EFiled: Mar 31 2017 04:42PM EDT
Transaction ID 60412205
Case No. N17C-03-1695 JAP

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

PRAECIPE PURSUANT TO 10 *DEL. C.* § 3104

PLEASE ISSUE SUMMONS and a copy of the Complaint to the plaintiffs' counsel of record, commanding plaintiffs' counsel to summon and direct the below named defendants to answer the Complaint by serving the defendants with the Summons and a copy of the Complaint at the Defendant's address by Certified Mail, Return Receipt requested in accordance with 10 *Del. C.* § 3104:

PROCTER & GAMBLE MANUFACTURING COMPANY
c/o CT Corporation System
CT Corporation System
1300 East Ninth Street
Cleveland,OH 4411

THE PROCTER & GAMBLE COMPANY
c/o CT Corporation System
CT Corporation System
1300 East Ninth Street

Cleveland,OH 4411

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (# 2746)
919 N. Market Street, Suite 1801
Wilmington, DE 19801
Telephone: (302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff(s)

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SUMMONS PURSUANT TO 10 DEL. C. § 3104

THE STATE OF DELAWARE,
TO PLAINTIFFS' COUNSEL:

YOU ARE COMMANDED:

To summon the above defendant so that, within 20 days after service hereof upon defendants' agent, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiff's attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendants' agent a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiff) pursuant to 10 *Del. C.* § 3104.

Dated:

SUSAN A. HEARN
Prothonotary

_____
Per Deputy

TO THE ABOVE DEFENDANT:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN A. HEARN
Prothonotary

_____
Per Deputy

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IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

COMPLAINT

COMES NOW, Plaintiff, A'Lydia M. Gibbs (hereinafter "Plaintiff") by and through undersigned counsel, and files this Complaint against the Defendants, AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Procter & Gamble Manufacturing Company; The Procter & Gamble Company, Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals International, Inc.; Takeda Pharmaceuticals LLC; Takeda Pharmaceutical Company Limited; and Takeda Pharmaceuticals U.S.A., Inc. (collectively "Defendants") and in support thereof alleges as follows:

I. INTRODUCTION

1. This is a personal injury case against Defendants who were responsible for designing, developing, researching, manufacturing, testing, packaging, promoting, marketing,

advertising, distributing, labeling, and/or selling a class of drugs known as proton pump inhibitors ("PPI"s), which are prescription and over-the-counter ("OTC") medications referred to herein as PPIs.

2. PPIs are used to reduce acid production in order to lower the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as gastroesophageal reflux disease (GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions, including Zollinger-Ellison Syndrome.

3. 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").

4. 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.

5. 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.

II. PARTIES

6. Plaintiff, a resident of the State of Alabama, ingested PPIs, including Nexium, Prilosec and Prevacid for an extended period of time in 2015, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining PPIs, including Nexium, Prilosec and Prevacid recovery of all past, present, and future health

and medical care costs related to her kidney related injuries caused by her ingestion of PPIs, including Nexium, Prilosec and Prevacid.

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

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

9. In doing the acts alleged herein, said AstraZeneca Defendants (including ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP) 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 PHARMACEUTICALS LP and ASTRAZENECA LP are collectively referred to as "ASTRAZENECA").

10. Defendant PROCTER & GAMBLE MANUFACTURING COMPANY is an Ohio corporation that is registered to do business and conducts substantial business in this state, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

11. Defendant THE PROCTER & GAMBLE COMPANY is an Ohio corporation that is registered to do business and conducts substantial business in this state, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

12. In doing the acts alleged herein, said Procter & Gamble Defendants (including PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE COMPANY) 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 PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE COMPANY are collectively referred to as "PROCTER & GAMBLE").

13. Defendant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A.") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

14. Defendant Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

15. Defendant Takeda Pharmaceuticals International, Inc. ("Takeda International") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

16. Defendant Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

17. In doing the acts alleged herein, said Takeda Defendants (including Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals International, Inc.; Takeda Pharmaceuticals LLC; Takeda Pharmaceutical Company Limited; and Takeda Pharmaceuticals U.S.A., Inc.) 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.

III. JURISDICTION AND VENUE

18. Venue in this action properly lies in Delaware because, *inter alia*, Defendants Astrazeneca Pharmaceuticals LP, Astrazeneca LP, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International, Inc., and Takeda Pharmaceuticals LLC are Delaware corporations and/or entities. Further, upon information and belief, at all times relevant hereto, Defendants transacted, solicited, conducted business in the State of Delaware, contracted to supply goods to the State of Delaware and derived substantial revenue from such business.

IV. FACTUAL BACKGROUND

19. 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.

20. 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.

21. 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.

22. 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 sales of over $50 billion with approximately 240 million units dispensed.

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

24. 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. In 1997, David Badov, et al., described two further case studies documenting the causal connection between omeprazole and interstitial nephritis in the elderly.[1]

25. Between 1995 and 1999, Nicholas Torpey, et al. conducted a single-center retrospective analysis of renal biopsy results from 296 consecutive patients to determine the etiology of acute tubule-interstitial nephritis (TIN).[2] Acute AIN was identified in 24 (8.1%) biopsies. Eight out of fourteen cases with presumed drug-related AIN could be attributed to the PPIs omeprazole and lansoprazole.

26. Defendants knew or should have known that between 1992 and 2004 over 23 cases of biopsy-proven AIN secondary to omeprazole (Prilosec) had been reported.

27. In 2004, Defendants knew or should have known of 8 biopsy-proven cases reported from Norwich University Hospital in the United Kingdom.[3]

28. International organizations also recognized the danger posed by PPIs to kidney health, finding both AIN and insidious renal failure resulting from PPIs. In 2006, Professor Ian Simpson and his team at the University of Auckland published an analysis of the clinical features of 15 patients with AIN and acute renal failure from PPI over three years. In all patients, the tie-course of drug exposure and improvement of renal function on withdrawal suggested the PPI

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[1] Badov, D., et al. Acute Interstitial Nephritis Secondary To Omeprazole, *Nephrol Dial Transplant* (1997) 12: 2414–2416.

[2] Torpey, N., et al. *Drug-Induced Tubulo-Interstitial Nephritis Secondary To Proton Pump Inhibitors: Experience From A Single UK Renal Unit,* Nephrol. Dial. Transplant. (2004) 19: 1441–1446.

[3] *Id*.

were causal. "Although four patients presented with an acute systemic allergic reaction, 11 were asymptomatic with an insidious development of renal failure."[4]

29. Furthermore, in the New Zealand study, Defendants knew or should have known that twelve of the reported cases were biopsy-proven.

30. In 2006, Nimeshan Geevasinga, et al., found "evidence to incriminate all the commercially available PPIs, suggesting there is a class effect" with regard to PPI-induced AIN.[5] "Failure to recognize this entity might have catastrophic long-term consequences including chronic kidney disease." This study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases as two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team identified eighteen cases of biopsy-proven PPI-induced AIN. The TGA registry data identified an additional thirty-one cases of "biopsy proven interstitial nephritis." An additional ten cases of "suspected interstitial nephritis," twenty cases of "unclassified acute renal failure," and twenty-six cases of "renal impairment" were also identified. "All Five commercially available PPIs were implicated in these cases."

31. In 2006, the Center for Adverse Reaction Monitoring (CARM) in New Zealand, found that PPI products were the number one cause of AIN.[6]

32. 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."

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[4] Simpson, I., et al., *PPI and Acute Interstitial Nephritis*, NEPHROLOGY (2006)11: 381-85.

[5] Geevasinga, N., et al. *Proton Pump Inhibitors and Acute Interstitial Nephritis*, CLINICAL GASTROENTEROLOGY AND HEPATOLOGY, (2006)4:597-604.

[6] Ian J. Simpson, Mark R. Marshall, Helen Pilmore, Paul Manley, Laurie Williams, Hla Thein, David Voss, *Proton pump inhibitors and acute interstitial nephritis: Report and analysis of 15 cases*, (September 29, 2006).

33. 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.

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

35. In 2013, Klepser, et al. found that "patients with a renal disease diagnosis were twice as likely to have used a previous prescription for a PPI."[7] Klepser's study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

36. Also in 2013, Sampathkumar, et al. followed four cases of PPI users, finding that AIN developed after an average period of four weeks of PPI therapy.[8] Researchers further noted that "a high index of suspicion about this condition should prompt the physician to stop the drug, perform a renal biopsy if needed and start steroid therapy for halting a progressive renal disease."

37. In 2014, New Zealand researchers conducted a nested case-control study using routinely collected national health and drug dispensing data in New Zealand to estimate the relative and absolute risks of acute interstitial nephritis resulting in hospitalization or death in users of PPIs.[9] The study compared past use with current and ongoing use of PPIs, finding a significantly increased risk of acute interstitial nephritis for patients currently taking PPIs.

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[7] Klepser, D., et al. Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case-Control Study, BMC NEPHROLOGY (2013) 14:150.

[8] Sampathkumar, K., et al. *Acute Interstitial Nephritis Due to Proton Pump Inhibitors*, INDIAN J. NEPHROLOGY (2013) 23(4): 304-07.

[9] Blank, M., et al. *A Nationwide Nested Case-Control Study Indicates an Increased Risk of Acute Interstitial Nephritis with Proton Pump Inhibitor Use*, KIDNEY INTERNATIONAL (2014) 86, 837–844.

38. 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.

39. 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."

40. 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.

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

42. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.[10] The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n ¼ 10,482) and the Geisinger Health System (n ¼ 248,751), in order to evaluate the relationship between PPI use and the development of chronic kidney disease (CKD). Over a median of 13.9 years of follow-up in the Atherosclerosis Risk in Communities study, the incidence of documented CKD or end-stage renal disease was significantly higher in patients with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14–1.96).

43. "Consistent with prior studies, the authors also observed a significant association between baseline PPI use and acute kidney injury as defined by diagnostic codes (adjusted

[10] Lazarus, B., et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*, JAMA INTERN. MED., published online 11 Jan. 2016.

hazard ratio 1.64, 95% confidence interval 1.22–2.21). The results were then validated in the Geisenger Health System cohort using prescription data to define baseline PPI use and laboratory data to define the CKD outcome, defined as sustained outpatient estimated glomerular filtration rate the validation cohort also suggest a possible dose-response relationship between PPI use and CKD risk, with higher risk observed in patients prescribed a PPI twice daily at baseline (adjusted hazard ratio 1.46, 95% confidence interval 1.28–1.67). Despite the limitations inherent in observational studies, the robustness of the observations in this large study suggests a true association between PPI use and increased CKD risk."[11]

44. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with propensity score–matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

[11] See Schoenfeld, A. and Deborah Grady. *Adverse Effects Associated with Proton Pump Inhibitors*, JAMA INTERNAL MEDICINE, published online 11 Jan. 2016.

45. Lazarus's data was confirmed and expanded by Yan Xie, et al.[12] Using Department of Veterans Affairs national databases to build a primary cohort of new users of PPI (n=173,321) and new users of histamine H2-receptor antagonists (H2 blockers; n=20,270), this study patients over 5 years to ascertain renal outcomes. In adjusted Cox survival models, the PPI group, compared with the H2 blockers group, had an increased risk of CKD, doubling of serum creatinine level, and end-stage renal disease.

46. However, evidence of the connection of PPI's with AIN and CKD existed as early as 2007.[13] In Brewster and Perazella's review, they found that not only are PPIs "clearly associated with the development of AIN," most PPI patients they studied were "left with some level of chronic kidney disease." This CKD existed despite recovery of kidney function following PPI withdrawal. Furthermore, Härmark, et al., noted that the Netherlands Pharmacovigilance Centre Lareb received reports of AIN with the use of omeprazole, pantoprazole, and rabeprazole, demonstrating that "AIN is a complication associated with all PPIs."[14]

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

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

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

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[12] Xie, Y., et al. *Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD*, J. AM. SOC. NEPHROL. (2016) 27: ccc–ccc.

[13] Brewster, UC and MA Perazella. *Acute Kidney Injury Following Proton Pump Inhibitor Therapy*, KIDNEY INTERNATIONAL (2007) 71, 589–593.

[14] Härmark, L., et al. *Proton Pump Inhibitor-Induced Acute Interstitial Nephritis*, BRIT. J. OF CLIN. PHARMACOLOGY (2007) 64(6): 819-23.

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

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

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

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

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

Federal Requirements

67. Defendants had an obligation to comply with the law in the manufacture, design, and sale of PPIs.

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

69. With respect to PPIs, the Defendants, upon information and belief, have 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. PPIs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they fail to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. PPIs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or their quality or purity falls below the standard set

forth in the official compendium for Nexium and such deviations are not plainly stated on their labels.

c. PPIs are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading.

d. PPIs 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. PPIs 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. PPIs are misbranded pursuant to 21 U.S.C. §352 because they are 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. PPIs 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 they are intended, including conditions, purposes, or uses for which they are 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 they are 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. PPIs 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 PPIs 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 PPIs.

l. PPIs 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.

m. PPIs 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.

n. PPIs violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

o. PPIs violate 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.

p. PPIs violate 21 CFR § 211.165 in that Nexium fails to meet established standards or specifications and any other relevant quality control criteria.

q. PPIs violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding PPIs were not followed.

r. PPIs violate 21 CFR § 310.303 in that PPIs are not safe and effective for their intended use.

s. 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.

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

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

v. 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.

w. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of PPIs 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.

x. 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).

70. 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 State law.

Fraudulent Concealment

71. 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 PPIs.

72. 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 - THEORIES OF RECOVERY

COUNT ONE -NEGLIGENCE

(As to All Defendants)

73. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

74. Defendants had a duty to Plaintiff to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of PPIs into the stream of commerce, including a duty to assure that PPI's would not cause users to suffer unreasonable, dangerous side effects such as kidney injuries.

75. Defendants failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of PPIs into interstate commerce in that Defendants knew or should have known that using PPIs caused a risk of unreasonable, dangerous side effects, including kidney injuries.

76. Despite the fact that Defendants knew or should have known that PPIs were associated with and/or caused kidney injuries, Defendants continued to market, manufacture, distribute and/or sell PPIs to consumers, including the Plaintiff.

77. 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.

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

79. As a result Defendants' negligence and/or recklessness, the Plaintiff was caused to suffer serious and dangerous side effects, 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, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

80. 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, believes, and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

COUNT TWO - STRICT PRODUCTS LIABILITY - FAILURE TO WARN
(As to All Defendants)

81. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

82. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced PPIs into the stream of commerce, and in the course of same, directly advertised or marketed PPIs to consumers or persons responsible for consumers, and therefore, had a duty to both the Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of PPIs.

83. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of PPIs and/or are associated with the use of PPIs.

84. The PPIs manufactured and/or supplied by the Defendants were defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of kidney injuries from PPI use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physicians, and continued to aggressively promote PPIs.

85. Due to the inadequate warning regarding kidney injuries, PPIs were in a defective condition and unreasonably dangerous at the time that they left the control of the Defendants.

86. Defendants' failure to adequately warn Plaintiff and Plaintiff's prescribing physicians of kidney injuries risk prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of PPIs.

87. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' PPI, Plaintiff would not have purchased or taken the PPI and could have chosen to request other treatments or prescription medications.

88. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the potential life-threatening side effects of the Defendants' PPIs, Plaintiff's prescribing physicians would have discussed the risks of kidney injuries and PPIs with the Plaintiff and/or would not have prescribed them.

89. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

COUNT THREE – STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN
(As to All Defendants)

90. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

91. PPIs were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

92. At all times relevant, PPIs were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

93. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation because when they left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of PPIs.

94. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, because when they left the hands of Defendants' manufacturers and suppliers they were unreasonably dangerous and were also more dangerous than the ordinary consumer would expect.

95. At all times herein mentioned, the PPIs were in a defective condition and were unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when PPIs were used in a form and manner instructed and provided by Defendants.

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

97. At the time of Plaintiff's use of PPIs, it was being used for its intended purpose, and in a manner that it was normally intended.

98. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an

unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

99. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of their product. This was demonstrated by the existence of other PPIs which had a more established safety profile and a considerably lower risk profile.

100. Plaintiff could not, by the reasonable exercise of care, have discovered PPIs' defects and perceived their danger.

101. The defects in Defendants' product were substantial and contributing factors in causing Plaintiffs injuries.

102. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages. Due to the unreasonably dangerous condition of PPIs, Defendants are strictly liable to Plaintiff.

COUNT FOUR – BREACH OF EXPRESS WARRANTY
(As to All Defendants)

103. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

104. Defendants expressly warranted that PPIs were safe for their intended use and as otherwise described in this Complaint. PPIs did not conform to these express representations, including, but not limited to, the representation that they were safe and the representation that they did not have high and/or unacceptable levels of side effects like kidney injuries.

105. The express warranties made by the Defendants were a part of the basis for Plaintiff's use of PPIs and Plaintiff relied on these warranties in deciding to use PPIs.

106. At the time of making the express warranties, the Defendants had knowledge of the purpose for which the PPIs were to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

107. PPIs do not conform to these express representations because PPIs are not safe or effective and may produce serious side effects, including kidney injuries, degrading Plaintiff's health.

108. As a result of the foregoing breaches of express warranties the Plaintiff was caused to suffer Acute Kidney Failure, 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, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

109. 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 her use of Defendants' PPI drug.

110. 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.

COUNT FIVE– BREACH OF IMPLIED WARRANTY
(As to All Defendants)

111. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

112. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold PPIs.

113. The Defendants impliedly represented and warranted to the users of PPIs that PPIs were safe and fit for the particular purpose for which said product was to be used.

114. These aforementioned representations and warranties were false, misleading, and inaccurate because PPIs were unsafe, and degraded Plaintiff's health.

115. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

116. Plaintiff reasonably relied upon the skill and judgment of Defendants with respect to whether PPIs were safe and fit for their intended use.

117. PPIs were 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.

118. Defendants breached the aforesaid implied warranties as PPIs were not fit for their intended purposes and uses.

119. As a result of the foregoing breach of warranties, the Plaintiff was caused to suffer serious and dangerous side effects, 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, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff’s kidney injuries, as well as the need

for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

120. 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.

COUNT SIX– VIOLATION OF THE DELAWARE DECEPTIVE TRADE PRACTICES LAW, DEL. CODE ANN. TIT. 6, § 2531 et seq.
(As to All Defendants)

121. 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.

122. 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.

123. The Plaintiff used Defendants' PPIs and suffered ascertainable losses as a result of the Defendants' actions in violation of the aforementioned consumer protection laws.

124. The Defendants violated Title 6 of the Delaware Code, section 2531 et seq, through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of PPIs.

125. The Defendants uniformly communicated the purported benefits of PPIs while failing to disclose the serious and dangerous side effects related to the use of PPIs and of the true state of PPIs' regulatory status, their safety, their efficacy, and their 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 campaigns described herein.

126. 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.

127. The Defendants have a statutory duty to refrain from unfair trade practices in the design, development, manufacture, promotion and sale of PPIs.

128. Had the Defendants not engaged in the deceptive conduct described herein, the Plaintiff would not have purchased and/or paid for PPIs, 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.

129. 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 PPIs constituted unfair trade practices in violation of the state consumer protection statutes listed above.

130. The Defendants uniformly communicated the purported benefits of PPIs while failing to disclose the serious and dangerous side effects related to the use of PPIs and the true state of PPIs' regulatory status, their safety, their efficacy, and their 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.

131. The Defendants' conduct in connection with PPIs 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 PPIs.

132. 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.

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

134. 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.

COUNT SEVEN- PUNITIVE DAMAGES
(As to All Defendants)

135. 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.

136. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint, were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other PPI users and for the primary purpose of

increasing Defendants' profits from the sale and distribution of PPIs. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

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

138. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in PPIs and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in PPIs. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of PPIs knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

139. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by

Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

DAMAGES

140. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Exemplary and Punitive Damages;

h. Treble damages and

i. Reasonable and necessary attorney's fees.

WHEREFORE, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiff for the injuries suffered or will suffer. Plaintiff further demands judgment against each of the Defendants for punitive damages. Plaintiff further demands payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiff further demands payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demand a trial by jury on all counts and as to all issues.

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

Dated: March 31, 2017

SUPERIOR COURT
CIVIL CASE INFORMATION STATEMENT (CIS)

COUNTY: ☑ N ☐ K ☐ S CIVIL ACTION NUMBER: _____

Caption:
A'LYDIA M. GIBBS v.
ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP;
PROCTER & GAMBLE MANUFACTURING COMPANY;THE PROCTER & GAMBLE COMPANY;
Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals International, Inc.; Takeda Pharmaceuticals LLC;
Takeda Pharmaceutical Company Limited; and Takeda Pharmaceuticals U.S.A., Inc.

Civil Case Code: CPRL

Civil Case Type: CPRL - Products Liability

(See Reverse Side for Code and Type)

Name and Status of Party filing document:
A'LYDIA M. GIBBS, Plaintiff

Document Type:(e.g.; Complaint; Answer with Counterclaim)
Complaint

Jury Demand: Yes ☑ No ☐

Attorney Name(s):
James D. Heisman

Attorney ID(s):
2746

Firm Name:
Napoli Shkolnik, LLC

Address:
919 North Market Street, Suite 1801
Wilmington, DE 09801

Telephone Number:
302-330-8025

Fax Number:
646-843-7603

E-Mail Address:
JHeisman@Napolilaw.com

Identify any related cases now pending in the Superior Court or any related cases that have been closed in this court within the last two years by caption and civil action number including judge's initials:
N17C-02-237 JAP; N17C-03-057 JAP and N17C-03-059 JAP

Explain the relationship(s):

Other unusual issues that affect Case Management:

(If additional space is needed, please attach page)

The Prothonotary will not process the complaint, answer, or first responsive pleading in this matter for service until the case information statement (CIS) is filed. The failure to file the CIS and have the pleading processed for service may result in the dismissal of the complaint or may result in the answer or first responsive pleading being stricken.

SUPERIOR COURT CIVIL CASE INFORMATION STATEMENT (CIS) INSTRUCTIONS

CIVIL CASE TYPE

Please select the appropriate civil case code and case type (e.g., **CODE** - **AADM** and **TYPE** - **Administrative Agency**) from the list below. Enter this information in the designated spaces on the Case Information Statement.

APPEALS
AADM - Administrative Agency
ACER - Certiorari
ACCP - Court of Common Pleas
AIAB - Industrial Accident Board
APSC - Public Service Commission
AUIB - Unemployment Insurance Appeal Board

COMPLAINTS
CABT – Abatement
CASB – Asbestos
CAAA - Auto Arb Appeal
CMIS - Civil Miscellaneous
CACT - Class Action
CCON - Condemnation
CCLD - Complex Commercial Litigation Division **(NCC ONLY)**
CDBT - Debt/Breach of Contract
CDEJ - Declaratory Judgment
CDEF - Defamation
CEJM - Ejectment
CATT - Foreign & Domestic Attachment
CFJG - Foreign Judgment
CFRD - Fraud Enforcement
CINT - Interpleader
CLEM - Lemon Law
CLIB - Libel
CMAL - Malpractice
CMED - Medical Malpractice
CPIN - Personal Injury
CPIA - Personal Injury Auto
CPRL - Products Liability
CPRD - Property Damage
CRPV - Replevin
CSPD - Summary Proceedings Dispute
CCCP - Transfer from CCP
CCHA - Transfer from Chancery

MASS TORT
CBEN - Benzene Cases
CPEL - Pelvic Mesh Cases
CPLX - Plavix Cases
CXAR - Xarelto Cases

INVOLUNTARY COMMITMENTS
INVC- Involuntary Commitment

MISCELLANEOUS
MAGM - AG Motion - Civil/Criminal Investigations *
MADB - Appeal from Disability Board *
MAFF - Application for Forfeiture
MAAT - Appointment of Attorney
MGAR - Appointment of Guardianship
MCED - Cease and Desist Order
MCON - Civil Contempt/Capias
MCVP - Civil Penalty
MSOJ - Compel Satisfaction of Judgment
MSAM - Compel Satisfaction of Mortgage
MCTO - Consent Order
MIND - Destruction of Indicia of Arrest *
MESP - Excess Sheriff Proceeds
MHAC - Habeas Corpus
MTOX - Hazardous Substance Cleanup
MFOR - Intercept of Forfeited Money
MISS - Issuance of Subpoena
MLEX - Lien Extension
MMAN - Mandamus
MWIT - Material Witness *
MWOT - Material Witness - Out of State
MRAT - Motion for Risk Assessment
MROP - Petition for Return of Property
MCRO - Petition Requesting Order
MROD - Road Resolution
MSEL - Sell Real Estate for Property Tax
MSEM - Set Aside Satisfaction of Mortgage
MSSS - Set Aside Sheriff's Sale
MSET - Structured Settlement
MTAX - Tax Ditches
MREF - Tax Intercept
MLAG - Tax Lagoons
MVAC - Vacate Public Road
MPOS - Writ of Possession
MPRO - Writ of Prohibition

MORTGAGES
MCOM - Mortgage Commercial
MMED - Mortgage Mediation
MORT - Mortgage Non-Mediation (Res.)

MECHANICS LIENS
LIEN - Mechanics Lien

* Not eFiled

DUTY OF THE PLAINTIFF

Each plaintiff/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the complaint.

DUTY OF THE DEFENDANT

Each defendant/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the answer and/or first responsive pleading.

EFiled: Mar 31 2017 04:42PM EDT
Transaction ID 60412205
Case No. N17C-03-1695 JAP

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

PLAINTIFF'S ANSWERS TO FORM 30 INTERROGATORIES

1. Give the name and present or last-known residential and employment address and telephone number of each eyewitness to the incident which is the subject of the litigation.

   ANSWER: A'Lydia M. Gibbs
   535 Buster Willet Road
   Attalla, AL 35954

   To be supplemented, if applicable.

2. Give the name and present or last-known residential and employment address and telephone number of each person who has knowledge of the facts relating to the litigation.

   ANSWER: Plaintiff, who may be contacted only through the undersigned counsel. Plaintiff's treating physicians. The names and contact information of said treating physicians will be supplied by plaintiff. To be supplemented, if applicable.

3. Give the names of all persons who have been interviewed in connection with the above litigation, including the names and present or last-known residential and employment addresses and telephone numbers of the persons who made said interviews and the names and present or last-known residential and employment addresses and telephone numbers of persons who have the original and copies of the interview.

ANSWER: None.

4. Identify all photographs, diagrams, or other representations made in connection with the matter in litigation, giving the name and present or last-known residential and employment address and telephone number of the person having the original and copies thereof. (In lieu thereof, a copy can be attached.)

   ANSWER: None currently in possession.

5. Give the name, professional address, and telephone number of all expert witnesses presently retained by the party together with the dates of any written opinions prepared by said expert. If an expert is not presently retained, describe by type the experts whom the party expects to retain in connection with the litigation.

   ANSWER: Experts in epidemiology, Experts in Kidney Disease, Nephrologist, FDA Regulatory Experts, Causation Experts, Damages Experts and other experts will be retained.

6. Give a brief description of any insurance policy, including excess coverage, that is or may be applicable to the litigation, including:
   a. The name and address of all companies insuring the risk;
   b. The policy number(s);
   c. The type of insurance;
   d. The amounts of primary, secondary, and excess coverage.

   ANSWER: Not Applicable**.**

7. Give the name, professional address, and telephone number of all physicians, chiropractors, psychologists, and physical therapists who have examined or treated you at any time during the ten year period immediately prior to the date of the incident at issue in this litigation.

   ANSWER: To be supplemented.

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

DATED: March 31, 2017

EFiled: Mar 31 2017 04:42PM EDT
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IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

HAGUE CONVENTION PRAECIPE

PLEASE ISSUE Summons and Complaint through Plaintiff's Attorneys to the defendants listed below at the addresses indicated herein pursuant to the Article 5 of the Hague Convention:

TAKEDA PHARMACEUTICAL COMPANY LIMITED
1-1, Doshomachi 4-chome
Chuo-ku, Osaka, Japan

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

DATED: March 31, 2017

EFiled: Mar 31 2017 04:42PM EDT
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IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

SUMMONS PURSUANT TO ARTICLE 5 OF THE HAGUE CONVENTION

THE STATE OF DELAWARE,
PLAINTIFF'S COUNSEL
YOU ARE COMMANDED:

To summon the above-named defendant so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiff's attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiff).

Dated:

SUSAN A. HEARN
Prothonotary

_____
Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN A. HEARN
Prothonotary

_____
Per Deputy

U.S. Department of Justice
United States Marshals Service

EFiled: Mar 31 2017 04:42PM EDT
Transaction ID 60412205
Case No. N17C-03-1695 JAP

REQUEST
FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

DEMANDE
AUX FINS DE SIGNIFICATION OU DE NOTIFICATION À L'ETRANGER
D'UN ACTE JUDICIAIRE OU EXTRAJUDICIAIRE

Convention on the service abroad of judicial and extrajudicial documents in civil or commercial matters, signed at The Hague, November 15, 1965.
Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

Identity and address of the applicant *Identité et adresse du requérant*	**Address of receiving authority** *Adresse de l'autorité destinataire*
JAMES D. HEISMAN, ESQUIRE NAPOLI SHKOLNIK, LLC 919 N. MARKET STREET SUITE 1801 WILMINGTON, DE 19801	Ministry of Foreign Affairs 2-2-1 Kasumigaseki Chiyoda-ku Tokyo 100-8919 Japan

The undersigned applicant has the honour to transmit -- in duplicate-- the documents listed below and, in conformity with article 5 of the above-mentioned Convention, requests prompt service of one copy thereof on the addressee, i.e., (identity and address)
Le requérant soussignée a l'honneur de faire parvenir--en double exemplaire--à l'autorité destinataire les documents ci-dessous énumérés, en la priant, conformément à l'article 5 de la Convention précitée, d'en faire remettre sans retard un exemplaire au destinataire, à savoir:
(identité et adresse)

TAKEDA PHARMACEUTICAL COMPANY LIMITED
1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan

☒ (a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention.*
a) selon les formes légales (article 5 alinéa premier, lettre a).

☐ (b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of article 5)*:
b) selon la forme particulière suivante (article 5, alinéa premier, lettre b) :

☐ (c) by delivery to the addressee, if he accepts it voluntarily (second paragraph of article 5)*:
c) le cas échéant, par remise simple (article 5, alinéa 2).

The authority is requested to return or to have returned to the applicant a copy of the documents and of the annexes with a certificate as provided on the reverse side.
Cette autorité est priée de renvoyer ou de faire renvoyer au requérant un exemplaire de l'acte - et de ses annexes - avec l'attestation figurant au verso.

List of documents
Enumération des pièces

Summons to Initiate lawsuit
Complaint initiating lawsuit
Form 30 Interrogatories
Order Appointing Special Process Server

Done at _____, the _____
Fait à _____, le

Signature and/or stamp
Signature et/ou cachet

*Delete if inappropriate
Rayer les mentions inutiles.

CERTIFICATE
ATTESTATION

The undersigned authority has the honour to certify, in conformity with article 6 of the Convention,
L'autorité soussignée a l'honneur d'attester conformément à l'article 6 de ladite Convention,

1) that the document has been served *
1) que la demande a été exécutée
-- the (date) -- *le (date)* _____
-- at (place, street, number) - *à (localité, rue, numéro)*

_____

-- in one of the following methods authorized by article 5:
-- *dans une des formes suivantes prévues à l'article 5:*

☐ (a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of article 5 of the Convention*.
a) selon les formes légales (article 5. alinéa premier, lettre a)

☐ (b) in accordance with the following particular method:
b) selon la forme particulière suivante: _____

☐ (c) by delivery to the addressee, who accepted it voluntarily.*
c) par remise simple.

The documents referred to in the request have been delivered to:
Les documents mentionnés dans la demande ont été remis à:

- (identity and description of person)
- (Identité et qualité de la personne)

_____

- relationship to the addressee family, business or other
- liens de parenté de subordination ou autres avec le destinataire de l'acte:

_____

2) that the document has not been served, by reason of the following facts*:
2) que la demande n'a pas été exécutée, en raison des faits suivants:

_____

In conformity with the second paragraph of article 12 of the Convention, the applicant is requested to pay or reimburse the expenses detailed in the attached statement*
Conformément à l'article 12, alinéa 2, de ladite Convention, le requérant est prié de payer ou de rembourser les frais dont le détail figure au mémoire ci-joint.

ANNEXES
Annexes

Documents returned:
Pieces renvoyées

_____
_____
_____

In appropriate cases, documents establishing the service:
Le cas échéant, les documents justificatifs de l'exécution:

_____
_____

Done at _____, the _____
Fait à _____, le

Signature and/or stamp
Signature et/ou cachet

_____

SUMMARY OF THE DOCUMENT TO BE SERVED
ÉLÉMENTS ESSENTIELS DE L'ACTE

Convention on the service abroad of judicial and extrajudicial documents In civil or commercial matters, signed at The Hague, November 15, 1965.

Convention relative à la signification et à la notification à l'étranger des actes judiciaires ou extrajudiciaires en matière civile ou commerciale, signée à La Haye, le 15 novembre 1965.

(article 5, fourth paragraph)
(article 5, alinéa quatre)

Name and address of the requesting authority:
Nom et adresse de l'autorité requérante:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, WILMINGTON, DELAWARE, USA 19801

Particulars of the parties:
Identité des parties:

A'LYDIA M. GIBBS V. ASTRAZENECA PHARMACEUTICALS LP et al.

JUDICIAL DOCUMENT
ACTE JUDICIA IRE

Nature and purpose of the document:
Nature et objet de l'acte:

LAWSUIT-COMPLAINT AND SUMMONS TO INITIATE LAWSUIT IN DELAWARE USA

Nature and purpose of the proceedings and, where appropriate, the amount in dispute:
Nature et objet de l'instance, le cas échéant, le montant du litige:

PRODUCT LIABILITY CIVIL LAWSUIT

Date and place for entering appearance:
Date et lieu de la comparution:

NAPOLI SHKOLNIK, LLC, 919 N. MARKET ST., STE. 1801, WILMINGTON, DE 19801 USA

Court which has given judgment:**
Juridiction qui a rendu la décision:

THE SUPERIOR COURT OF THE STATE OF DELAWARE, USA

Dale of judgment:**
Date de la décision:

n/a-CASE HAS JUST BEGUN

Time limits stated in the document:**
Indication des délais figurant dans l'acte:

120 DAYS OF RECEIPT OF SUMMONS AND COMPLAINT

EXTRAJUDICIAL DOCUMENT
ACTE EXTRAJUDICIAIRE

Nature and purpose of the document:
Nature et objet de l'acte:

Time limits stated in the document:**
Indication des délais figurant dans l'acte:

EFiled: Mar 31 2017 04:42PM EDT
Transaction ID 60412205
Case No. N17C-03-1695 JAP

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

NEW CASTLE COUNTY PRAECIPE

PLEASE ISSUE Summons and Complaint through the Sheriff of New Castle County to the defendants at the addresses indicated herein:

ASTRAZENECA PHARMACEUTICALS LP
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

ASTRAZENECA LP
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

TAKEDA PHARMACEUTICALS AMERICA, INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

TAKEDA PHARMACEUTICALS LLC
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

TAKEDA PHARMACEUTICALS U.S.A., INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

DATED: March 31, 2017

EFiled: Mar 31 2017 04:42PM EDT
Transaction ID 60412205
Case No. N17C-03-1695 JAP

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

A'LYDIA M. GIBBS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC.; TAKEDA PHARMACEUTICALS LLC; TAKEDA PHARMACEUTICAL COMPANY LIMITED; and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	)	C.A. No.:_____ JURY TRIAL DEMANDED

SUMMONS

THE STATE OF DELAWARE,
TO THE SHERIFF OF NEW CASTLE COUNTY:

YOU ARE COMMANDED:

To summon the above-named defendant so that, within 20 days after service hereof upon defendant, exclusive of the day of service, defendant shall serve upon James D. Heisman, Esquire, plaintiff's attorney, whose address is 919 N. Market Street, Suite 1801, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiff).

Dated:

SUSAN A. HEARN
Prothonotary

_____
Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN A. HEARN
Prothonotary

_____
Per Deputy