

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF KENTUCKY  
LOUISVILLE DIVISION

RICKIE WOODWARD	)	CASE NO: <u>3:16-CV-486-DJH</u>
	)	ELECTRONICALLY FILED
Plaintiff,	)	
	)	
vs.	)	
	)	
JANSSEN RESEARCH &	)	
DEVELOPMENT, LLC, a foreign	)	
limited liability company; JANSSEN	)	
PHARMACEUTICALS, INC., a	)	
foreign corporation; and JOHNSON &	)	
JOHNSON, INC., a foreign corporation,	)	
	)	
Defendants.	)	

**COMPLAINT**

COMES NOW the above-named Plaintiff and for his cause of action against the above-named Defendants, states:

**I. PROCEDURAL AND FACTUAL BACKGROUND**

**A. BACKGROUND**

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants’ negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of INVOKANA (also known as CANAGLIFLOZIN).

**B. PARTIES**

2. At the time of Plaintiff’s use of Invokana and injuries, Plaintiff, Rickie Woodward, was a resident and citizen of Independence, Kenton County, Kentucky. The Plaintiff currently resides in and is a citizen of Independence, Kenton County, Kentucky.

3. 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. The agent for service of process for Janssen Research & Development LLC is the Kentucky Secretary of State, whose address is 152 State Capitol, 700 Capital Avenue, Frankfort, Kentucky 40601-3493.

4. Defendant Janssen Pharmaceuticals, Inc. (Janssen) is a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Both Janssen, and its wholly owned LLC, Janssen R&D, are subsidiaries of Johnson & Johnson. The agent for service of process for Janssen Pharmaceuticals, Inc. is CT Corporation System, 4169 Westport Road, Louisville, Kentucky 40207.

5. Defendant Johnson & Johnson, Inc. is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. The agent for service of process for Johnson & Johnson, Inc. is the Kentucky Secretary of State, whose address is 152 State Capitol, 700 Capital Avenue, Frankfort, Kentucky 40601-3493.

6. 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.

**C. JURISDICTION AND VENUE**

7. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds \$75,000 exclusive of interest and costs, and because,

among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

8. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

**D. FACTUAL ALLEGATIONS**

9. This action for damages is brought on behalf of the Plaintiff who was prescribed and supplied with, received and who has taken and applied the prescription drug Invokana, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

10. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

11. At all times herein mentioned, Defendants were engaged in the business or 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.

12. At all times herein mentioned, Defendants were authorized to do business within the state of Kentucky.

13. 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.

14. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of his injuries, as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that he had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein 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.

15. This case involves the prescription drug Invokana, which is manufactured, sold, distributed and promoted by the Defendants Janssen Research & Development, LLC, Janssen Pharmaceuticals, and Johnson & Johnson as a treatment for Type 2 Diabetes Mellitus.

16. Defendants 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 complication, including but not limited to

Diabetic Ketoacidosis and its sequelae, Kidney Failure and its sequelae, as well as serious cardiovascular problems.

17. Invokana was the first drug in the SGLT2 inhibitor class to be approved by the FDA. It is a sodium-glucose transport protein inhibitor that blocks glucose from being absorbed by the kidneys.

18. These effects, if not monitored and controlled properly, can lead to kidney failure, profound cardiovascular problems, and diabetic ketoacidosis, a serious condition where the body produces high levels of blood acids called ketones.

19. These conditions require hospitalization, can be life threatening, and lead to serious complications.

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

21. Janssen R&D obtained approval from the Food and Drug Administration (“FDA”) to market Invokana on February 28, 2013.

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

23. Despite their 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, including this judicial district.

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

25. Defendants engaged in aggressive direct-to-consumer and physician marketing and advertising campaigns for Invokana.

26. 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 kidney failure, diabetic ketoacidosis, cardiovascular problems, and life-threatening complications thereof.

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

28. Despite the FDA's announcement, Invokana's label continues to fail to warn consumers of the serious risk of developing diabetic ketoacidosis while using Invokana.

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

30. Plaintiff was prescribed Invokana to improve glycemic control as an adjunct to diet and exercise.

31. Plaintiff sustained a myocardial infarction on or about July 29, 2015, as a result of treatment with Invokana and was hospitalized at St. Elizabeth Medical Center, 1 Medical Village Drive, Edgewood, KY 41017.

32. As a result of his myocardial infarction, Plaintiff developed serious complications which continue today.

33. Defendants had a duty to warn prescribing physicians about the risks of Invokana use, including the risk of myocardial infarction and resulting complications.

34. Had Plaintiff and his physicians known the true risks associated with the use of SGLT2 inhibitors, including Invokana, he would not have consumed the Invokana, and/or would

have been adequately monitored for its side effects, and as a result, would not have incurred the injuries or damages he did as a result of his use of Invokana.

## II. CAUSES OF ACTION

### **Count One – Strict Products Liability – Failure to Warn**

35. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

36. Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

37. The Invokana manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

38. Defendants failed to adequately warn consumers and/or their health care providers that Invokana could lead to myocardial infarction and the life threatening complications thereof.

39. Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking Invokana it was necessary to frequently monitor for signs of complications linked to the ingestion of Invokana.

40. The Invokana manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Invokana, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

41. As a direct and proximate result of Plaintiff's reasonably anticipated use of Invokana as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

**Count Two -- Negligence**

42. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

43. At all times herein mentioned, Defendants had a duty 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.

44. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, the hazards and dangers of Invokana to cause, or increase the harm of ketoacidosis, kidney failure, cardiovascular problems, and the life threatening complications of those conditions.

45. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of Invokana to ketoacidosis, kidney failure, cardiovascular problems and the life threatening complications of those conditions.

46. At all times herein mentioned, Defendants breached its duty of care when Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled,



packaged, prepared for use and sold Invokana and failed to adequately test and warn of the risks and dangers of Invokana as described herein.

47. 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 Plaintiff, when there were safer alternative methods available.

48. Defendants' negligence was a proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

### **Count Three – Breach of Implied Warranty**

49. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

50. Prior to the time that the aforementioned products were used by Plaintiff, Defendants impliedly warranted to Plaintiff and his agents and physicians that Invokana was of merchantable quality and safe and fit for the use for which it was intended.

51. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including Invokana, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Invokana. As a result, Plaintiff used Defendants' product as it was warranted to be intended.

52. Invokana was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Invokana has dangerous propensities when used as intended and will cause severe injuries to users.

53. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**Count Four – Breach of Express Warranty**

54. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

55. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and his agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physical, medical patients and the general public, that Invokana was safe, effective, fit and proper for its intended use. Plaintiff purchased Invokana relying upon these warranties.

56. In utilizing Invokana, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. 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, kidney failure, diabetic ketoacidosis, and cardiovascular problems.

57. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**Count Five – Negligent Misrepresentation**

58. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

59. From the time Invokana was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, his physicians and the general public, including but not limited to the misrepresentation that Invokana was safe, fit, and effective for human consumption.

60. Defendants made the foregoing representation without any reasonable ground for believing them to be true. The representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

61. 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 serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

62. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Invokana.

63. Plaintiff relied on the misrepresentations made by the Defendant to his detriment.

64. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Invokana. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Invokana. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations

were made and conducted by individuals and entities that were in a position to know the true facts.

65. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

#### **Count Six – Design Defect**

66. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

67. Defendants manufactured, sold, and promoted this drug which contained a defective condition because the design was defective and unsafe in that it caused serious injuries and death as the result of ketoacidosis, kidney failure, and cardiovascular problems.

68. This design defect made the drug unreasonably dangerous, yet the Defendants knowingly introduced the drug into the market.

69. The drug as manufactured by the Defendants remained unchanged and was in the same condition at the time of the injury hereafter alleged.

70. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained injuries.

#### **Count Seven – Unjust Enrichment**

71. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

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

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

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

75. 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 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.

#### **Punitive Damages Allegations**

76. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

77. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff 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.

78. 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 Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Invokana.

79. 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 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.

80. 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 Plaintiff, entitling Plaintiff to exemplary damages.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for judgment against the Defendants, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

- a. Trial by jury;
- b. General damages in an amount in excess of the jurisdictional limits of this Court that will conform to proof at time of trial;

- c. Special damages in an amount in excess of the jurisdictional limits of this Court that will conform to proof at time of trial
- d. Loss of earnings and impaired earning capacity according to proof at the time of trial;
- e. Medical expenses, past and future, according to proof at the time of trial;
- f. For past and future mental and emotional distress, according to proof at time of trial;
- g. For punitive or exemplary damages according to proof at time of trial;
- h. For costs of suit incurred herein;
- i. For such other and further relief as the Court may deem just and proper.

/s/ Maxwell D. Smith, Esq.  
John O. Hollon, Esq.  
Maxwell D. Smith  
Ward, Hocker & Thornton, PLLC  
333 West Vine Street, Suite 1100  
Lexington, KY 40507  
(859)422-6000  
max.smith@whtlaw.com  
[john.hollon@whtlaw.com](mailto:john.hollon@whtlaw.com)  
*Counsel for Plaintiff*

and

Alva A. Hollon, Jr., Esq.  
Sams & Hollon, PA  
9424 Baymeadows Road, Suite 160  
Jacksonville, FL 32256  
(904)737-1995  
[hollonlaw@bellsouth.net](mailto:hollonlaw@bellsouth.net)  
*Co-Counsel for Plaintiff*

JS 44 (Rev. 07/16)

**CIVIL COVER SHEET**

3:16-CV-486-DJH

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.)

<p><b>I. (a) PLAINTIFFS</b> Rickie Woodward</p> <p><b>(b)</b> County of Residence of First Listed Plaintiff <u>Kenton</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p><b>(c) Attorneys (Firm Name, Address, and Telephone Number)</b> Maxwell D. Smith and John O. Hollon Alva A. Hollon, Jr. 333 W. Vine Street, Suite 1100 9424 Baymeadows Rd., Ste.160 Lexington, KY 40507 Jacksonville, FL 32256</p>	<p><b>DEFENDANTS</b> Jansen Research &amp; Development, LLC; Jansen Pharmaceuticals, Inc.; and Johnson &amp; Johnson, Inc.</p> <p>County of Residence of First Listed Defendant <u>New Jersey Corporation</u> <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED</p> <p>Attorneys (If Known)</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p><b>II. BASIS OF JURISDICTION</b> (Place an "X" in One Box Only)</p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)</p> <p><input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)</p>	<p><b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (Place an "X" in One Box for Plaintiff and One Box for Defendant)</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%;"></td> <td style="width:33%; text-align: center;"><b>PTF</b></td> <td style="width:33%; text-align: center;"><b>DEF</b></td> <td style="width:33%;"></td> <td style="width:33%; text-align: center;"><b>PTF</b></td> <td style="width:33%; text-align: center;"><b>DEF</b></td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		<b>PTF</b>	<b>DEF</b>		<b>PTF</b>	<b>DEF</b>	Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
	<b>PTF</b>	<b>DEF</b>		<b>PTF</b>	<b>DEF</b>																				
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4																				
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5																				
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

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

<b>CONTRACT</b>	<b>TORTS</b>	<b>FORFEITURE/PENALTY</b>	<b>BANKRUPTCY</b>	<b>OTHER STATUTES</b>
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other  <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157  <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark  <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 IIIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b>	<b>CIVIL RIGHTS</b>	<b>PRISONER PETITIONS</b>	<b>FEDERAL TAX SUITS</b>	
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

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

1 Original Proceeding     2 Removed from State Court     3 Remanded from Appellate Court     4 Reinstated or Reopened     5 Transferred from Another District (specify)     6 Multidistrict Litigation - 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. Section 1332

Brief description of cause:  
Plaintiff sustained injuries due to a defective pharmaceutical product.

**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 David J. Hale    DOCKET NUMBER 3:16-CV-265-DJH

DATE 07/29/2016    SIGNATURE OF ATTORNEY OF RECORD /s/ Maxwell D. Smith, Esq.

**FOR OFFICE USE ONLY**

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_



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

UNITED STATES DISTRICT COURT

for the

Western District of Kentucky

Rickie Woodward )

\_\_\_\_\_  
*Plaintiff(s)*

v. )

Janssen Research & Development, LLC, a foreign  
limited liability company, Jansen Pharmaceuticals,  
Inc. a foreign corporation; and Johnson & Johnson,  
Inc., a foreign corporation )

\_\_\_\_\_  
*Defendant(s)*

Civil Action No. 3 : 16 - CV - 486 - DJH

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Johnson & Johnson, Inc.  
c/o Kentucky Secretary of State  
700 Capital Avenue, Ste. 86  
Frankfort, KY 40601

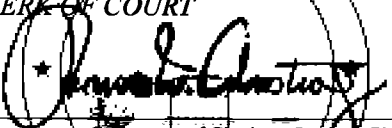
A lawsuit has been filed against you.

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:

John O. Hollon, Esq.  
Maxwell D. Smith, Esq.  
Ward, Hocker & Thornton, PLLC  
333 W. Vine Street, Suite 1100  
Lexington, KY 40507

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.

Date: 7/29/16 \_\_\_\_\_

CLERK OF COURT  
  
\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

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)* \_\_\_\_\_  
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:

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

UNITED STATES DISTRICT COURT
for the
Western District of Kentucky

Rickie Woodward

Plaintiff(s)

v.

Janssen Research & Development, LLC, a foreign
limited liability company, Janssen Pharmaceuticals,
Inc. a foreign corporation; and Johnson & Johnson,
Inc., a foreign corporation

Defendant(s)

Civil Action No. 3 : 16 - CV - 486 - DJH

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Janssen Pharmaceuticals, Inc.
c/o CT Corporation System
4169 Westport Road
Louisville, KY 40207

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: John O. Hollon, Esq.
Maxwell D. Smith, Esq.
Ward, Hocker & Thornton, PLLC
333 W. Vine Street, Suite 1100
Lexington, KY 40507

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.

Date: 7/29/2016

CLERK OF COURT

[Handwritten signature]

Signature of Clerk or Deputy Clerk

AO 440 (Rev 06/12) Summons in a Civil Action (Page 2)

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)* \_\_\_\_\_  
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:

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

UNITED STATES DISTRICT COURT

for the

Western District of Kentucky

Rickie Woodward )

Plaintiff(s)

v.

Janssen Research & Development, LLC, a foreign limited liability company, Jansen Pharmaceuticals, Inc. a foreign corporation; and Johnson & Johnson, Inc., a foreign corporation

Defendant(s)

Civil Action No. 3 : 16 - CV \_ 486 - DJH

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Janssen Research & Development, LLC c/o Kentucky Secretary of State 700 Capital Avenue, Ste. 86 Frankfort, KY 40601

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:

John O. Hollon, Esq. Maxwell D. Smith, Esq. Ward, Hocker & Thornton, PLLC 333 W. Vine Street, Suite 1100 Lexington, KY 40507

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.

Date: 7/29/16



AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

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)* \_\_\_\_\_  
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: