Court File No.: CV-17-578782 0000

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

DOUGLAS CARTER AND CALVIN JESSOME

Plaintiffs

-and-

ASTRAZENCA CANADA INC., BGP PHARMA ULC, MYLAN PHARMACEUTICALS ULC, and TAKEDA PHARMACEUTICALS AMERICA INC.

Defendants

Proceeding under the *Class Proceedings Act*, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario. If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date: July 12th, 2017

Issued by: Dale Steiner
Local Registrar
393 University Avenue, 10th Floor
Toronto, Ontario M5G 1E6

TO: **ASTRAZENCA CANADA INC.**

1004 Middlegate Road

Mississauga, Ontario

Canada L4Y 1M4

AND TO: **BGP PHARMA ULC**

1950 Upper Water Street, Suite 900

Halifax, Nova Scotia

Canada B3J 2X2

AND TO: **MYLAN PHARMACEUTICALS ULC**

Osler, Hoskin & Harcourt LLP

450 1st Street SW Suite 2500

Calgary, Alberta T2P5H1

AND TO: **TAKEDA PHARMACEUTICALS AMERICA INC.**

1 Takeda Parkway, Deer Field

Illinois, United States, 63015

The Corporation Trust Company (Registered agent)

Corporation Trust Center

1209 Orange Street

Wilmington, Delaware, 19801

A. Relief Claimed

1. The Plaintiff's claims against the Defendants for:

a) an order pursuant to the *Class Proceedings Act*, 1992, So. 1992, c.6, certifying this action as a class proceeding and appointing them as the representative plaintiff's for the Class;

b) a declaration that the defendants were negligent and are liable in damages;

c) general damages, special damages, compensatory, and aggravated damages in the sum of $500 million for personal injury, costs, and economic loss;

d) prejudgment and postjudgment interest, compounded, or pursuant to ss. 128 and 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

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

f) punitive or exemplary damages in the sum of $500 million or some other sum this Court finds just;

g) costs of this action on a substantial indemnity basis or in an amount that provides full indemnity plus, the costs of distribution of an award under ss.24 or 25 of the *Class Proceedings Act*, including costs of notice associated with distribution and fees payable to a person administering the distribution pursuant to s.26 of the *Class Proceedings Act*; and

h) such further and other relief as to this Honourable Court seems just.

B. Nature of the Action

1. "PPIs" are proton pump inhibitors, including Nexium®, Prevacid®, and Losec®. From

(a) December 31st, 1989, as a global partnership, AstraZenca Canada Inc. manufactured and marketed **"Losec®"** (Omeprazole) in Canada,

(b) December 31, 1995, as a global partnership, Mylan Pharmaceuticals ULC manufactured and marketed **"Prevacid®"** (Lansoprazole) in Canada, and

(c) August 20th, 2001, as a global partnership, AstraZenca Canada Inc. manufactured and marketed **"Nexium®"** (Esomeprazole) in Canada,

2. Proton pump inhibitors (PPIs) are used to reduce stomach acid and are prescribed to treat conditions such as acid reflux (heartburn) and stomach ulcers.

3. PPIs increase the risk of 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;

C. Parties

plaintiffs

4. Calvin Jessome resides in St. Catherine's, Ontario.

5. In or around 2004, Mr. Jessome was prescribed Losec. Because of Losec, Mr. Jessome developed kidney failure. Mr. Jessome also developed bladder cancer and underwent surgery to have his bladder removed in 2011.

6. Douglas Carter resides in Flesherton, Ontario.

7. In or around 2013, Mr. Carter was prescribed Prevacid and Nexium. Because of Prevacid and Nexium, Mr. Carter developed kidney cancer. On May 31st, 2016, Mr. Carter underwent surgery to remove his right kidney.

defendants

8. AstraZeneca Canada Inc. ("AstraZeneca") is a corporation established pursuant to the laws of Ontario.

9. 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, regarding Nexium and Losec, as defined in this claim, in Canada.

10. 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.

11. 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, of 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.

12. Takeda Pharmaceuticals America Inc., is a corporate entity established pursuant to the laws of Delaware.

13. BGP Pharma ULC, which operates under the business name Mylan ERD, is an unlimited liability corporation established pursuant to the laws of Nova Scotia and is a subsidiary of Mylan Pharmaceuticals ULC.

14. Mylan Pharmaceuticals ULC is an unlimited liability corporation established pursuant to the laws of Alberta.

15. 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".

16. 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.

17. 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.

18. 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.

D. Duty of Care

19. PPIs can cause, contribute to, or materially increase the risk of 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;

20. Before and after the Defendants manufactured and marketed PPIs in Canada, they knew or ought to have known that PPIs can cause, contribute to, or materially increase the risk of risk of 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.

21. Publicly available scientific literature of which the Defendants had a duty to be aware, indicated that PPIs had a common biological mechanism of action that could cause 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.

22. 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.

23. The Defendants took no action to inform the public, including the Plaintiff's 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.

24. From 2015, published epidemiological studies in reputable medical and scientific journals reported acute kidney injuries increased substantially in elderly patients that were newly prescribed PPIs. The study revealed that acute kidney injuries occurred within about 120 days of the patients starting the PPIs and that there was an increase in the risk of acute kidney injury in older patients who were treated with PPIs.

25. These and other recent studies have shown that the long term use of PPIs was independently associated with a significantly 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.

26. In another study, PPIs were linked to acute kidney injuries to increased risk of chronic kidney disease. 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.

27. PPIs use has also been linked with an overall increased risk of death

28. The Defendants owed class members duties of care.

(a) The Defendants owed class members a duty of care to inform prescribing physician that PPIs can cause 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) The Defendants are strictly liable, or alternatively owed a duty of care, to class members for their 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;

E. Breach

29. The Defendants breached duties of care.

(a) The Defendants ought to have, but failed to include a warning in their product monographs that PPIs can cause 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; and

(b) The Defendants ought to have,but failed to adequately warn against the negative effects and risks associated with PPIs including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

30. Mr. Carter's physician prescribed, and he ingested Prevacid® in 2013 and Nexium® in 2013. Because of Prevacid® and Nexium®, Mr. Carter developed kidney cancer.

31. Mr. Jessome's physician prescribed, and he ingested Losec® in 2004. Because of Losec®, Mr. Jessome developed kidney failure.

F. Causation

32. As a result of AstraZenca's breach of its duties of care, Mr. Carter's physicians prescribed Prevacid and Nexium to treat heartburn and Mr. Carter took Preavaid and Nexium and developed kidney cancer.

33. As a result of the Mylan's breach of its duties of care, Mr. Jessome's physicians prescribed Mylan to treat heartburn and Mr. Jessome took Losec and developed kidney.

34. The Defendants' breaches of their duties of care were a factual and legally proximate cause of Mr. Carter's and Mr. Jessome's kidney issues and the legally compensable loss and expense consequent thereon.

G. Damages

35. Kidney failure and kidney cancer are lifelong conditions, and the associated costs are a lifetime burden.

36. 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.

37. 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.

38. As a result of injuries suffered by class members, provincial and territorial governments incurred and paid Education Costs and Health Care Costs.

(A) The Plaintiffs claim "Health Care Costs" incurred by class members and paid by provincial and territorial governments.

(i) On behalf of Her Majesty the Queen in right of the Province of New

Brunswick, the Plaintiffs claim the cost of "entitled services".[1]

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

(iii) 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]

(iv) 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]

(v) 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]

(vi) On behalf of the Government of Yukon, and the Ministers of Health of the Northwest Territories and Nunavut, the Plaintiffs claim the cost of

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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.

[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.

providing "insured services", including in-patient and out-patient services.[6]

(vii) 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".

H. Violations of Consumer Protection Legislation

39. *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.

40. 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.

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[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.

41. 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.

42. 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.

43. 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.

I. Waiver of Tort

44. 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.

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

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

47. 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.

48. 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.

J. Punitive Damages

49. 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.

50. 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.

51. 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.

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

K. Statutes

56. The Plaintiffs plead and rely upon the following statues and the regulations made thereunder:

(a) *Class Proceedings Act*, 1992, S.O. 1992, c.6;

(b) *Courts of Justice Act*, R.S.O. 1990, c.43;

(c) *Family Law Act*, R.S.O. 1990, c. F.3; and

(d) *Negligence Act*, R.S.O. 1990, c. N.1.

L. Real and Substantial Connection to Ontario

57. This action has a real and substantial connection between the subject matter of this action and Ontario for the following reasons, inter alia:

(a) all of the Defendants carry on business in Ontario;

(b) the head office of AstraZenca is in Mississauga, Ontario;

(c) the Defendants distribute and sell their products, including the PPIs discussed herein, in Ontario and derive substantial revenue from such business;

(d) the damages of the Plaintiffs and other Class Members resident in Ontario

were sustained in Ontario; and,

(e) the Defendants marketed and sold their products, including the PPIs discussed herein, in Ontario.

M. Service Outside Ontario

58. The originating process may be served outside Ontario without court order because the claim is in respect of a tort committed in Ontario, damages sustained in Ontario arising from a tort or breach of contract however committed, against a person carrying on business in Ontario, and against a person outside Ontario who is a necessary and proper party to this proceeding being brought against another person served in Ontario.

59. The Plaintiff proposes that this action be tried at Toronto, Ontario.

Dated at Toronto, Ontario, this 12th day of July, 2017.

July 12 . 2017

MERCHANT LAW GROUP LLP
120 Adelaide Street W, Suite 1201
Toronto, Ontario
M5H 1T1
Venessa Vuia (LSUC #69499L)
Tel: (416) 828-7777
Fax: (647) 478-1967
Email: vvuia@merchantlaw.com
Counsel for the Plaintiffs

Court File No.

DOUGLAS CARTER AND CALVIN JESSOME PLAINTIFFS	**ASTRAZENCA CANADA INC., BGP PHARMA ULC, MYLAN PHARMACEUTICALS ULC, and TAKEDA PHARMACEYTICALS AMERICA INC.** DEFENDANTS

ONTARIO SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED AT *TORONTO*

STATEMENT OF CLAIM

Merchant Law Group LLP

120 Adelaide Street West Suite 1201

Toronto, ON, M5H 1T1

Venessa Vuia
Tel: (416) 828-7777
Fax: (647) 478-1967
LSUC # : 69499L
vvuia@merchantlaw.com

Lawyers for the Plaintiffs