UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

TAGI MODICUE,

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; ASTRA USA INC.; ASTRAZENECA AB; ASTRAZENECA UK LTD; ASTRAZENECA, PLC; PROCTER & GAMBLE MANUFACTURING COMPANY; and
THE PROCTER & GAMBLE COMPANY

Defendants

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, Tagi Modicue (alternatively referred to as "Plaintiff"), residing in Richland County within the State of Louisiana, by and through the undersigned attorneys, hereby brings this cause of action against Defendants AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharmaceuticals"), AstraZeneca LP, Astra USA Inc., Astrazeneca AB, Astrazeneca UK Ltd., AstraZeneca PLC, Procter & Gamble Manufacturing Company, and The Procter & Gamble Company (collectively "Defendants") and as for her Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

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 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 in this case, Tagi Modicue, ingested PPIs, which resulted in injuries to her kidneys.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of 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 Plaintiff resides.

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 Middle District of Louisiana.

PLAINTIFF

7. Plaintiff, Tagi Modicue, is a natural person and a resident of East Baton Rouge, Louisiana and ingested PPIs, Prilosec and Nexium from approximately 2010 to 2012 that were prescribed and/or directed by her physician.

8. Plaintiff, Tagi Modicue was diagnosed with Chronic Kidney Disease in approximately 2012 as well as suffering Acute Kidney Injuries in approximately 2013 and 2015, as a result of her use of PPIs, Prilosec and Nexium and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement costs of obtaining PPIs, Prilosec and Nexium and reimbursement for all past, present, and future health and medical care costs related to her PPIs, Prilosec and Nexium and kidney related injuries and sequelae.

DEFENDANTS

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

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

11. Defendant ASTRA USA INC. is a Delaware corporation, which has its principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437.

12. Defendant ASTRAZENECA AB is a foreign corporation, which has its principal place of business at Västra Mälarehamnen, 9 Södertälje SE-151 85, Sweden.

13. Defendant ASTRAZENECA UK LTD is a foreign corporation with its principal place of business located at 2 Kingdom Street, London W2 6BD, United Kingdom.

14. Defendant ASTRAZENECA PLC is a foreign corporation with its principal place of business located at 2 Kingdom Street, London W2 6BD, United Kingdom.

15. On information and belief, ASTRAZENECA PLC is either the direct or indirect owner of substantially all the stock or other ownership interests of ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP.

16. In doing the acts alleged herein, said 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 (hereinafter ASTRAZENECA PLC, ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA LP are collectively referred to as "ASTRAZENECA").

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

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

19. On information and belief, THE PROCTER & GAMBLE COMPANY is either the direct or indirect owner of substantially all the stock or other ownership interests of PROCTER & GAMBLE MANUFACTURING COMPANY.

20. In doing the acts alleged herein, said 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 (hereinafter THE PROCTER & GAMBLE COMPANY and PROCTER & GAMBLE MANUFACTURING COMPANY are collectively referred to as "PROCTER & GAMBLE").

21. On information and belief, Defendants have transacted and conducted business in the State of Louisiana, and/or contracted to supply goods and services within the State of Louisiana, and these causes of action have arisen from the same.

22. On information and belief, 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 Louisiana.

23. On information and belief, at all relevant times, Defendants derived and derive substantial revenue from goods and products used in the State of Louisiana and from interstate commerce.

24. On information and belief, at all relevant times, Defendants committed tortious acts within the State of Louisiana causing injury within the State of Louisiana, out of which act(s) these causes of action arise.

SUMMARY OF THE CASE

25. 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").

26. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, her 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.

27. As a result of Defendants' actions and inactions, Plaintiff was injured due to her 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

28. 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.

29. 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.

30. 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.

31. 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.

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

33. 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.

34. 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."

35. 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.

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

37. 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.

38. 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."

39. 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.*

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

41. 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.

42. 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."

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

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

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

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

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

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

57. 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.

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

59. As a result of Defendants' actions, Plaintiff and her 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.

60. 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.

61. 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 her new lifestyle.

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

FEDERAL REQUIREMENTS

63. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Proton Pump Inhibitors.

64. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

65. With respect to Proton Pump Inhibitors, the Defendants, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Proton Pump Inhibitors are adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. Proton Pump Inhibitors are adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for PPIs, Prilosec and Nexium and such deviations are not plainly stated on their labels.

c. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. Proton Pump Inhibitors do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. Proton Pump Inhibitors are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Proton Pump Inhibitors to cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took Proton Pump Inhibitors.

q. Proton Pump Inhibitors are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established

r. Proton Pump Inhibitors violate 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. Proton Pump Inhibitors violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. Proton Pump Inhibitors violates 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. Proton Pump Inhibitors violate 21 CFR § 211.165 in that PPIs, Prilosec and Nexium fail to meet established standards or specifications and any other relevant quality control criteria.

v. Proton Pump Inhibitors violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding Proton Pump Inhibitors were not followed.

w. Proton Pump Inhibitors violates 21 CFR § 310.303 in that Proton Pump Inhibitors are not safe and effective for its intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with Proton Pump Inhibitors as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drugs experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with Proton Pump Inhibitors, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Proton Pump Inhibitors or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

66. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under Louisiana law.

FRAUDULENT CONCEALMENT

67. 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.

68. 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.

CAUSES OF ACTION
FIRST CAUSE OF ACTION
VIOLATION OF THE LOUISIANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, La. R.S. § 51:1401, et seq.

69. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

70. The Plaintiff pleads this Count in the broadest sense available under law to include pleading same pursuant to all substantive law that applies to this case as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

71. The Plaintiff used Defendants' Proton Pump Inhibitors and suffered ascertainable losses as a result of the Defendants' actions in violation of the aforementioned consumer protection laws.

72. The Defendants violated the Louisiana Unfair Trade Practices and Consumer Protection Law, La. R.S. §51:1401, et seq, through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Proton Pump Inhibitors.

73. The Defendants uniformly communicated the purported benefits of Proton Pump Inhibitors while failing to disclose the serious and dangerous side effects related to the use of Proton Pump Inhibitors and of the true state of Proton Pump Inhibitor's regulatory status, its safety, its efficacy, and its usefulness. The Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as the Plaintiff, in the marketing and advertising campaign described herein.

74. The Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

75. The Defendants have a statutory duty to refrain from unfair trade practices in the design, development, manufacture, promotion and sale of Proton Pump Inhibitors.

76. Had the Defendants not engaged in the deceptive conduct described herein, the Plaintiff would not have purchased and/or paid for Proton Pump Inhibitors, and would not have incurred related medical costs. Specifically the Plaintiff, the Plaintiff's physicians and other Healthcare Professionals were misled by the deceptive conduct described herein.

77. The Defendants' deceptive, unconscionable, false, misleading and/or fraudulent representations and material omissions to patients, physicians and consumers, including the Plaintiff, of material facts relating to the safety of Proton Pump Inhibitors constituted unfair trade practices in violation of the state consumer protection statutes listed above.

78. The Defendants uniformly communicated the purported benefits of Proton Pump Inhibitors while failing to disclose the serious and dangerous side effects related to the use of Proton Pump Inhibitors and the true state of Proton Pump Inhibitor's regulatory status, its safety, its efficacy, and its usefulness. The Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as the Plaintiff, in the marketing and advertising campaign described herein.

79. The Defendants' conduct in connection with Proton Pump Inhibitors was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding because the Defendants misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of Proton Pump Inhibitors.

80. By reason of wrongful acts engaged in by the Defendants, the Plaintiff suffered ascertainable loss and damages for which the Plaintiff is now entitled to recover.

81. As a direct and proximate result of the Defendants' wrongful conduct, the Plaintiff was damaged by paying in whole or in part for Proton Pump Inhibitors and for the Plaintiff's medical treatment. Plaintiff is now entitled to recover those damages.

82. As a direct and proximate result of the Defendants' violations of unfair trade practices, the Plaintiff sustained economic losses and other damages for which the Plaintiff is entitled to statutory and compensatory damages and attorneys' fees, in an amount to be proven at trial.

SECOND CAUSE OF ACTION
LOUISIANA PRODUCTS LIABILITY ACT

83. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

84. Plaintiff's damages were caused by characteristics of Proton Pump inhibitors manufactured by the Defendants that rendered the Proton Pump Inhibitors unreasonably dangerous after a reasonably anticipated use of the products by Plaintiff making Defendants liable to Plaintiff pursuant to LSA R.S. 9:2800.54.

85. Proton Pump Inhibitors are unreasonably dangerous under the following:

a. It is unreasonably dangerous in construction or composition as per LSA R.S. 9:2800.55;

b. It is unreasonably dangerous in design as per LSA R.S. 9:2800.56.

c. It is unreasonably dangerous because an accurate warning about the product was not provided as required by LSA R.S. 9:2800.57.

d. It is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as per LSA R.S. 9:2800.58.

86. The characteristics of Proton Pump Inhibitors that render it unreasonably dangerous under LSA R.S. 9:2800.55, LSA R.S. 9:2800.56, and LSA R.S. 9:2800.57 et seq. existed at the time the product left the control of the manufacturers.

87. For all of the reasons alleged herein, Proton Pump Inhibitors were unreasonably dangerous in design at the time the products left the manufacturers' control in that:

a. There existed an alternate design for the product that was capable of preventing the Plaintiff's damages; and

b. The likelihood that the product's design would cause the Plaintiff's damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

88. For all of the reasons alleged herein, Proton Pump Inhibitors were unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide adequate warning that such characteristic and its dangers to users of the product.

89. Further, Defendants, before, during, and after the product left its control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which

arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

90. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or its authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that Proton Pump Inhibitors were safe, effective, fit and proper for its intended use.

91. In using Proton Pump Inhibitors, Plaintiff and her physicians relied on the skill, judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended

THIRD CAUSE OF ACTION
REDHIBITION

92. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

93. The subject product contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

94. Defendants sold and promoted Proton Pump Inhibitors, which defendants placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product sold and promoted by Defendants, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that

a buyer would not have bought the subject product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the subject product.

95. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction of the purchase price.

96. Defendants are liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, is liable to Plaintiff for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, under Louisiana law, Defendants are deemed to know that Proton Pump Inhibitors possessed a redhibitory defect. La. C.C. art. 2545.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES UNDER LA. CC. ART. 2524

97. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

98. In addition to warranting against redhibitory defects, Defendants warrant that the subject product is reasonably fit for its ordinary and intended use. La. C.C. art. 2524.

99. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, acute interstitial nephritis ("AIN"),

acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

100. As a direct and proximate result of Defendants' actions, Plaintiff has sustained serious, significant and permanent injuries including but not limited to Chronic Kidney Disease, Acute Kidney Injury, Kidney Failure and related sequelae. In addition, Plaintiff required and will continue to require healthcare and services as a result of his injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of his injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

a. Awarding actual damages to the Plaintiff incidental to her purchase and use of Proton Pump Inhibitors in an amount to be determined at trial;

b. Awarding pre-judgment and post-judgment interest to the Plaintiffs;

c. Awarding the costs and the expenses of this litigation to the Plaintiffs;

d. Awarding reasonable attorneys' fees and costs to the Plaintiffs as provided by law; and

e. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, Tagi Modicue hereby demands a trial by jury on all counts and as to all issues.

Date: October 14, 2016

/s/ Patrick C. Morrow
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JS 44 (Rev. 08/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

TAGI MODICUE

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Patrick C. Morrow; MORROW, MORROW, RYAN, BASSETT & HAIK
324 West Landry Street, Opelousas, LA 70571; 800-655-4783

DEFENDANTS

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; ASTRA USA INC.; ASTRAZENECA AB; ASTRAZENECA UK LTD; ASTRAZENECA, PLC; PROCTER & GAMBLE MANUFACTURING C

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

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

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

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

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332 (a)(1)

Brief description of cause:
Products liability litigation

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
10/14/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Pat C. Morrow

FOR OFFICE USE ONLY

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