serious injuries to users, including but not limited to the injuries and damages suffered by Plaintiff as alleged herein.

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

**COUNT EIGHT – UNJUST ENRICHMENT**

155. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

156. Plaintiff conferred a benefit on Defendants by purchasing Invokana.

157. Plaintiff, however, did not receive a safe and effective drug for which Plaintiff paid.

158. It would be inequitable for the Defendants to retain this money, because Plaintiff did not, in fact, receive a safe and efficacious drug.

159. By virtue of the conscious wrongdoing alleged in this Complaint, Defendants have been unjustly enriched at the expense of Plaintiff, who hereby seeks the disgorgement and restitution of the Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

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

**COUNT NINE – LOSS OF CONSORTIUM**

160. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

161. Plaintiff-Spouse Jaime Layton is the wife of plaintiff Thomas Layton and was his lawful wife on all material and relevant dates

162. As a direct and proximate result of the negligence and other acts and omissions of Defendants described heretofore, Plaintiff-Spouse has suffered a loss of consortium, society, affections and services of her husband, Thomas Layton, as well as other economic damages.

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

**PUNITIVE DAMAGES ALLEGATIONS**

163. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were wanton, willful, fraudulent, dishonest and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Thomas Layton and other Invokana users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Invokana. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

164. Prior to the manufacturing, sale, and distribution of Invokana, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Thomas Layton and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Invokana.

165. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately

failed to remedy the known defects in Invokana and failed to warn the public, including Plaintiff, of the extreme risk of permanent injury occasioned by said defects inherent in Invokana. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Invokana knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits. Said conduct was motivated by the reprehensible motive of increasing monetary profits for the sale of Invokana.

166. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Thomas Layton, entitling Plaintiffs to exemplary damages.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory damages as well as exemplary damages and loss of wages to which he is entitled by law, as well as all costs of this action, to the full extent of the law including:

1. Judgment for Plaintiffs and against Defendants;
2. Damages to compensate Plaintiffs for injuries sustained as a result of the use of Invokana for past and future loss of income proven at trial;
3. Pre and post judgment interest at the lawful rate;
4. Exemplary and punitive damages in an amount in excess of the jurisdictional limits.
5. A trial by jury on all issues of the case; and,

6. For any other relief as this court may deem just, or that may be available under the law of another forum to the extent the law of another forum is applied including but not limited to reasonable attorneys' fees and costs and expert fees.

**DEMAND FOR A TRIAL BY JURY**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a jury trial as to all issues and defenses.

DATED: September 29, 2017

RESPECTFULLY SUBMITTED,

/s/ Dae Y. Lee
Dae Y. Lee
BERNSTEIN LIEBHARD LLP
10 E. 40th Street
New York, NY 10016
Tel: (212) 779-1414
Fax: (212) 779-3218
NJ Bar Identification No.: 033702012
dlee@bernlieb.com

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

DATED: September 29, 2017

RESPECTFULLY SUBMITTED,

/s/ Dae Y. Lee
Dae Y. Lee
BERNSTEIN LIEBHARD LLP
10 E. 40th Street
New York, NY 10016
Tel: (212) 779-1414
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NJ Bar Identification No.: 033702012
dlee@bernlieb.com

# 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

Thomas Layton and Jaime Layton

**(b)** County of Residence of First Listed Plaintiff Hays Co., TX
*(EXCEPT IN U.S. PLAINTIFF CASES)*

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

Bernstein Liebhard LLP
10 East 40th Street, New York, NY 10016
(212) 779-1414

## DEFENDANTS

Janssen Pharmaceuticals, Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC

County of Residence of First Listed Defendant Mercer Co., NJ
*(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)*

**CONTRACT**
- ☐ 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 Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

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

**CIVIL RIGHTS**
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities Employment
- ☐ 446 Amer. w/Disabilities Other
- ☐ 448 Education

**PRISONER PETITIONS**
- ☐ 510 Motions to Vacate Sentence

**Habeas Corpus:**
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

**FORFEITURE/PENALTY**
- ☐ 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
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

**BANKRUPTCY**
- ☐ 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

**OTHER STATUTES**
- ☐ 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

## 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 (Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 USC Section 1332, Product Liability Litigation involving Invokana

## VII. Previous Bankruptcy Matters (For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

## VIII. 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

## IX. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE Brian R. Martinotti DOCKET NUMBER 3:16-md-2750

**X. This case** (check one box) ■ Is not a refiling of a previously dismissed action ☐ is a refiling of case number _____ previously dismissed by Judge____

DATE 9/29/2017

SIGNATURE OF ATTORNEY OF RECORD /s/ Dae Y. Lee

## Naomi Smith

**From:** paygovadmin@mail.doc.twai.gov
**Sent:** Friday, September 29, 2017 3:25 PM
**To:** Naomi Smith
**Subject:** Pay.gov Payment Confirmation: NJD CM ECF

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact NJD Finance Dept at 609-989-0468.

Application Name: NJD CM ECF
Pay.gov Tracking ID: 26554P8B
Agency Tracking ID: 0312-8125594
Transaction Type: Sale
Transaction Date: Sep 29, 2017 3:25:27 PM

Account Holder Name: Sandy Liebhard
Transaction Amount: $400.00
Card Type: AmericanExpress
Card Number: **********2004

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.