

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

BRYAN GROSS AND ANN GROSS,	)	<b>Case No.:</b> 5:17-CV-1200
	)	
Plaintiffs,	)	
	)	<b>Judge:</b>
v.	)	
	)	
ASTRAZENECA PHARMACEUTICALS	)	<b>COMPLAINT AND DEMAND FOR</b>
LP; ASTRAZENECA LP; PROCTER &	)	<b>JURY TRIAL</b>
GAMBLE MANUFACTURING	)	
COMPANY; and THE PROCTER &	)	
GAMBLE COMPANY,	)	
	)	
Defendants.	)	

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Plaintiffs, Bryan Gross (“Plaintiff”) and Ann Gross (collectively referred to as “Plaintiffs”), hereby bring this cause of action against Defendants AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Procter & Gamble Manufacturing Company; and The Procter & Gamble Company (collectively “Defendants”) and upon information and belief and based on the investigation counsel, allege as follows:

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## **INTRODUCTION**

1. This is a personal injury action against Defendants who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling proton pump inhibitors (“PPI”s), which are prescription and over-the-counter medications herein collectively referred to as PPIs.

2. PPIs are used to reduce the production of stomach acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

3. Plaintiff Bryan Gross ingested Defendants’ PPI, Prilosec OTC, which resulted in injuries to his kidneys.

## **JURISDICTION AND VENUE**

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), because the amount in controversy exceeds \$75,000.00, exclusive of interests and costs, and because Defendants are all incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

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

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs’ claims occurred, in part, in the Northern District of Ohio, Eastern Division.

## **PLAINTIFFS**

7. Plaintiffs, Bryan Gross and Ann Gross, are natural persons and a residents of Barberton, Summit County, Ohio.

8. Plaintiff, Bryan Gross, ingested Defendants' PPI, Prilosec OTC, from approximately 2009 to 2015.

9. Plaintiff, Bryan Gross was diagnosed with chronic kidney disease and acute interstitial nephritis in approximately 2015. He suffered chronic kidney disease and acute interstitial nephritis as a result of his use of PPIs and Prilosec OTC, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement costs of obtaining Prilosec OTC and reimbursement for all past, present, and future health and medical care costs for his kidney related injuries and sequelae.

10. Plaintiff was first diagnosed with acute interstitial nephritis on June 15, 2015, and on that date Plaintiff's nephrologist instructed Plaintiff to discontinue his use of Prilosec OTC. Thus, Plaintiff did not and could not have discovered his injury or its relationship to his use of Prilosec OTC until June 15, 2015, thus making the filing of this action timely.

#### **DEFENDANTS**

11. Defendant ASTRAZENECA PHARMACEUTICALS LP is a Delaware corporation, which has its principal place of business at 1800 Concord Pike, Wilmington, DE 19897.

12. Defendant ASTRAZENECA LP is a Delaware corporation, which has its principal place of business at 1800 Concord Pike, Wilmington, DE 19897.

13. Defendant PROCTER & GAMBLE MANUFACTURING COMPANY is an Ohio corporation, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, Ohio 45202.

14. Defendant THE PROCTER & GAMBLE COMPANY is an Ohio corporation, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, Ohio 45202.

15. In doing the acts alleged herein, PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE COMPANY (“P&G Defendants”) were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence, and ratification of each other.

16. In doing the acts alleged herein, Defendants were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence, and ratification of each other.

17. Defendants have transacted and conducted business in the State of Ohio, and contracted to supply goods and services within the State of Ohio, and these causes of action have arisen from the same.

18. At all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America and the State of Ohio.

19. At all relevant times, Defendants derived and derive substantial revenue from goods and products used in the State of Ohio and from interstate commerce.

20. At all relevant times, Defendants committed tortious acts within the State of Ohio causing injury within the State of Ohio, out of which act(s) these causes of action arise.

#### **SUMMARY OF THE CASE**

21. As a result of the defective nature of PPIs, persons who ingested this product, including Plaintiff, have suffered and may continue to suffer from kidney injuries including acute interstitial nephritis (“AIN”), acute kidney injuries (“AKI”), chronic kidney disease (“CKD”) and renal failure, also known as end-stage renal disease (“ESRD”).

22. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of PPIs.

23. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries and sequelae.

### **FACTUAL ALLEGATIONS**

24. Over 60 million Americans experience heartburn, a major symptom of GERD, at least once a month and some studies have suggested more than 15 million Americans experience heartburn on a daily basis.

25. About 21 million Americans used one or more prescription PPIs in 2009 accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

26. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

27. PPIs are one of the most commercially successful groups of medication in the United States. Upon information and belief, between the period of 2008 and 2013, prescription PPIs had a sale of over \$50 billion with approximately 240 million units dispensed.

28. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold PPIs.

29. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the

first article associating PPI usage with kidney injuries in *The American Journal of Medicine*, followed by years of reports from national adverse drug registries describing this association.

30. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's *Kidney International* finding that PPI use, by way of AIN, left most patients "with some level of chronic kidney disease."

31. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks associated with PPIs including AIN.

32. According to the petition, at the time of its filing there was "no detailed risk information on any PPI for this adverse effect."

33. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs.

34. The FDA noted "that the prescription PPI labeling should be consistent with regard to this risk" and that "there is reasonable evidence of a causal association."

35. In December of 2014, the labels of prescription PPIs were updated to read:

*Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [Brand] if acute interstitial nephritis develops.*

36. The FDA did **not** require the consistent labeling regarding risk of AIN on over-the-counter PPIs.

37. In January of 2016, a study published in the *Journal of the American Medical Association* found that PPI use was independently associated with a 20 – 50% higher risk of CKD.

38. In February of 2016, a study published in the *Journal of the American Society of Nephrology* found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

39. To date, over-the-counter PPIs lack detailed risk information for AIN.

40. To date, prescription and over-the-counter PPIs lack detailed risk information for CKD.

41. Parietal cells in the stomach lining secrete gastric juices containing hydrochloric acid to catalyze the digestion of proteins.

42. Excess acid secretion results in the formation of most ulcers in the gastroesophageal system and symptoms of heartburn and acid reflux.

43. PPIs irreversibly block the acidic hydrogen/potassium ATPase enzyme system ( $H^+/K^+$  ATPase) of the gastric parietal cells, thereby halting the production of most hydrochloric acid.

44. In spite of their commercial success and global popularity, up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.

45. As a result of the defective nature of PPIs, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

46. From these findings, PPIs and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis (“AIN”), a sudden kidney inflammation that can result in mild to severe problems.



47. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

48. In April 2016, a study published in the *Journal of Nephrology* suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

49. CKD describes a slow and progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

50. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can be treated completely, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals.

51. Consumers, including the Plaintiff, who have used PPIs for the treatment of increased gastric acid have and had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI therapy.

52. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with PPI use.

53. Defendants concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community

against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD and ESRD.

54. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

55. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

56. As a direct result of ingesting PPIs, Plaintiff has been permanently and severely injured, having suffered serious consequences from PPI use. Plaintiff requires and will in the future require ongoing medical care and treatment.

57. Plaintiff, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to his new lifestyle.

58. Plaintiff would not have used PPIs had Defendants properly disclosed the risks associated with long-term use.

#### **FRAUDULENT CONCEALMENT**

59. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, physicians, the medical community, and the general public the true risks associated with Proton Pump Inhibitors. As a result of Defendants' actions, Plaintiff and physicians were unaware, and could not reasonably have known or have learned through

reasonable diligence, that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

**FIRST CAUSE OF ACTION – NEGLIGENCE**

60. Plaintiffs incorporate paragraphs 1-59 by reference as if fully stated herein further state:

61. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Prilosec OTC into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

62. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Prilosec OTC into interstate commerce in that Defendants knew or should have known that using Prilosec OTC could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Prilosec OTC. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

- a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that plaintiff would suffer a serious injury or death by ingesting Prilosec OTC;
- b. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Prilosec OTC in unsafe doses;

- c. Failure to use reasonable care in testing and inspecting Prilosec OTC so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
- d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Prilosec OTC;
- e. Failure to use reasonable care in the process of manufacturing Prilosec OTC in a reasonably safe condition for the use for which it was intended;
- f. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Prilosec OTC in unsafe doses; and
- g. Such further acts and/or omissions that may be proven at trial.

63. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

64. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec OTC without thoroughly testing it;
- b. Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec OTC without adequately testing it;
- c. Not conducting sufficient testing programs to determine whether or not Prilosec OTC was safe for use; in that Defendants herein knew or should have known that Prilosec OTC was unsafe and unfit for use by reason of the dangers to its users;

- d. Selling Prilosec OTC without making proper and sufficient tests to determine the dangers to its users;
  - e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Prilosec OTC;
  - f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Prilosec OTC;
  - g. Failing to test Prilosec OTC and/or failing to adequately, sufficiently and properly test Prilosec OTC;
  - h. Negligently advertising and recommending the use of Prilosec OTC without sufficient knowledge as to its dangerous propensities;
  - i. Negligently representing that Prilosec OTC was safe for use for its intended purpose, when, in fact, it was unsafe;
  - j. Negligently designing Prilosec OTC in a manner which was dangerous to its users;
  - k. Negligently manufacturing Prilosec OTC in a manner which was dangerous to its users;
  - l. Negligently producing Prilosec OTC in a manner which was dangerous to its users;
  - m. Negligently assembling Prilosec OTC in a manner which was dangerous to its users;
  - n. Concealing information from the Plaintiff in knowing that Prilosec OTC was unsafe, dangerous, and/or non-conforming with FDA regulations.
65. Defendants under-reported, underestimated and downplayed the serious dangers of Prilosec OTC.

66. Defendants negligently compared the safety risk and/or dangers of Prilosec OTC with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

67. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Prilosec OTC in that they:

- a. Failed to use due care in designing and manufacturing Prilosec OTC so as to avoid the aforementioned risks to individuals when Prilosec OTC was used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Prilosec OTC;
- c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Prilosec OTC;
- d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Prilosec OTC;
- e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Prilosec OTC;
- g. Failed to warn Plaintiff, prior to actively encouraging the sale of Prilosec OTC, either directly or indirectly, orally or in writing, about the need for more comprehensive,

more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

h. Were otherwise careless and/or negligent.

68. Despite the fact that Defendants knew or should have known that Prilosec OTC caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Prilosec OTC to consumers, including the Plaintiff.

69. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

70. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered and/or will continue to suffer.

71. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, End Stage Renal Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

72. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

73. As a direct and proximate cause of Defendants' negligence, Plaintiff suffered serious bodily injury, pain and suffering, disability, physical impairment, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of

medical care and expenses, loss of earnings capacity and loss of future earning capacity, all of which damage and losses are permanent and will continue into the future.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as contained in the Prayer for Relief.

**SECOND CAUSE OF ACTION – STRICT PRODUCTS LIABILITY**

74. Plaintiffs incorporate paragraphs 1-59 by reference as if fully stated herein further state:

75. This cause of action is being brought pursuant to Ohio Revised Code §§ 2307.75 and 2307.76.

76. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Prilosec OTC as hereinabove described that was used by the Plaintiff.

77. That Prilosec OTC was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

78. At those times, Prilosec OTC was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

79. The Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Prilosec OTC.

80. The Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that,



when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

81. At all times herein mentioned, Prilosec OTC was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

82. Defendants knew, or should have known that at all times herein mentioned its Prilosec OTC was in a defective condition, and was and is inherently dangerous and unsafe.

83. At the time of the Plaintiff's use of Prilosec OTC, Prilosec OTC was being used for the purposes and in a manner normally intended for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

84. Defendants with this knowledge voluntarily designed its Prilosec OTC in a dangerous condition for use by the public, and in particular the Plaintiff.

85. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

86. Defendants created a product unreasonably dangerous for its normal, intended use.

87. The Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Prilosec OTC left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

88. The Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Prilosec OTC was manufactured.

89. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

90. The Plaintiff could not, by the exercise of reasonable care, have discovered Prilosec OTC's defects herein mentioned and perceived its danger. Had Plaintiff received proper or adequate warnings as to the risks associated with taking Prilosec OTC, Plaintiff would not have taken Prilosec OTC.

91. Prilosec OTC was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, kidney injuries, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

92. Prilosec OTC was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

93. Prilosec OTC was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, kidney injuries, as well as other severe and permanent health consequences from Prilosec OTC, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Prilosec OTC.

94. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Prilosec OTC.

95. At all relevant times, there were practical and technically feasible alternative designs for Prilosec OTC that would have prevented the harm Prilosec OTC caused to Plaintiff.

96. Defendants' defective design, manufacturing defect, and inadequate warnings of Prilosec OTC were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

97. That said defects in Defendants' drug Prilosec OTC were a substantial factor in causing Plaintiff's injuries.

98. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, kidney injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

99. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

100. As a direct and proximate cause of Prilosec OTC being unreasonably dangerous, Plaintiff suffered serious bodily injury, pain and suffering, disability, physical impairment, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings capacity and loss of future earning capacity, all of which damage and losses are permanent and will continue into the future.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as contained in the Prayer for Relief.

**THIRD CAUSE OF ACTION – FAILURE TO CONFORM TO REPRESENTATIONS**

101. Plaintiffs incorporate paragraphs 1-59 by reference as if fully stated herein further state:

102. This cause of action is being brought pursuant to Ohio Revised Code § 2307.77

103. Defendants expressly represented that Prilosec OTC was safe and well accepted by users.

104. Prilosec OTC does not conform to these express representations because Prilosec OTC is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of such nonconformity, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

105. Plaintiff did rely on the express representations of the Defendants herein.

106. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Prilosec OTC in recommending, prescribing, and/or dispensing Prilosec OTC.

107. Defendants expressly represented to Plaintiff, his physicians, healthcare providers, and/or the FDA that Prilosec OTC was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

108. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Prilosec OTC was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

109. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, End Stage Renal Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

110. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Prilosec OTC drug.

111. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

112. As a direct and proximate cause of Defendants' Breach of Express Warranty as alleged above, Plaintiff suffered serious bodily injury, pain and suffering, disability, physical impairment, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings capacity and loss of future earning capacity, all of which damage and losses are permanent and will continue into the future.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as contained in the Prayer for Relief.

**FOURTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTIES**

113. Plaintiffs incorporate paragraphs 1-59 by reference as if fully stated herein further state:

114. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Prilosec OTC and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Prilosec OTC for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

115. At the time Defendants marketed, sold, and distributed Prilosec OTC for use by Plaintiff, Defendants knew of the use for which Prilosec OTC was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

116. The Defendants impliedly represented and warranted to the users of Prilosec OTC and their physicians, healthcare providers, and/or the FDA that Prilosec OTC was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

117. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Prilosec OTC was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

118. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

119. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Prilosec OTC was of merchantable quality and safe and fit for its intended use.

120. Prilosec OTC was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

121. The Defendants herein breached the aforesaid implied warranties, as their drug Prilosec OTC was not fit for its intended purposes and uses.

122. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, kidney injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

123. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

124. As a direct and proximate cause of Defendants' Breach of Implied Warranty as alleged above, Plaintiff suffered serious bodily injury, pain and suffering, disability, physical impairment, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings capacity and loss of future earning capacity, all of which damage and losses are permanent and will continue into the future.

WHEREFORE, Plaintiffs respectfully requests that they be granted relief against Defendants as contained in the Prayer for Relief.

**FIFTH CAUSE OF ACTION – FRAUDULENT MISREPRESENTATION**

125. Plaintiffs incorporate paragraphs 1-59 by reference as if fully stated herein further state:

126. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, Prilosec OTC had been tested and was found to be safe and/or effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

127. That representations made by Defendants were, in fact, false.

128. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

129. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Prilosec OTC, for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

130. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Prilosec OTC, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.



131. In reliance upon said representations, the Plaintiff was induced to and did use Prilosec OTC, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

132. said Defendants knew and were aware or should have been aware that Prilosec OTC had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

133. Defendants knew or should have known that Prilosec OTC had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

134. Defendants brought Prilosec OTC to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

135. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Interstitial Nephritis and End Stage Renal Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

136. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

137. As a direct and proximate cause Defendants' Fraudulent Misrepresentation as alleged above Plaintiff suffered serious bodily injury, pain and suffering, disability, physical impairment, mental anguish, inconvenience, aggravation of a pre-existing condition, loss of the capacity for the

enjoyment of life, the costs of medical care and expenses, loss of earnings capacity and loss of future earning capacity, all of which damage and losses are permanent and will continue into the future.

WHEREFORE, Plaintiffs respectfully requests that they be granted relief against Defendants as contained in the Prayer for Relief.

**SIXTH CAUSE OF ACTION – LOSS OF CONSORTIUM**

138. Plaintiffs incorporate paragraphs 1-59 by reference as if fully stated herein further state:

139. At all relevant times hereto, Plaintiff Ann Gross suffered injuries and losses as a result of the Plaintiff's injuries from PPI/Prilosec.

140. For the reasons set forth herein, Ann Gross has necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

141. Ann Gross has suffered and will continue to suffer the loss of her husband's support, companionship, services, society, love and affection.

142. Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife have been altered.

143. Ann Gross has suffered great emotional pain and mental anguish.

144. As a direct and proximate result of Defendants' wrongful conduct, Ann Gross has sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Ann Gross and severally for all general, special and equitable relief to which Ann Gross is entitled by law.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs demand judgment against Defendants, as follows:

- a. Awarding compensatory to the Plaintiffs caused by Bryan Gross's purchase and use of Proton Pump Inhibitors in an amount to be determined at trial;
- b. Awarding punitive damages against Defendants;
- c. Awarding pre-judgment and post-judgment interest to the Plaintiffs;
- d. Awarding the costs and the expenses of this litigation to the Plaintiffs;
- e. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law;  
and
- f. Granting all such other relief as the Court deems necessary, just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs, Bryan Gross and Ann Gross, hereby demand a trial by jury on all counts and as to all issues.

Dated: June 8, 2017

Respectfully submitted,

s/ Dustin B. Herman  
Dustin B. Herman (0093163)  
Peter J. Brodhead (0006733)  
SPANGENBERG SHIBLEY & LIBER LLP  
1001 Lakeside Avenue East, Suite 1700  
Cleveland, Ohio 44114  
(216) 696-3232  
(216) 696-3924 (Fax)  
dherman@spanglaw.com  
pbrodhead@spanglaw.com

*Counsel for Plaintiffs*

## 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**

BRYAN AND ANN GROSS

(b) County of Residence of First Listed Plaintiff Summit - OH

(EXCEPT IN U.S. PLAINTIFF CASES)

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

Dustin B. Herman, Esq., Peter J. Brodhead: Spangenberg Shibley &amp; Liber LLP, 1001 Lakeside Avenue, Suite 1700, Cleveland, OH 44114

**DEFENDANTS**ASTRAZENECA PHARMACEUTICALS LP;  
ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING  
COMPANY; and THE PROCTER & GAMBLE COMPANYCounty of Residence of First Listed Defendant New Castle - DE

(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

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

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

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

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <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 <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <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 <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <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 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</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	<b>CIVIL RIGHTS</b> <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>PRISONER PETITIONS</b> <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			

**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. § 1332Brief description of cause:  
Ingestion of PPI causing kidney injury**VII. REQUESTED IN COMPLAINT:**

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

**DEMAND \$**  
+ 75,000.00

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

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE \_\_\_\_\_

DOCKET NUMBER \_\_\_\_\_

DATE

06/08/2016

SIGNATURE OF ATTORNEY OF RECORD

s/Dustin B. Herman

FOR OFFICE USE ONLY

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

**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

## Authority For Civil Cover Sheet

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

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.  
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.  
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.  
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.  
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.  
 Original Proceedings. (1) Cases which originate in the United States district courts.  
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.  
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.  
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.  
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.  
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.  
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.  
**PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.  
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.  
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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

## Northern District of Ohio

Civil Action No. 5:17-cv-1200

Signature of Clerk or Deputy Clerk

Civil Action No. 5:17-cv-1200

**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:

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

BRYAN GROSS AND ANN GROSS

*Plaintiff(s)*

v.

ASTRAZENECA PHARMACEUTICALS LP;  
ASTRAZENECA LP; PROCTER & GAMBLE  
MANUFACTURING COMPANY; and THE  
PROCTER & GAMBLE COMPANY

*Defendant(s)*

Civil Action No. 5:17-cv-1200

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AstraZeneca Pharmaceuticals LP  
1800 Concord Pike  
P.O. Box 15437  
Wilmington, DE 19850-5437

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: Dustin B. Herman, Esq.  
Peter J. Brodhead, Esq.  
Spangenberg Shibley & Liber LLP  
1001 Lakeside Avenue, Suite 1700  
Cleveland, OH 44114

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

CLERK OF COURT

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*



Civil Action No. 5:17-cv-1200

**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:

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UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

BRYAN GROSS AND ANN GROSS

---

*Plaintiff(s)*

v.

ASTRAZENECA PHARMACEUTICALS LP;  
ASTRAZENECA LP; PROCTER & GAMBLE  
MANUFACTURING COMPANY; and THE  
PROCTER & GAMBLE COMPANY

---

*Defendant(s)*

)  
)  
)  
)  
)  
) Civil Action No. 5:17-cv-1200  
)  
)  
)  
)  
)

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)* PROCTER & GAMBLE MANUFACTURING COMPANY  
1 Procter & Gamble Plaza  
Cincinnati, OH 45202

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:

Dustin B. Herman, Esq.  
Peter J. Brodhead, Esq.  
Spangenberg Shibley & Liber LLP  
1001 Lakeside Avenue, Suite 1700  
Cleveland, OH 44114

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

CLERK OF COURT

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

Civil Action No. 5:17-cv-1200

**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:

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

BRYAN GROSS AND ANN GROSS

*Plaintiff(s)*

v.

ASTRAZENECA PHARMACEUTICALS LP;  
ASTRAZENECA LP; PROCTER & GAMBLE  
MANUFACTURING COMPANY; and THE  
PROCTER & GAMBLE COMPANY

*Defendant(s)*

Civil Action No. 5:17-cv-1200

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* THE PROCTER & GAMBLE COMPANY  
1 Procter & Gamble Plaza  
Cincinnati, OH 45202

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: Dustin B. Herman, Esq.  
Peter J. Brodhead, Esq.  
Spangenberg Shibley & Liber LLP  
1001 Lakeside Avenue, Suite 1700  
Cleveland, OH 44114

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

CLERK OF COURT

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

Civil Action No. 5:17-cv-1200

**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: