COURT FILE NUMBER	Q.B.G. 1731 of 2017
COURT OF QUEEN'S BENCH FOR SASKATCHEWAN	
JUDICIAL CENTRE	REGINA
PLAINTIFF	ASHTON KING
DEFENDANTS	APOTEX INC., ASTRAZENECA CANADA INC., BGP PHARMA ULC, DOMINION PHARMACAL, JANSSEN INC., LABORATOIRE RIVA INC., MYLAN PHARMACEUTICALS ULC, PHARMASCIENCE INC., PRO DOC LIMITEE, RANBAXY PHARMACEUTICALS CANADA INC, SANDOZ CANADA INCORPORATED, SANIS HEALTH INC., SIVEM PHARMACEUTICALS ULC, TAKEDA CANADA INC., TAKEDA PHARMACEUTICALS AMERICA INC., and TEVA CANADA LIMITED

Brought under *The Class Actions Act*

STATEMENT OF CLAIM

NOTICE TO DEFENDANTS

1. The plaintiff may enter judgment in accordance with this Statement of Claim or such judgment as may be granted pursuant to the Rules of Court unless, in accordance with paragraph 2, you:

(a) serve a Statement of Defence on the plaintiff; and

(b) file a copy of it in the office of the local registrar of the Court for the judicial centre named above.

2. The Statement of Defence must be served and filed within the following period of days after you are served with the Statement of Claim (excluding the day of service):

- within 20 days if you were served in Saskatchewan;
- within 30 days if you were served elsewhere in Canada or in the United States of America;
- within 40 days if you were served outside Canada and the United States of America

3. In many cases a defendant may have the trial of the action held at a judicial centre other than the one at which the Statement of Claim is issued. Every defendant should consult his lawyer as to his rights.

4. This Statement of Claim is to be served within six months from the date on which it is issued.

5. This Statement of Claim is issued at the above-named judicial centre the 10th day of July, 2017.

J. WEBSTER
DY. LOCAL REGISTRAR

Local Registrar

I. THE PARTIES

Plaintiff

1. The Plaintiff, Ashton King (the "**Plaintiff**"), is a resident of Regina, Saskatchewan.

Defendants

AstraZeneca Canada Inc.

2. The Defendant, AstraZeneca Canada Inc. ("**AstraZeneca**") is a corporation established pursuant to the laws of the Province of Ontario with its head office at 1004 Middlegate Road, Mississauga, Ontario, L4Y 1M4.

3. At all material times, AstraZeneca was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Nexium and Losec, as defined in this claim, in Canada.

4. The development of Nexium and Losec for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Nexium and Losec and other actions central to the allegations of this lawsuit, were undertaken by AstraZeneca in Canada and elsewhere.

5. Any subsidiary, parent, or holding company of AstraZeneca that engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Nexium and Losec in Canada; or was involved in the development of Nexium and Losec for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Nexium and Losec and other actions central to the allegations of this lawsuit is jointly, severally, and vicariously liable:

(a) as a global partnership or common business enterprise which manufactured Nexium and Losec and distributed it throughout the world, including in Canada.

(b) as each was the partner or agent of the others:

(i) as each company's business was and is inextricably connected with AstraZeneca; and

(ii) as each company and AstraZeneca had a common plan to manufacture and distribute Nexium and Losec throughout the world, including in Canada, for profit.

(c) as they are joint tortfeasors.

Takeda Pharmaceuticals America Inc., BGP Pharma ULC, and Mylan Pharmaceuticals ULC

6. The Defendant, Takeda Pharmaceuticals America Inc., is a corporate entity established pursuant to the laws of the State of Delaware, with its head office at 1 Takeda Parkway, Deer Field, Illinois, United States, 63015, with its registered agent for the purpose of service being The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

7. The Defendant, BGP Pharma ULC, which operates under the business name Mylan ERD, is an unlimited liability corporation established pursuant to the laws of the Province of Nova Scotia with its head office at 1950 Upper Water Street, Suite 900, Halifax, Nova Scotia, B3J 2X2 and is a subsidiary of Mylan Pharmaceuticals ULC.

8. The Defendant, Mylan Pharmaceuticals ULC is an unlimited liability corporation established pursuant to the laws of Canada with its head office at 85 Advance Road Etobicoke, Ontario, M8Z 2S6.

9. The business operations of Takeda Pharmaceuticals America Inc., Mylan ERD, Mylan Pharmaceuticals ULC are inextricably linked in a manner known only to the defendants; however, based on the product monographs, Mylan ERD and Mylan Pharmaceuticals ULC operates, at a minimum, as the Canadian distributor of Prevacid, as defined in this claim, on behalf of Takeda Pharmaceuticals America Inc. For the purposes of this application, Takeda Pharmaceuticals America Inc., Mylan ERD, and Mylan Pharmaceuticals ULC will be described together and collectively as "**Mylan**".

10. At all material times, Mylan was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Prevacid in Canada.

11. The development of Prevacid for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Prevacid and other actions central to the allegations of this lawsuit, were undertaken by Mylan in Canada and elsewhere.

12. Any subsidiary, parent, or holding company of Mylan that engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Prevacid in Canada; or was involved in the development of Prevacid for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Prevacid and other actions central to the allegations of this lawsuit is jointly, severally, and vicariously liable:

(a) as a global partnership or common business enterprise which manufactured Prevacid and distributed it throughout the world, including in Canada.

(b) as each was the partner or agent of the others:

(i) as each company's business was and is inextricably connected with Mylan; and

(ii) as each company and Mylan had a common plan to manufacture and distribute Prevacid throughout the world, including in Canada, for profit.

(c) as they are joint tortfeasors.

Takeda Canada Inc.

13. The Defendant, Takeda Canada Inc. ("**Takeda**") is a corporation established pursuant to the laws of Canada with its registered office located at suite 1600, 100 King Street West, 1 First Canadian Place, Toronto, Ontario, M5X 1G5.

14. At all material times, Takeda was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Dexilant, Pantoloc, Panto IV, and Tecta, as defined in this claim, in Canada.

15. The development of Dexilant, Pantoloc, Panto IV, and Tecta for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Dexilant, Pantoloc, Panto IV, and Tecta and other actions central to the allegations of this lawsuit, were undertaken by Takeda in Canada and elsewhere.

16. Any subsidiary, parent, or holding company of Takeda that engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Dexilant, Pantoloc, Panto IV, and Tecta in Canada; or was involved in the development of Dexilant, Pantoloc, Panto IV, and Tecta for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Dexilant, Pantoloc, Panto

IV, and Tecta and other actions central to the allegations of this lawsuit is jointly, severally, and vicariously liable:

(a) as a global partnership or common business enterprise which manufactured Dexilant, Pantoloc, Panto IV, and Tecta and distributed it throughout the world, including in Canada.

(b) as each was the partner or agent of the others:

(i) as each company's business was and is inextricably connected with Takeda; and

(ii) as each company and Takeda had a common plan to manufacture and distribute Dexilant, Pantoloc, Panto IV, and Tecta throughout the world, including in Canada, for profit.

(c) as they are joint tortfeasors.

Apotex Inc., Dominion Pharmacal, PharmaScience Inc., Pro Doc Limitee, Sivem Pharmaceuticals ULC, Sanis Health Inc., Ranbaxy Pharmaceuticals Canada Inc., Laboratoire Riva Inc., Sandoz Canada Incorporated, and Teva Canada Limited

17. Apotex Inc., Dominion Pharmacal, PharmaScience Inc., Pro Doc Limitee, Sivem Pharmaceuticals ULC, Sanis Health Inc, Ranbaxy Pharmaceuticals Canada Inc., Laboratoire Riva Inc, Sandoz Canada Incorporated, and Teva Canada Limited are collectively referred to herein as the "**Rabeprazole Group**".

18. The Defendant, Apotex Inc. is a corporation established pursuant to the laws of Canada with its registered office located at 755 Boul., St-Jean Pointe-Claire, Québec, H9R 5M9.

19. The Defendant, Dominion Pharmacal is a corporation established pursuant to the laws of Canada with its registered office located at 100 - 6111 av., Royalmount, Montréal (Québec) H4P 2T4.

20. The Defendant, Laboratoire Riva Inc. is a corporation established pursuant to the laws of Canada with its registered office located at 660 boul., Industriel, Blainville, Québec, J7C 3V4.

21. The Defendant, PharmaScience Inc. is a corporation established pursuant to the laws of Canada with its registered office located at 100 - 6111 Royalmount Ave, Montréal, Québec, H4P 2T4.

22. The Defendant, Pro Doc Limitee is a corporation established pursuant to the laws of Canada with its registered office located at 2925 boul., Industriel, Laval, Québec, H7L 3W9.

23. The Defendant, Ranbaxy Pharmaceuticals Canada Inc. is a corporation established pursuant to the laws of Canada with its registered office located at 126 East Drive, Brampton, Ontario, L6T 1C1.

24. The Defendant, Sandoz Canada Incorporated is a corporation established pursuant to the laws of Canada with its registered office located at 145 rue., Jules-Leger, Boucherville, Québec J4B 7K8.

25. The Defendant, Sanis Health Inc. is a corporation established pursuant to the laws of Canada with its registered office located at Suite 400, 371 Phoenix Square, Queen Street Fredericton, New Brunswick, E3B 1B1.

26. The Defendant, Sivem Pharmaceuticals ULC is a corporation established pursuant to the laws of Canada with its registered office located at 2600 - 595, St. Burrard, Vancouver, British Columbia, V7X 1L3.

27. The Defendant, Teva Canada Limited is a corporation established pursuant to the laws of Canada with its registered office located at 30 Novopharm Court, Toronto, Ontario, M1B 2K9.

28. At all material times, the Rabeprazole Group was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Rabeprazole, as defined in this claim, in Canada.

29. The development of Rabeprazole for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Rabeprazole and other actions central to the allegations of this lawsuit, were undertaken by the Rabeprazole Group in Canada and elsewhere.

30. Any subsidiary, parent, or holding company of any of the entities within the Rabeprazole Group that engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Rabeprazole in Canada; or was involved in the development of Rabeprazole for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Rabeprazole and other actions central to the allegations of this lawsuit is jointly, severally, and vicariously liable (as between related entities):

(a) as a global partnership or common business enterprise which manufactured Rabeprazole and distributed it throughout the world, including in Canada.

(b) as each was the partner or agent of the others,

(i) as each company's business was and is inextricably connected; and,

(ii) as each company had a common plan to manufacture and distribute Rabeprazole throughout the world, including in Canada, for profit.

(c) as they are joint tortfeasors.

Janssen Inc.

31. The Defendant, Janssen Inc., ("**Janssen**") is a corporate entity established pursuant to the laws of the State of Delaware, with its Canadian office at 19 Green Belt Dr. Toronto, Ontario, M3C 1L9 and with its registered agent for the purpose of service being The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

32. At all material times, Janssen was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Pariet, as defined in this claim, in Canada.

33. The development of Pariet for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Pariet and other actions central to the allegations of this lawsuit, were undertaken by Janssen in Canada and elsewhere.

34. Any subsidiary, parent, or holding company of Janssen that engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Pariet in Canada; or was involved in the development of Pariet for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Pariet and other actions central to the allegations of this lawsuit is jointly, severally, and vicariously liable:

(a) as a global partnership or common business enterprise which manufactured Pariet and distributed it throughout the world, including in Canada.

(b) as each was the partner or agent of the others:

(i) as each company's business was and is inextricably connected with Janssen; and

(ii) as each company and Janssen had a common plan to manufacture and distribute Pariet throughout the world, including in Canada, for profit.

(c) as they are joint tortfeasors.

Definitions

35. In this statement of claim, the following words and phrases mean the following, and the singular includes the plural and vice versa, as context requires:

(a) "**Antacids**" means Nexium, Prevacid, Dexilant, Pariet, and Rabeprazole as defined below in this paragraph.

(b) The "**Class**" or "**Class Members**" means all persons residing in Canada who ingested any of Nexium®, Losec®, Prevacid®, Dexilant®, Pantoloc®, Panto IV®, Tecta®, or Pariet® branded drugs, or drugs containing the active ingredient rabeprazole or their generic equivalents, with each such group forming a sublcass thereof, and their successors and assigns;

(c) "**Dexilant**" means Dexilant®, Pantoloc®, Panto IV®, and Tecta® branded drugs or their generic equivalents sold, distributed, or otherwise marketed by Takeda in Canada in a variety of forms and concentrations, as shown, but not limited to, the forms and concentrations listed in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monograph
02354950	DEXILANT 30 MG	2010-08-05	-	2016-12-16
02354969	DEXILANT 60 MG	2010-08-05	-	2016-12-16
02229453	PANTOLOC 40 MG	1997-03-05	-	2016-12-16
02241804	PANTOLOC 20 MG	2000-05-02	-	2016-12-16
02441527	PANTO IV 40 MG/vial	1999-04-06	2017-02-27	2016-12-15
02267233	TECTA 40 MG	2006-03-15	-	2016-12-06

(d) "**Nexium**" means Nexium® and Losec® branded drugs or their generic equivalents sold, distributed, or otherwise marketed by AstraZeneca in Canada in a variety of forms and concentrations, as shown, but not limited to, the forms and concentrations listed in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monorgraph
02230737	LOSEC 10 MG	1997-04-28	-	2016-11-10
02190915	LOSEC 20 MG	1996-12-31	-	2016-11-10
02119579	LOSEC CAPSULES 10MG	2000-10-03	2013-12-04	2013-04-05
00846503	LOSEC CAPSULES 20MG	1989-12-31	-	2016-11-10
02016788	LOSEC CAPSULES 40MG	2003-10-17	2010-06-30	2010-04-30
02242461	LOSEC MUPS 10MG	2001-02-22	2009-12-02	2008-12-03
02242462	LOSEC MUPS 20MG	2001-02-22	2009-12-01	2008-12-03
02300524	NEXIUM 10MG	2008-01-02	-	2016-11-10
02244521	NEXIUM 20MG	2001-08-20	-	2016-11-10
02244522	NEXIUM 40MG	2001-08-20	-	2016-11-10

(e) "**Pariet**" means Pariet® branded drugs or their generic equivalents sold, distributed, or otherwise marketed by Janssen in Canada in a variety of forms and concentrations, as shown, but not limited to, the forms and concentrations listed in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monorgraph
02243796	PARIET, ENTERIC-COATED TABLET 10MG	2002-04-02	-	2017-06-23
02243797	PARIET, ENTERIC-COATED TABLET 10MG	2002-04-02	-	2017-06-23

(f) "**Prevacid**" means Prevacid® branded drugs or their generic equivalents sold, distributed, or otherwise marketed by Mylan in Canada in a variety of forms and concentrations, as shown, but not limited to, the forms and concentrations listed in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monorgraph
02165503	PREVACID 15MG	1995-12-31	-	2017-06-06
02165511	PREVACID 30MG	1995-12-31	-	2017-06-06
02249464	PREVACID FASTAB 15MG	2006-11-24	-	2017-06-06
02249472	PREVACID FASTAB 30MG	2005-12-01	-	2017-06-06

(f) "**Rabeprazole**" means all generic versions of drugs containing the active ingredient "rabeprazole" marketed by the Rabeprazole Group and other defendants in Canada in a variety of forms and concentrations, as shown, but not limited to, the forms and concentrations listed in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monograph
02422638	ABBOTT-RABEPRAZOLE 10MG	2014-10-17	2015-12-31	2015-01-06
02422646	ABBOTT-RABEPRAZOLE 20MG	2014-07-21	2015-12-31	2015-01-06
02345579	APO-RABEPRAZOLE 10MG	2012-05-01	-	2015-02-09
02345587	APO-RABEPRAZOLE 20MG	2012-05-01	-	2015-02-09
02320460	DOM-RABEPRAZOLE EC 20MG	2012-09-26	-	2013-01-09
02408392	MYLAN-RABEPRAZOLE 10MG	2013-07-10	-	2017-06-05
02408406	MYLAN-RABEPRAZOLE 20MG	2013-07-10	-	2017-06-05
02381737	PAT-RABEPRAZOLE 10MG	2012-05-08	2014-11-11	2013-06-28
02381745	PAT-RABEPRAZOLE 20MG	2012-05-08	2014-11-18	2013-06-28
02310805	PMS-RABEPRAZOLE EC 10MG	2008-06-03	-	2012-08-15
02310813	PMS-RABEPRAZOLE EC 20MG	2008-06-03	-	2012-08-15
02315181	PRO-RABEPRAZOLE 10MG	2009-02-10	-	2013-01-08
02315203	PRO-RABEPRAZOLE 20MG	2009-02-10	-	2013-01-08
02385449	RABEPRAZOLE 10MG	2012-06-10	-	2017-04-28
02385457	RABEPRAZOLE 20MG	2012-06-10	-	2017-04-28
02320614	RABEPRAZOLE EC 10MG	2010-02-18	2014-06-25	2013-01-09
02320622	RABEPRAZOLE EC 20MG	2010-02-18	2014-06-25	2013-01-09
02356511	RABEPRAZOLE EC 10MG	2010-11-23	-	2017-05-09
02356538	RABEPRAZOLE EC 20MG	2010-11-23	-	2017-05-09
02298074	RAN-RABEPRAZOLE 10MG	2007-11-09	-	2015-05-12
02298082	RAN-RABEPRAZOLE 20MG	2007-11-09	-	2015-05-12
02330083	RIVA-RABEPRAZOLE EC 10MG	2009-09-28	-	2009-07-17
02330091	RIVA-RABEPRAZOLE EC 20MG	2009-09-30	-	2009-07-17
02314177	SANDOZ RABEPRAZOLE 10MG	2008-07-29	-	2017-02-16
02314185	SANDOZ RABEPRAZOLE 20MG	2008-07-29	-	2017-02-16
02296632	TEVA-RABEPRAZOLE EC 10MG	2007-11-13	-	2017-03-10
02296640	TEVA-RABEPRAZOLE EC 20MG	2007-11-13	-	2017-03-10

II. CLAIM

General Facts

36. Antacids which are pharmaceutical proton pump inhibitors are one of the most commonly prescribed medications in the Canada.

37. Proton pump inhibitors are drugs used to reduce stomach acid and are widely used to treat conditions such as acid reflux (heartburn) and stomach ulcers.

38. Dexilant, Nexium, Pariet, Prevacid and Rabeprazole, as defined above, are pharmaceutical proton pump inhibitors (hereinafter referred to as "**PPI**" or "**PPIs**")

39. With more than four million prescriptions in Canada in 2010, the aforementioned PPIs are one of the most commonly prescribed drugs in Canada.

40. It has been estimated that a significant percentage of prescriptions for PPI's have no appropriate indication and a significant percentage of long-term PPI users could discontinue therapy without developing any symptoms.

41. Since at least December 31, 1989, AstraZeneca has sold, distributed, or otherwise marketed PPIs such as Nexium and Losec in Canada in a variety of forms and concentrations.

42. Since at least December 31, 1995, Mylan has sold, distributed, or otherwise marketed PPIs such as Prevacid in Canada in a variety of forms and concentrations.

43. Since at least April 2, 2002, Janssen has sold, distributed, or otherwise marketed Pariet in Canada in a variety of forms and concentrations.

44. Since at least March 15, 2006, Takeda has sold, distributed, or otherwise marketed Dexilant, Pantoloc, Panto IV, and Tecta in Canada in a variety of forms and concentrations.

45. Since at least November 9, 2007, various members of the Rabeprazole Group have sold, distributed, or otherwise marketed Rabeprazole in a variety of forms and concentrations.

46. Astrazeneca, Mylan, Janssen, Takeda, and the Rabeprazole Group (the "**Defendants**") failed to adequately warn against the negative effects and risks associated with PPIs, even if used as directed, including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

47. During the period in which PPIs have been sold in the Canada and other countries, reports of injury have been submitted to the Government of Canada and other governmental health bodies in association with the ingestion of PPIs.

48. The Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, the Defendants have received numerous case reports of kidney injuries in patients that had ingested PPIs by as early as 2004.

49. These reports of numerous kidney injuries put the Defendants on notice as to the excessive risks of kidney injuries related to the use of PPIs.

50. The Defendants took no action to inform the public, including the Plaintiff or the Plaintiff's physicians, of this known risk. Instead, the Defendants continued to represent that the PPIs did not pose any risks of kidney injuries.

51. Since the introduction of PPIs to the market, several observational studies have linked PPI use to serious adverse health outcomes, including hip fracture, community acquired pneumonia, *Clostridium difficile* infection, acute interstitial nephritis, increased susceptibility to enteric bacterial infection, acute kidney injury, and the development of chronic kidney disease.

52. A study from 2015 shows that acute kidney injuries increased 250% in elderly patients who were newly prescribed PPIs. The acute kidney injuries occurred within 120 days of the patients starting the PPIs: Antoniou, T. et al., (2015). Proton pump inhibitors and the risk of acute kidney injury in older patients:a population-based cohort study. *CMAJ Open*. DOI:10.9778/cmajo.20140074.

53. These and other recent studies have shown the long term use of PPIs was independently associated with a 20% to 50% higher risk of incident chronic kidney disease, even after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications.

54. In addition, a study has linked the acute kidney injuries caused by PPIs to a later increased risk of chronic kidney disease: Lazarus, B. et al. (2016). Proton pump inhibitor use and the risk of chronic kidney disease. *Journal of the American Medical Association*, 176(2): 238-246. The study noted that as PPI induced acute kidney disease is often subtle and slowly diagnosed. The delay in diagnosis causes damage to the kidney to be increased and the patient has a higher risk of later developing chronic kidney disease.

55. Worse yet, the use of PPIs has been linked with an overall increased risk of death: Xie, Y. et al. (2017). Risk of death among users of Proton Pump Inhibitors: a longitudinal observational cohort study of United States veterans. *BMJ Open* 2017;7, doi:10.1136/bmjopen-2016-015735.

56. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body.

57. In the early stages, patients may have few signs or symptoms. Chronic kidney disease may not become apparent until kidney function is significantly impaired.

58. Treatment for chronic kidney disease focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. Chronic kidney disease can progress to end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often key to avoiding the most negative outcomes.

59. Chronic kidney disease is associated with a substantially increased risk of death and cardiovascular events.

60. Screening of at-risk people is important because treatments exist that delay the progression of chronic kidney disease; however, the Defendants did not adequately warn the public or their physicians of the importance of and need for such monitoring.

61. Alternatives to PPIs are and were available that provide the same benefits but act through a different mechanism.

62. One alternative is H2 antagonists, also called H2 blockers, a class of medications that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach.

63. The higher risks of chronic kidney disease are specific to PPI medications. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with chronic kidney disease.

Plaintiff's use of PPI's

64. The Plaintiff was prescribed Nexium, Prevacid, Tecta, Pariet, and Rabeprazole on numerous occasions beginning in 2012.

65. The Plaintiff read and followed the directions regarding the use of these drugs and would have explored alternatives to these drugs had she been properly appraised of the risks associated with the use of the same.

66. The Plaintiff suffers from kidney infections of greater severity and duration since ingesting Nexium, Prevacid, Tecta, Pariet, and Rabeprazole requiring extensive medical treatment and the use of significant amounts of decreasingly effective antibiotics to address issues arising from these infections.

Causes of Action

67. The Plaintiff incorporates by this reference the assertions set forth in the paragraphs above as if fully set forth under each of the causes of action pled below.

Violation of statutory obligations

68. The Plaintiff pleads and relies upon competition, consumer protection, and trade legislation and common law as it exists in this jurisdiction, and the equivalent/similar legislation and common law in all Canadian provinces and territories.

69. The misrepresentations by the Defendants as to the risks associated with the use of PPIs constitute unlawful, unfair and deceptive trade practices and the Defendants are in violation of sections 74.01 and 74.02 of the *Competition Act*, R.S.C. 1985, c.C-34.

70. The Defendants engaged in the unfair trade practices set forth above and specifically declared unlawful under section 9 of the *Food and Drugs Act*, R.S.C. 1985, c. F-27. Such practices included making false or misleading representations, knowingly or with reason to know, as to the characteristics of PPIs.

71. The PPIs were not of acceptable quality and were not fit for the sole and only purpose for which they were offered for sale in Canada, which constitutes a violation of s. 16 of *The Sale of Goods Act*, R.S.S. 1978, c. S-1 and other equivalent provincial legislation elsewhere. Pursuant to section 52 of that *The Sale of Goods Act*, the Plaintiff and Class Members are entitled to recover the amounts they paid for PPIs in addition to recovering compensation for other damages.

Strict liability

72. The Defendants are strictly liable for a product intended to be ingested by Class Members and could not be tested by them prior to use. They were engaged in the business of researching, creating, designing, testing, manufacturing, labeling, packaging, supplying, marketing, selling, advertising, and distributing PPIs in Canada, when they knew or ought to have known about the serious risks.

73. The PPIs manufactured and/or supplied by the Defendants were unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the severity or duration of the adverse side effects or the true potential or likelihood or rate of the side effects. The Defendants failed to perform adequate testing in that adequate testing would have shown that PPIs possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

74. The PPI's manufactured and/or distributed and/or supplied by the Defendants were defective due to inadequate post-marketing warning or instruction because the Defendants failed to provide adequate warnings to users or consumers of PPIs and continued to aggressively promote PPIs.

75. As the proximate cause and legal result of the defective condition of PPIs as manufactured and/or supplied and/or distributed by the Defendants, and as a direct and legal result of the conduct of the Defendants described herein, Plaintiff has been damaged.

76. The PPIs manufactured and/or distributed and/or supplied by the Defendants were defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design and formulation of the drug.

77. Alternatively, the PPIs manufactured and/or distributed and/or supplied by the Defendants were defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of Plaintiff's condition.

78. There existed, at all times material hereto, safer alternative medications.

79. The Defendants did not perform adequate testing upon PPIs. Adequate testing would have revealed that PPIs cause serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

80. The PPIs manufactured, designed, marketed, distributed and/or sold by the Defendants were unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of PPIs, and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

81. The Defendants did not warn the Government of Canada and relevant health bodies of material facts regarding the safety and efficacy of PPIs, which facts the Defendants knew or should have known.

82. The PPIs manufactured and/or distributed and/or supplied by the Defendants were defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risk of injury from PPIs, the Defendants failed to provide adequate warnings to users or consumers of PPIs and continued to promote PPIs.

83. As a result of the defective condition of PPIs, the Plaintiff has suffered damage and injury.

Negligence

84. In light of the above-mentioned evidence, the Defendants knew or ought to have known that the PPIs increased the risk of serious complications, including acute and chronic kidney injuries.

85. The Defendants failed to adequately inform Class Members or their physicians of the increased risk of serious complications associated with the use of PPIs.

86. The Defendants owed a duty of care to the Plaintiff and Class Members to:

(a) take reasonable care in formulating PPIs and testing for the adverse health effects of PPIs;

(b) ensure PPIs were safe for human ingestion and offer only safe drugs for sale and human consumption in the streams of commerce;

(c) provide adequate warnings regarding the side effects of PPIs;

(d) conduct ongoing testing and analyses to learn of any new health risks posed by PPIs and to inform the public and proper governmental authorities of the results; and,

(e) recall PPIs promptly after becoming aware of adverse health risks.

87. In discharging their duties of care, the Defendants breached the standards of care expected of them.

88. The Defendants were negligent in:

(a) Failing to use care in designing, developing and manufacturing PPIs so as to avoid complications to users of the drugs, including acute and chronic kidney injuries;

(b) Failing to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine and provide continued assurance of the safety of PPIs;

(c) Failing to adequately and sufficiently advise the medical and scientific communities that the use of PPI's could increase the risk of serious side effects, including acute and chronic kidney injuries;

(d) Failing to provide Class Members or their physicians with adequate and timely warnings and/or indications of the aforementioned risks;

(e) Failing to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the risks associated with the use of PPIs;

(f) Failing, after receiving actual or constructive notice of problems concerning PPIs, including evidence of concern with PPIs generally, to issue adequate warnings, to publicize the problem and otherwise act properly and in a timely manner to alert the public, the Class Members and their physicians, of the inherent dangers to the use of PPIs;

(g) Failing to monitor and to initiate a timely and adequate review, evaluation and investigation of reports of complications associated with PPIs in Canada and around the world;

(h) Failing to accurately and promptly disclose to Health Canada information relating to complications associated with PPIs, and to modify product labelling accordingly in a timely manner;

(i) Failure to remove the PPIs from the market when the Defendants knew or ought to have known that the these products were unreasonably dangerous;

(j) Falsely stating or implying that PPIs were safe when they knew or ought to have known that this representation was false; and,

(k) Demonstrating a callous and reckless disregard for the health and safety of their consumers;

89. The Defendants failed to use sufficient quality control, to conduct adequate testing, and to perform proper manufacturing, production, or processing, or failed to take sufficient measures to prevent harmful products such as the PPIs from being offered for sale, sold, or used by consumers.

90. The Defendants failed to adequately and promptly warn consumers about the adverse side effects of PPIs.

91. The Defendants negligently and carelessly represented that PPIs were safe for use by the public, including the Plaintiff and Class Members, when in fact, the Defendants knew or ought to have known that it was unsafe.

92. As a result of breach of the standard of care imposed upon them, the Defendants deprived the Plaintiff and the Class Members of the right to know what risks were involved in the use of PPIs and their right to make meaningful decisions as to which of a number of alternative forms of drugs available to them, based on a full understanding of those risks.

Breach of warranty

93. The Defendants expressly warranted to the public, including the Plaintiff and Class Members, by and through statements made by the Defendants or their authorized agents or sales representatives, orally or in publications, package inserts, product monographs or other written materials to the medical community or the public as they marketed and did business in Canada, that PPIs were safe, effective, and fit and proper for its intended use.

94. In using PPIs, the Plaintiff and Class Members 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 or was unfit for the purposes for which it was intended.

95. As a direct and proximate result of the Defendants' breaches of warranties, the Plaintiff and Class Members suffered special, general, and aggravated damages.

96. Prior to the time when PPIs were used by Class Members, the Defendants impliedly warranted to the market, including the Class Members, that PPIs were of merchantable quality and safe, and fit for the purposes for which it was intended.

97. The Defendants are the manufacturers and sellers of PPIs and Class Members are buyers within the meaning of statutes such as *The Sale of Goods Act*, R.S.S. 1978, c. S-1 and *The Consumer Protection and Business Practices Act*, S.S. 2013, c. C-30.2 and all provincial and federal equivalents. The Defendants are deemed to have given and breached the statutory warranty that PPIs, having been sold by description, corresponded with that description and was of acceptable quality. As a result of a breach of the statutory and common law warranties, Class Members are entitled to all the remedies contained in the statutes of *The Sale of Goods Act*, R.S.S. 1978, c. S-1 and *The*

Consumer Protection and Business Practices Act, S.S. 2013, c. C-30.2 , and all provincial and federal equivalents, and the common law.

98. The Defendants manufactured, marketed, and distributed PPIs that they knew to be defective, while misrepresenting the safety to the public to induce prescription and sale, constituting unlawful business practice contrary to s. 21 of the *Consumer Protection and Business Practices Act*, S.S. 2013, c. c-30.2 and similar provincial legislation.

Negligent misrepresentation

99. The Defendants are the manufacturers, designers, distributors, sellers or suppliers of PPIs and, while engaged in the course of such business, made representations to the public, including the Plaintiff their physicians, and Class Members, regarding the character and quality of PPIs.

100. The Defendants' representations regarding the character or quality of PPIs were untrue.

101. The Defendants had knowledge based upon research, studies, published reports, and clinical experience that PPIs created an unreasonable increased risk of serious bodily injury, or should have known such information.

102. The Defendants negligently and intentionally misrepresented or omitted information in their product labeling, promotions, and advertisements and instead labeled, promoted, and advertised their product as safe and effective in order to avoid losses and sustain profits.

103. In supplying such false information, the Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including the Plaintiff, Class Members, and their physicians.

104. The Plaintiff, Class Members, and their physicians reasonably relied, to their detriment, upon the Defendants' misrepresentations and omissions in their labeling, advertisements, and promotions concerning the serious risks posed by its products. The Plaintiff and Class Members reasonably relied upon the Defendants' representations that PPIs were safe and effective.

105. As a direct and proximate result of the Defendants' negligent and intentional misrepresentations or omissions, the Plaintiff and Class Members suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

Violations of Consumer Protection Legislation

106. *The Consumer Protection Act*, S.S. 1996, c. C-30.1, as am., including s. 14 and Part III; the *Fair Trading Act*, R.S.A. 2000, c. F-2, as am. including s. 13; *The Business Practices Act*, S.M. 1990-91, c. 6; *Consumer Protection Act*, 2002, S.O. 2002, c. 30, Sched. A, as am., including s. 8; the *Trade Practices Act*, R.S.N.L. 1990, c. T-71, as am., including s. 14; and other similar legislation throughout Canada, apply to the Defendants' actions and conduct, as described herein, because it extends to transactions that are intended to result, or which have resulted in the sale or lease of goods or services to consumers.

107. At all times relevant, the Defendants manufactured, marketed, and distributed PPIs that they knew or ought to have known were defective and unfit for their stated purpose, in an unlawful, unfair, and deceptive manner that was likely to deceive the Plaintiff and members of the Class.

108. The Defendants' marketing of PPIs that they knew to be defective, while misrepresenting the safety of the drugs to the public, constitutes unlawful, unfair and deceptive business acts, or practices within the meaning of the aforementioned legislation.

109. As a result of these violations, the Defendants caused the Plaintiff and the class to purchase and ingest PPIs which are subject to either the same or other dangerous defects.

110. As a result of the foregoing, the Plaintiff and the Class have suffered economic damages, personal injuries, and endangerment, and are entitled to damages in an amount to be proven at trial.

Waiver of tort

111. In the alternative to recovery under consumer protection, competition, and sale of goods statutes, the Plaintiff and Class Members are entitled to elect to "waive the tort" and require the Defendants to repay to Class Members all of the revenue they received from the sale of PPIs.

112. The Defendants tortiously introduced or kept PPIs in the Canadian marketplace.

113. The Defendants withheld the information they had regarding health risks from consumers, healthcare providers, and regulators.

114. As a result of the Defendants' breach of duty, they have generated a substantial amount of revenue that they should not in good conscience retain.

115. If the Defendants had complied with the standard of care expected of them, they would not have sold PPIs to Class Members, nor received any of the revenues they received therefrom.

Punitive Damages

116. At all material times, the acts and omissions of the Defendants are as set forth above and they:

(a) were oppressive towards their customers and the public and the Defendants conducted themselves in a wilful, wanton, and reckless manner;

(b) demonstrated a cavalier and arbitrary approach with respect to their obligations to Class Members; and

(c) pursued conduct which constitutes unfair business practices and dealings with their customers and the public as defined by sections 6 and 7 of *The Consumer Protection and Business Practices Act*, S.S. 2013, c. C-30.2 and similar legislation elsewhere.

117. The Defendants continued to manufacture, market, and promote PPIs in Canada, and without providing sufficient warning of the risks, despite knowledge of research showing the adverse side effects.

118. The Defendants have made no attempt to compensate Class Members for the injuries they suffered as a result of using PPIs. The Defendants have made no suggestion that an attempt will be made to compensate those who assert a causal link between PPIs and the injuries suffered.

119. In these circumstances punitive or exemplary damages and aggravated damages should be awarded.

Subrogated Medical Claims

120. The Plaintiff relies upon health and hospital insurance legislation in Saskatchewan and similar legislation elsewhere and claims health care costs incurred by herself and Class Members and paid by provincial and territorial governments:

(a) On behalf of Her Majesty the Queen in right of the Province of New Brunswick, the Plaintiffs claim the cost of "entitled services".[1]

(b) On behalf of the government of British Columbia, the Plaintiffs claim the past and future cost of providing "health care services".[2]

(c) On behalf of Her Majesty in right of Alberta and the Minister of Health of Saskatchewan, the Plaintiffs claim the direct and indirect costs of past and future "health services".[3]

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1 *Health Services Act*, SNB 2014, c 112, ss 1 and 3 and *General Regulation*, NB Reg 84-115, s 2 and Schedule II.

2 *Health Care Costs Recovery Act*, SBC 2008, c 27, ss 1-3 and 7 and *Health Care Costs Recovery Regulation*, BC Reg 397/2008, s 3.

3 *Crown's Right of Recovery Act*, SA 2009, c C-35, ss 1 and 38 and *Crown's Right of Recovery Regulation*, Alta Reg 87/2012, s 3; and *The Health Administration Act*, RSS 1978, c H-0.0001, s 19.

(d) On behalf of the Minister of Health of Manitoba, the Plaintiffs claim the past and future cost of "insured hospital, medical, and other services".[4]

(e) On behalf of Her Majesty in right of the Province of Nova Scotia, the Plaintiffs claim the past and future cost of "insured hospital services", and other care, services, and benefits.[5]

(f) On behalf of the Government of Yukon, and the Ministers of Health of the Northwest Territories and Nunavut, the Plaintiffs claim the cost of providing "insured services", including in-patient and out-patient services.[6]

(g) On behalf of the Ontario Health Insurance Plan, the province of Quebec, the Minister of Health and Wellness of Prince Edward Island, and the Crown in right of Newfoundland and Labrador, the Plaintiffs claim the cost of "insured services."[7]

Damages

121. The acts, omissions, wrong doings, and breaches of legal duties and obligations of the Defendants have caused or materially contributed to the Plaintiff and Class Members suffering injury, economic loss, and damages.

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4 *The Health Services Insurance Act*, RSM 1987, c H35, ss 2, 97 and *The Medical Services Insurance Regulation*, Man Reg 49/93, s 1.

5 *Health Services and Insurance Act*, RSNS 1989, c 197, ss 2 and 18.

6 *Hospital Insurance Services Act*, RSY 2002, c 112, ss 1 and 10-11 and *Yukon Hospital Insurance Services Regulations*, YCO 1960/35, s 2; *Hospital Insurance and Health and Social Services Administration Act*, RSNWT 1988, c T-3, ss 1 and 19-20 and *Hospital Insurance Regulations*, RRNWT 1990, c T-12, s 1; *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-3, ss 1 and 19-20 and *Hospital Insurance and Health and Social Services Administration Act*, RSNWT (Nu) 1988, c T-3, s 1.

7 *Health Insurance Act*, RSO 1990, c H.6, ss 1, 11.2, and 30-31 and General, RRO 1990, Reg 552; *Hospital Insurance Act*, CQLR c A-28, ss 1 and 10 and Regulation respecting the application of the *Hospital Insurance Act*, CQLR c A-28, r 1, s 3 and *Health Insurance Act*, CQLR A-29, ss 1, 3, and 18; *Hospital and Diagnostic Services Insurance Act*, RSPEI 1988, c H-8, ss 1 and 14 and *General Regulations*, PEI Reg EC539/63, s 1; and *Hospital Insurance Agreement Act*, RSNL 1990, c H-7, s 5 and *Hospital Insurance Regulations*, CNLR 742/96, s 2 and Schedule.

122. Categories of injuries that occurred as a result of the Defendants actions and omission include:

(a) personal injury including, but not limited to, hip fracture, community acquired pneumonia, *Clostridium difficile* infection, acute interstitial nephritis, increased susceptibility to enteric bacterial infection, acute kidney injury, and the development of chronic kidney disease;

(b) direct or indirect economic losses including, but not limited to out of pocket expenses for treatment, cost of future care, and loss of employment income; and

(c) other pain, suffering, or loss, stemming from illness of a Class Member as a result of the use of PPIs.

123. The same law applies to all Class Members. Alternatively, on behalf of the Class, the Plaintiff pleads:

(a) *Survival of Actions Act, R.S.A. 2000, c. S-27, ss. 2, 5(1), 5(2); The* Survival of Actions Act, S.S. 1990, c. S-66.1, ss. 3 and 6(1)-(3); *Survival of Actions Act*, R.S.N.S.1989, c. 453, ss. 2(1)-(2) and 5; *Survival of Actions Act*, R.S.N.B. 2011, c. 227, ss. 3(1)-(2) and 6(1)-(2); *Survival of Actions Act*, R.S.P.E.I. 1988, c. S-11, ss. 2 and 5; *Survival of Actions Act*, R.S.N.L. 1990, c. S-32, ss. 2 and 4.

(b) *Fatal Accidents Act*, RSY 2002, c 86, ss 2-3; *Family Compensation Act*, RSBC 1996, c 126, ss 2 and 3(8)-(9); *Fatal Accidents Act*, RSNWT 1988, c F-3, ss 2-3; *Fatal Accidents Act*, RSA 2000, c F-8, ss 1, 2, and 3(1); *The Fatal Accidents Act*, RSS 1978, c F-11, ss 2, 3(1), and 4(1)-(3); *Fatal Accidents Act*, SNu 2010, c 14, s 6, ss 2-3; *The Fatal Accidents Act*, CCSM c F50, ss 2-3; *Family Law Act*, RSO 1990, c F 3, ss 61(1)-(2); *Fatal Accidents Act*, RSNL 1990, c F-6, ss 2-4; *Fatal Accidents Act*, SNB 2012, c 104, ss 3, 4, and 7; *Fatal Injuries Act*, RSNS 1989, c 163, ss 2-3 and 5; and *Fatal Accidents Act*, RSPEI 1988, c F-5, ss 1-2 and 6.

III. RELIEF SOUGHT

124. The Plaintiff claims, on behalf of each of the following subclasses, against each anmed defendant group, jointly and severally:

Subclass(es)	Defendant Group
Nexium®, Losec®	AstroZeneca
Prevacid®	Mylan
Pariet®	Jansen
Rabeprazole	Rabeprazole Group

on behalf of herself and Class Members:

(a) general damages, special damages, compensatory and aggravated damages for personal injury, costs, and economic loss;

(b) accounting, disgorgement, or restitution of revenue the Defendants earned from selling PPIs, including as a aggregate monetary award;

(c) exemplary, aggravated, and punitive damages;

(d) pre-judgment and post-judgment interest; and

(e) other relief as this Honourable Court may allow.

DATED at Regina, Saskatchewan, this 10th day of July, 2017.

MERCHANT LAW GROUP LLP

CONTACT INFORMATION AND ADDRESS FOR SERVICE

Name of firm:	Merchant Law Group LLP
Name of lawyers in charge of file:	E. F. Anthony Merchant, Q.C.
Address of legal firms:	2401 Saskatchewan Drive Regina, Saskatchewan S4P 4H8
Telephone number:	306-359-7777
Fax number:	306-522-3299