CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO 500-06-000871-174

SUPERIOR COURT
(Class Action)

LILY SURETTE residing and domiciled at [redacted] in the city of Montreal-Nord, Province of Quebec [redacted]

and

MICHEL GENOIS residing and domiciled at [redacted], in the city of Quebec, Province of Quebec [redacted]

Applicants

-vs.-

ASTRAZENECA CANADA INC, a legal person duly constituted, having its head office at 1004 Middlegate Road, Suite 5000, Mississauga, Ontario, L4Y 1M4

and

TAKEDA PHARMACEUTICALS AMERICA INC., a legal person duly constituted, having its head office at 1 Takeda Parkway, Deer Field, Illinois, United States, 63015

and

BGP PHARMA ULC, a legal person duly constituted, having its head office at 1950 Upper Water Street, Suite 900, Halifax, Nova Scotia, B3J 2X2

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT A REPRESENTATIVE PLAINTIFF
(Art. 574 C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, THE APPLICANT STATES AS FOLLOWS:

I. GENERAL PRESENTATION

1. Applicant wishes to institute a class action on behalf of the following group, of which she is a member, namely "all persons residing in Quebec who ingested Prevacid, Nexium, Prilosec or Losec, and their successors and assigns" (the "**Class**" or the "**Group**");

The 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, as indicated in the Ontario corporate profile report produced herein as **Exhibit P-1**;

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, Priolsec, and Losec in Canada;

4. The development of Nexium, Priolsec, 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, Priolsec and Losec and other actions central to the allegations of this lawsuit, were undertaken by AstraZeneca in Canada and elsewhere;

5. AstraZeneca does business throughout Canada, including within the province of Quebec, as shown in the report from the *Registraire des enterprises*, produced herein as **Exhibit P-2**;

Takeda Pharmaceuticals America Inc. and BGP Pharma 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, as shown on the corporate profile report produced herein as **Exhibit P-3**;

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, as shown in the Nova Scotia corporate profile report produced herein as **Exhibit P-4;**

8. Mylan does business throughout Canada, including within the province of Quebec, as shown in the report from the *Registraire des enterprises*, produced herein as **Exhibit P-5**;

9. The business operations of Takeda Pharmaceuticals America Inc. and Mylan ERD are inextricably linked in a manner known only to the Defendants; however, based on the product monographs, Mylan ERD operates, at a minimum, as the Canadian distributor of Prevacid on behalf of Takeda Pharmaceuticals America Inc. For the purposes of this application, Takeda Pharmaceuticals America Inc. and Mylan ERD 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;

General Facts

12. Prevacid, Nexium, Priolsec and Losec (collectively, the "**Antacids"**) are pharmaceutical proton pump inhibitors ("**PPIs**") used to reduce stomach acid and to treat common conditions such as acid reflux (heartburn) and stomach ulcers;

13. PPIs operate by precluding or reducing the secretion of stomach acid which may otherwise cause discomfort, pain, and injury.

14. A more fulsome discussion of the technical and medical operation of PPIs generally can be found in Shin, J.M. and Sachs, G. (2008). Pharmacology of proton pump inhibitors. *Curr Gastroenterol* Rep, 10(6): 528-534, produced herein as **Exhibit P-6;**

15. Since at least December 31, 1989, AstraZeneca has sold, distributed, or otherwise marketed Nexium, Prilosec and Losec in Canada in a variety of forms and concentrations, as shown in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monorgraph
02230737	LOSEC 10 MG	1997-04-28	-	2016-11-10 (Exhibit P-7)
02190915	LOSEC 20 MG	1996-12-31	-	2016-11-10 (Exhibit P-7)
02119579	LOSEC CAPSULES 10MG	2000-10-03	2013-12-04	2013-04-05 (Exhibit P-8)
00846503	LOSEC CAPSULES 20MG	1989-12-31	-	2016-11-10 (Exhibit P-9)
02016788	LOSEC CAPSULES 40MG	2003-10-17	2010-06-30	2010-04-30 (Exhibit P-10)
02242461	LOSEC MUPS 10MG	2001-02-22	2009-12-02	2008-12-03 (Exhibit P-11)
02242462	LOSEC MUPS 20MG	2001-02-22	2009-12-01	2008-12-03 (Exhibit P-11)
02300524	NEXIUM 10MG	2008-01-02	-	2016-11-10 (Exhibit P-12)
02244521	NEXIUM 20MG	2001-08-20	-	2016-11-10 (Exhibit P-12)
02244522	NEXIUM 40MG	2001-08-20	-	2016-11-10 (Exhibit P-12)

16. Since at least December 31, 1995, Mylan has sold, distributed, or otherwise marketed Prevacid in Canada in a variety of forms and concentrations, as shown in the following table:

DIN	Description	Marketed	Cancelled	Latest Product Monorgraph
02165503	PREVACID 15MG	1995-12-31	-	2017-06-06 (Exhbiit P-13)
02165511	PREVACID 30MG	1995-12-31	-	2017-06-06 (Exhibit P-13)
02249464	PREVACID FASTAB 15MG	2006-11-24	-	2017-06-06 (Exhibit P-13)
02249472	PREVACID FASTAB 30MG	2005-12-01	-	2017-06-06 (Exhibit P-13)

17. Even if used as directed, AstraZeneca and Mylan failed to adequately warn against the negative effects and risks associated with the Antacids including, but not necessarily limited to, long term usage and the cumulative effects of long term usage;

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

19. The Defendants has 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;

20. 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 including the Antacids;

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

22. 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, acute kidney injury, and the development of chronic kidney disease;

23. A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that 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, produced herein as **Exhibit P-14**;

24. 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;

25. 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, produced herein as **Exhibit P-15**. 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;

26. 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, produced herein as **Exhibit P-16**;

27. 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;

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

29. 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;

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

31. 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;

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

33. 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;

34. 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;

Negligence

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

36. The Defendants failed to adequately inform Group Members or their physicians of the increased risk of serious complications associated with the use of Prevacid, Nexium, Prilosec or Losec;

37. The Defendants were negligent in:

a. Failing to use care in designing, developing and manufacturing Prevacid, Nexium, Prilosec or Losec 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 Prevacid, Nexium, Prilosec and Losec;

c. Failing to adequately and sufficiently advise the medical and scientific communities that the use of Prevacid, Nexium, Prilosec and Losec could increase the risk of serious side effects, including acute and chronic kidney injuries;;

d. Failing to provide Group 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 Prevacid, Nexium, Prilosec and Losec;

f. Failing, after receiving actual or constructive notice of problems concerning Prevacid, Nexium, Prilosec or Losec, 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 Group Members and their physicians, of the inherent dangers to the use of Prevacid, Nexium, Prilosec or Losec;

g. Failing to monitor and to initiate a timely and adequate review, evaluation and investigation of reports of complications associated with Prevacid, Nexium, Prilosec or Losec in Canada and around the world;

h. Failing to accurately and promptly disclose to Health Canada information relating to complications associated with Prevacid, Nexium, Prilosec, and Losec, and to modify product labelling accordingly in a timely manner;

i. Failure to remove the Prevacid, Nexium, Prilosec or Losec 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 Prevacid, Nexium, Prilosec and Losec 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;

38. As a direct and proximate result of the Defendants' negligence, the Applicants and other Group Members utilized Prevacid, Nexium, Prilosec or Losec which caused them to suffer injuries, incur medical bills, lost wages, pain and suffering;

II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE APPLICANTS

Lily Surette

39. For approximately the past 10 years, the Applicant, Lily Surette ("**Lily**") has utilized Prilosec;

40. Approximately two years ago, Lily began experiencing pain in her right kidney;

41. She has lost approximately 90% of the usage of her right kidney, and the damage has been deemed to be irrepairable;

42. Her treating physicians have attributed the loss of kidney function with her use of Prilosec;

43. Lily is now required to engage in dialysis treatments to compensate for the reduced kidney function;

44. It is possible that Lily will be required to engage in even more substantial dialysis treatments in the future;

45. At no time was Lily made aware of the risk of chronic and acute kidney failure associated with the use of Prilosec;

46. Had the Defendants properly disclosed the risks associated with the Antacids, Lily would have avoided these risks by not taking Prilosec or other PPIs, and using a different form of control;

47. As a result of the Defendants' conduct, Lily has suffered damages and will continue to suffer increasing damages including, but not limited to physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems, and the apportioned cost of the Prilosec;

48. Lily's damages are a direct and proximate result of her having taken Prilosec, AstroZeneca's negligence or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of Prilosec;

49. As a consequence of the foregoing, Lily is justified in claiming damages;

Michel Genois

50. For a period of approximately 20 years, the Applicant, Michel Genois ("Michel") utilized Prevacid;

51. Approximately two years ago, Michel's physician discontinued the Prevacid because of signs that his kidneys were failing;

52. Since Michel discontinued use of Prevacid, the excessive build up of protein that had been observed has been remediated;

53. Michel's treating physicians have attributed the loss of kidney function with his use of Prevacid;

54. At no time was Michel made aware of the risk of chronic and acute kidney failure associated with the use of Prevacid;

55. Had the Defendants properly disclosed the risks associated with the Antacids, Michel would have avoided these risks by not taking Prevacid or other PPIs, and using a different form of control;

56. As a result of the Defendants' conduct, Michel has suffered damages including, but not limited to physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems, and the apportioned cost of the Prevacid;

57. Michel's damages are a direct and proximate result of her having taken Prevacid, Mylan's negligence or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of Prevacid;

58. As a consequence of the foregoing, Michel is justified in claiming damages;

III. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE CLASS

59. Every Member of the Group has ingested Prevacid, Nexium, Prilosec, and Losec, or is the successor or assign of such a person;

60. Each member of the Group is justified in claiming one or more of the following

(a) Compensatory damages in an amount to be determined at trial for:

(i) personal injury or death;
(ii) pain and suffering;
(iii) loss of income and earning capacity;
(iv) loss of amenities and enjoyment of life;
(v) costs of future care and related expenses;

(b) Out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of Nexium, Prilosec and Losec side effect services;

(c) Loss of income and loss of future income;

(d) Refund of the purchase price of Prevacid, Nexium, Prilosec or Losec or alternatively, the incremental costs of the same as paid for by the group members or by the *Régie de l'assurance maladie du Québec*; and

(e) Punitive damages;

61. As a direct result of the Defendants' conduct, the users' family members and dependents have, had, or will suffer damages and loss including;

(a) Out-of-pocket expenses, including paying or providing nursing, housekeeping and other services;

(b) Loss of income and loss of future income; and

(c) Loss of support, guidance, care, consortium and companionship that they might reasonably have expected to receive if the injuries had not occurred;

62. All of these damages to the group members are a direct and proximate result of the use of Prevacid, Nexium, Prilosec or Losec and the Defendants' conduct, negligence and reckless failure to adequately disclose necessary information and the risks associated with the use of the same;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

A) The composition of the class renders the application of articles 91 or 143 C.C.P. difficult or impractical;

63. The Applicants are unaware of the specific number of persons in Quebec who have utilized Prevacid, Nexium, Prilosec or Losec; however, it is safe to estimate that thousands of Quebec residents have utilized one or more of these drugs;

64. Class members are numerous and are scattered across the entire province and country;

65. In addition, given the costs and risks inherent in an action before the courts, many people will hesitate to institute an individual action against the Defendants. Even if the class members themselves could afford such individual litigation, it would place an unjustifiable burden on the courts. Further, individual litigation of the factual and legal issues raised by the conduct of the Defendants would increase delay and expense to all parties and to the court system;

66. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory judgments on questions of fact and law that are similar or related to all members of the class;

67. These facts demonstrate that it would be impractical, if not impossible, to contact each and every member of the class to obtain mandates and to join them in one action;

68. In these circumstances, a class action is the only appropriate procedure for all of the members of the class to effectively pursue their respective rights and have access to justice;

B) <u>The questions of fact and law which are identical, similar, or related with respect to each of the class members with regard to the Defendants and that which the Applicant wishes to have adjudicated upon by this class action</u>

69. Individual questions, if any, pale by comparison to the numerous common questions that are significant to the outcome of the litigation;

70. The damages sustained by the class members flow, in each instance, from a common nucleus of operative facts, namely, Defendant's misconduct;

71. The recourses of the members raise identical, similar or related questions of fact or law, namely:

    a) Do Prevacid, Nexium, Prilosec or Losec cause, exacerbate or contribute to an increased risk of acute kidney failure or chronic kidney disease?

    b) Were the Defendants negligent or did they fail in their duty of safety or duty to inform imposed upon them as researchers, designers, developers,

manufacturers, testers, marketers, packagers, promoters, advertisers, distributers, labelers or sellers of Prevacid, Nexium, Prilosec or Losec?

c) Were Prevacid, Nexium, Prilosec or Losec researched, designed, developed, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labeled, and sold with defects that increase a patient's risk of harm including acute kidney failure or chornic kidney disease?

d) Did the Defendants fail to conduct, supervise or adequately monitor clinical trials for Prevacid, Nexium, Prilosec or Losec?

e) Did the Defendants fail to adequately and properly test Prevacid, Nexium, Prilosec or Losec before or after placing it on the market?

f) Did the Defendants know or should the Defendant have known about the risks associated with the use of Prevacid, Nexium, Prilosec or Losec?

g) Did the Defendants knowingly, recklessly or negligently breach a duty to warn class members or their physicians of the risks of harm from the use of Prevacid, Nexium, Prilosec or Losec?

h) Did the Defendants knowingly, recklessly or negligently misrepresent to class members or their physicians the risks of harm from the use of Prevacid, Nexium, Prilosec or Losec?

i) Did the Defendants adequately and sufficiently warn the members or their physicians of the class about the risks associated with the use of Prevacid, Nexium, Prilosec, or Losec?

j) Did the Defendants engage in false advertising when it represented, through advertisements, promotions and other representations, that Prevacid, Nexium, Prilosec or Losec were was safe or omitted to disclose material facts regarding the safety of the same?

k) Were the members of the class prejudiced by use of Prevacid, Nexium, Prilosec or Losec instead of other acid control mechanisms, which have similar benefits, but do not pose such an increased risk of harm?

l) In the event of an affirmative answer to any of the above questions, did the Defendants' conduct engage their solidary liability toward the members of the class?

m) If the responsibility of the Defendant(s) is (are) established, what is the nature and the extent of damages and other remedies to which the members of the class can claim from the Defendants?

n) Are members of the class entitled to bodily, moral, and material damages?

o) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by their use of Prevacid, Nexium, Prilosec or Losec?

p) Are the members of the class entitled to recover as damages an amount equal to the purchase price of Prevacid, Nexium, Prilosec, or Losec, or any part of the purchase price?

q) Are members of the class entitled to aggravated or punitive damages?

72. A single class action against both the AstraZeneca and Mylan defendants is justified in circumstances where the factual and legal issues to be determined relate to an entire class of drugs (PPIs) and as such it is anticipated that there will be significant commonality in the answers to those questions as between the two defendant groups;

73. The interests of justice favour that this motion be granted in accordance with its conclusions;

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

74. The action that the Applicants wish to institute on behalf of the members of the class is an action in damages, injunctive relief, and declaratory judgment;

75. The conclusions that the Applicants wish to introduce by way of a motion to institute proceedings are:

GRANT the class action of the Applicants and each of the members of the class;

DECLARE that the Defendants each failed to provide adequate warnings with regard to the dangerous side effects of Prevacid, Nexium, Prilosec or Losec;

RESERVE the right of each of the members of the class to claim future damages related to the use of Prevacid, Nexium, Prilosec or Losec;

DECLARE the Defendants solidarily liable for the damages suffered by the Applicant and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

A) <u>The Applicant requests that she be attributed the status of representative of the Class</u>

76. The Applicants are each members of the proposed class;

77. The Applicants are ready and available to manage and direct the present action in the interest of the members of the class that they wish to represent and are determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the class, as well as to dedicate the time necessary for the present action before the Courts of Quebec and the *Fonds d'aide aux recours collectifs*, as the case may be, and to collaborate with their attorneys;

78. The Applicants have the capacity and interest to fairly and adequately protect and represent the interest of the members of the class;

79. The Applicants have given the mandate to their attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

80. The Applicants have, with the assistance of their attorneys, is ready and available to dedicate the time necessary for this action and to collaborate with other members of the class and to keep them informed;

81. The Applicants have given instructions to their attorneys to put information about this class action on its website and to collect the coordinates of those class members that wish to be kept informed and participate in any resolution of the present matter, the whole as will be shown at the hearing;

82. The Applicants have in good faith and has instituted this action for the sole goal of having her rights, as well as the rights of other class members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Defendants' conduct;

83. The Applicants understands the nature of the action;

84. The Applicants' interests are not antagonistic to those of other members of the class;

B) The Applicants suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal for the following reasons:

85. A great number of the members of the class reside in the judicial district of Montreal and in the appeal district of Montreal;

86. The Applicants' attorneys practice their profession in the judicial district of Montreal;

87. The present motion is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the bringing of a class action in the form of a motion to institute proceedings in damages, injunctive relief, and declaratory relief;

ASCRIBE the Applicants the status of representative of the persons included in the class herein described as "all persons residing in Quebec who ingested Prevacid, Nexium, Prilosec or Losec, and their successors and assigns";

IDENTIFY the principle questions of fact and law to be treated collectively as the following:

a) Do Prevacid, Nexium, Prilosec or Losec cause, exacerbate or contribute to an increased risk of acute kidney failure or chronic kidney disease?

b) Were the Defendants negligent or did they fail in their duty of safety or duty to inform imposed upon them as researchers, designers, developers, manufacturers, testers, marketers, packagers, promoters, advertisers, distributers, labelers or sellers of Prevacid, Nexium, Prilosec or Losec?

c) Were Prevacid, Nexium, Prilosec or Losec researched, designed, developed, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labeled, and sold with defects that increase a patient's risk of harm including acute kidney failure or chornic kidney disease?

d) Did the Defendants fail to conduct, supervise or adequately monitor clinical trials for Prevacid, Nexium, Prilosec or Losec?

e) Did the Defendants fail to adequately and properly test Prevacid, Nexium, Prilosec or Losec before or after placing it on the market?

f) Did the Defendants know or should the Defendant have known about the risks associated with the use of Prevacid, Nexium, Prilosec or Losec?

g) Did the Defendants knowingly, recklessly or negligently breach a duty to warn class members or their physicians of the risks of harm from the use of Prevacid, Nexium, Prilosec or Losec?

h) Did the Defendants knowingly, recklessly or negligently misrepresent to class members or their physicians the risks of harm from the use of Prevacid, Nexium, Prilosec or Losec?

i) Did the Defendants adequately and sufficiently warn the members or their physicians of the class about the risks associated with the use of Prevacid, Nexium, Prilosec, or Losec?

j) Did the Defendants engage in false advertising when it represented, through advertisements, promotions and other representations, that Prevacid, Nexium, Prilosec or Losec were was safe or omitted to disclose material facts regarding the safety of the same?

k) Were the members of the class prejudiced by use of Prevacid, Nexium, Prilosec or Losec instead of other acid control mechanisms, which have similar benefits, but do not pose such an increased risk of harm?

l) In the event of an affirmative answer to any of the above questions, did the Defendants' conduct engage their solidary liability toward the members of the class?

m) If the responsibility of the Defendant(s) is (are) established, what is the nature and the extent of damages and other remedies to which the members of the class can claim from the Defendants?

n) Are members of the class entitled to bodily, moral, and material damages?

o) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by their use of Prevacid, Nexium, Prilosec or Losec?

p) Are the members of the class entitled to recover as damages an amount equal to the purchase price of Prevacid, Nexium, Prilosec, or Losec, or any part of the purchase price?

q) Are members of the class entitled to aggravated or punitive damages?

IDENTIFY the conclusions sought by the class action to be instituted as being the following:

GRANT the class action of the Applicants and each of the members of the class;

DECLARE that the Defendants each failed to provide adequate warnings with regard to the dangerous side effects of Prevacid, Nexium, Prilosec or Losec;

RESERVE the right of each of the members of the class to claim future damages related to the use of Prevacid, Nexium, Prilosec or Losec;

DECLARE the Defendants solidarily liable for the damages suffered by the Applicant and each of the members of the Class;

CONDEMN the Defendants to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

DECLARE that all members of the class that have not requested their exclusion, be bound by any judgment to be rendered on the class action to be instituted in the manner provided for by the law;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the members, date upon which the members of the class that have not exercised their means of exclusion will be bound by any judgment to be rendered herein;

ORDER the publication of a notice to the members of the Class in accordance with article 579 C.C.P. within sixty (60) days from the judgment to be rendered herein in LA PRESSE and the NATIONAL POST;

ORDER that said notice be available on the Defendants' websites, Facebook page(s), and Twitter accounts with a link stating "Notice to all present and past users of Prevacid, Nexium, Prilosec or Losec";

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

THE WHOLE with costs, including all publications fees.

Montreal, July 5th, 2017

Merchant Law Group LLP
Attorneys for the Applicant

SUMMONS

(Articles 145 and following C.C.P.)

Filing of a Judicial Application

Take notice that the Applicant has filed this Application to Authorize the Bringing of a Class Action and to Ascribe the Status of Representative in the office of the Superior Court of Quebec in the judicial district of Montreal.

Defendants' Answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1 Rue Notre-Dame Street Est, Montréal, Québec, H2Y 1B6, within 15 days of service of the Application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the Applicant's lawyer or, if the Applicant is not represented, to the Applicant.

Failure to Answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of Answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the cases required by the Code, cooperate with the Applicant in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Québec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Change of judicial district
You may ask the court to refer the originating Application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the Applicant.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

Transfer of Application to Small Claims Division
If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the Application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Calling to a case management conference
Within 20 days after the case protocol mentioned above is filed, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

Exhibits supporting the application
In support of the Application to Authorize the Bringing of a Class Action and to Ascribe the Status of Representative, the Applicant intends to use the following exhibits:

Exhibit P-1: Corporate Profile Report for AstraZeneca Canada Inc. (Ontario), as of July 5, 2017

Exhibit P-2: Corporate Profile Report for AstraZeneca Canada Inc. (Quebec), as of July 5th, 2017

Exhibit P-3: Corporate Profile Report for BGP Pharma ULC (Nova Scotia), as of July 5th, 2017

Exhibit P-4: Corporate Profile Report for BGP Pharma ULC (Quebec), as of July 5th, 2017

Exhibit P-5: Corporate Profile Report for Takeda Pharmaceuticals American, Inc. (Delaware), as of Juyl 5th, 2017;

Exhibit P-6: Article: Shin, J.M. and Sachs, G. (2008). Pharmacology of proton pump inhibitors. Curr Gastroenterol Rep, 10(6): 528-534

Exhibit P-7: Product Monograph (as at November 10, 2016) for Losec 10mg, 20mg (DIN #02230737, 02190915)

Exhbiit P-8: Product Monograph (as at April 5, 2013) for Losec Capsules 10mg (DIN #02119579)

Exhibit P-9: Product Monograph (as at November 10, 2016) for Losec 20mg (DIN #00846503)

Exhibit P-10: Product Monograph (as at April 30, 2010) for Losec Capsules 40mg (DIN #02016788)

Exhibit P-11: Product Monograph (as at December 3, 2008) for Losec MUPS 10mg, 20mg (DIN #02242461, 02242462)

Exhibit P-12: Product Monograph (as at November 10, 2016) for Nexium 10mg, 20mg, 40mg (DIN #02300524, 02244521, 02244522)

Exhibit P-13 :Product Monograph (as at June 6, 2017) for Prevacid (15mg, 30mg)

Exhibit P-14 :Article: 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

Exhibit P-15: Article: 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

Exhibit P-16: 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

These Exhibits are available upon request.

Notice of presentation of an application

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

Montreal, July 5, 2017

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Montréal (Québec) H2Y 1B7
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Fax : 514-842-6687
Notifications : rdupont@merchantlaw.com
Attorneys for the Applicant

NOTICE OF PRESENTATION

(Articles 146 and 574 al.2 C.P.C.)

TO: **ASTRAZENECA CANADA INC,**
1004 Middlegate Road, Suite 5000
Mississauga, Ontario
L4Y 1M4

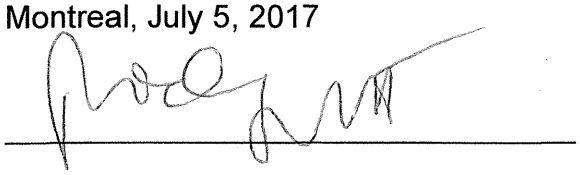
TO: **TAKEDA PHARMACEUTICALS AMERICA INC.**
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, Delaware, 19801

TO: **BGP PHARMA ULC**
1950 Upper Water Street, Suite 900
Halifax, Nova Scotia
B3J 2X2

TAKE NOTICE that the present FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT A REPRESENTATIVE PLAINTIFF will be presented before one of the Honourable Judges of the Superior Court of Québec, at the Montreal courthouse, located at 1, rue Notre-Dame Est, in the city and District of Montréal, on the date set by the coordinator of the class actions chamber.

PLEASE ACT ACCORDINGLY.

Montreal, July 5, 2017



Merchant Law Group LLP
Attorneys for the Applicant

Nº.: 500-06-000871-174

S U P E R I O R C O U R T
DISTRICT OF MONTREAL

LILY SURETTE
and
MICHEL GENOIS

Applicants

-vs-

ASTRAZENECA CANADA INC.
-and-
TAKEDA PHARMACEUTICALS AMERICAN, INC.
-and-
BGP PHARMA ULC

Defendants

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT A REPRESENTATIVE PLAINTIFF
(Art. 574 C.C.P. and following)

ORIGINAL

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