

CANADA  
PROVINCE OF QUEBEC  
DISTRICT OF MONTREAL  
NO: 500-06-000821-161

(Class Action)  
SUPERIOR COURT

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**P. MARTEL**

*Petitioner*

-vs.-

**MERCK CANADA INC.**, legal person duly constituted, having its head office at 16750 route Trans- Canada Highway, Kirkland, Quebec, H9H 4M7

and

**SCHERING-PLOUGH CANADA INC.**, legal person duly constituted, having its head office at 16750 route Trans- Canada Highway, Kirkland, Quebec, H9H 4M7

and

**DAIICHI SANKYO COMPANY, LTD.**, legal person duly constituted, having its head office at 3-5-1, Nihonbashi, Honcho, Chuo-ku, Tokyo, 103-8426, Japan

*Respondents*

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**MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION  
& TO APPOINT THE PETITIONER AS REPRESENTATIVE  
(Art. 574 C.C.P and following)**

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TO AN HONOURABLE JUSTICE OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER STATES AS FOLLOWS:

**I. GENERAL PRESENTATION**

A) The Action

1. Petitioner wishes to institute a class action on behalf of the following group, of which he is a member, namely:

- all persons residing in Canada who were prescribed and have ingested the drug(s) OLMETEC® (Olmesartan Medoxomil) and/or OLMETEC PLUS® (Olmesartan Medoxomil and Hydrochlorothiazide) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternately (or as a subclass)

- all persons residing in Quebec who were prescribed and have ingested the drug(s) OLMETEC® (Olmesartan Medoxomil) and/or OLMETEC PLUS® (Olmesartan Medoxomil and Hydrochlorothiazide) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;
2. “OLMETEC” is the brand name of the angiotensin II receptor blocker<sup>1</sup> drug Olmesartan Medoxomil, which is prescribed to patients in order to treat hypertension or mild to moderate high blood pressure and other medical conditions including renal disease;
3. “OLMETEC PLUS” is the brand name of the angiotensin II receptor blocker drug Olmesartan Medoxomil (as described above) in combination with Hydrochlorothiazide, which is a diuretic or “water pill” that helps control blood pressure by getting rid of excess salt and water;
4. Unless the context indicates otherwise, OLMETEC and OLMETEC PLUS will be collectively referred to as just OLMETEC;
5. Petitioner contends that Respondents represented to the medical and healthcare community, to Health Canada and to the Class Members that they researched, designed, developed, manufactured, and tested OLMETEC and that it had been found to be safe and/or effective for its intended use(s);
6. The Respondents concealed their knowledge and/or failed to warn the medical and healthcare community, Health Canada and from Class Members of the fact that the ingestion of OLMETEC increased the risk of developing multiple injuries, including, but not limited to:

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<sup>1</sup> Angiotensin II receptor blocker medicines are used to reduce blood pressure by blocking the actions of a chemical (angiotensin II) that causes blood vessels to constrict or tighten, thereby relaxing blood vessels.

- Serious gastrointestinal injuries,
- Olmesartan-Associated Enteropathy (OAE),
- Sprue-like enteropathy,
- Villous atrophy/blunting/damage,
- Inflammation,
- Nausea,
- Vomiting,
- Chronic diarrhea,
- Malnutrition,
- Dehydration,
- Atrophy,
- Kidney failure,
- Weight loss,
- Abdominal and gastrointestinal pain,
- Colitis,
- Gastritis,
- Permanent injuries resulting from the above, and
- Death;

(the “Gastrointestinal Disorders”)

7. The Respondents’ liability rests on (i) inadequate warning about the risk of developing Gastrointestinal Disorders, (ii) failure to notify of the full scope of risks known to be associated with and caused by OLMETEC, and (iii) safety misrepresentations;
8. The Respondents continue to manufacture, market, package, promote, advertise, distribute, label and/or sell OLMETEC throughout Canada, including within the province of Quebec, with inadequate warnings as to its serious and adverse side effect of the Gastrointestinal Disorders which have severe and life-threatening complications which are permanent and lasting in nature and this has caused physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications;

#### B) The Respondents

8. Respondent Merck Canada Inc. (“Merck”) is a Canadian pharmaceutical corporation, with its head office in Kirkland, Quebec. Merck is and was at all relevant times involved in the research, design, development, formulation, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including OLMETEC. It is a subsidiary of Respondent Schering-Plough Canada Inc. that does business throughout Canada, including within the province of Quebec, as

appears more fully from a copy of an extract from the *Registraire des entreprises*, produced herein as **Exhibit R-1**;

9. Respondent Merck is the sponsor or licensee for OLMETEC and OLMETEC PLUS in Canada and, is thus, responsible for its Product Monographs, which are the primary source of information for healthcare professionals and patients, setting out the uses, dosage, and risks associated with the drug;
10. Respondent Schering-Plough Canada Inc. ("Schering-Plough") is a Canadian pharmaceutical corporation, with its head office in Kirkland, Quebec. Schering-Plough is and was at all relevant times involved in the research, design, development, formulation, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including OLMETEC. It is a parent company of Respondent Merck that does business throughout Canada, including within the province of Quebec, as appears more fully from a copy of an extract from the *Registraire des entreprises*, produced herein as **Exhibit R-2**;
11. Respondent Daiichi Sankyo Company, Ltd. ("Daiichi") is a global pharmaceutical corporation with its head office in Japan. Daiichi is and was at all relevant times involved in the research, design, development, formulation, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of pharmaceutical products including OLMETEC. It is the owner of the following Canadian trade-marks: (word) OLMETEC (TMA613772), (design) OLMETEC PLUS (TMA704161), and (design) Man Design (TMA704669), as appears more fully from a copy of said trade-marks from the CIPO database, produced herein as **Exhibit R-3**;
12. Respondent Daiichi is the applicant and owner of the following Canadian patents: "COMPRESSED PREPARATION OF COMPOSITIONS COMPRISING OLMESARTAN MEDOXOMIL" (CA 2656181), "PULVERIZED CRYSTALS OF OLMESARTAN MEDOXOMIL" (CA 2681591), "METHOD FOR PRODUCING OLMESARTAN MEDOXOMIL" (CA 2759163), "ACETONE SOLVATE CRYSTALS OF TRITYL OLMESARTAN MEDOXOMIL" (CA 2760031), as appears more fully from a copy of said patents from the CIPO database, produced herein as **Exhibit R-4**;
13. All Respondents have either directly or indirectly designed, developed, formulated, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labelled and/or sold OLMETEC to distributors and retailers for resale to hospitals, medical practitioners and to the general public throughout Canada, including within the Province of Quebec;
14. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other;

## C) The Situation



### I. What is OLMETEC?

15. OLMETEC belongs to a group of medicines called angiotensin II receptor blockers (“ARB”s). Angiotensin II is a very potent chemical formed in the blood that causes muscles surrounding blood vessels to contract, thereby narrowing the vessels. This narrowing increases the pressure within the vessels and can cause high blood pressure (hypertension). Angiotensin II receptor blockers are medications that block the action of angiotensin II by preventing angiotensin II from binding to receptors on the muscles surrounding blood vessels. As a result, blood vessels enlarge (dilate) and blood pressure is reduced;
16. OLMETEC is an oral tablet prescription medication available in the 5 mg, 20 mg, and 40 mg dosages/strengths and OLMETEC PLUS is available in the 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg dosages/strengths;
17. OLMETEC and OLMETEC PLUS began being sold in Canada on December 22, 2008 as a prescription medication for the treatment of mild to moderate essential hypertension and as a prescription medication for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate;

### II. The Scientific Studies Behind the Drugs

18. Since as early as 2012, there have been numerous studies published in medical journals that demonstrate that the ingestion of OLMETEC causes an increased risk of Gastrointestinal Disorders. In addition, the studies indicate that for patients experiencing the Gastrointestinal Disorders, the cessation of OLMETEC oftentimes alleviates these symptoms, as appears more fully from copies of the studies, produced herein *en liasse* as **Exhibit R-5**;
19. These studies indicate the importance of informing patients and healthcare professionals of these adverse side effects so that they may make informed decisions regarding this medication. In addition, should the patient have made an informed decision to take OLMETEC in spite of the serious risks, knowledge

of these risks would have led to the cessation of its ingestion upon experiencing the Gastrointestinal Disorders as they would have been able to identify the reason for their existence;

20. The Respondents, in failing to advise doctors and patients of the increased risks associated with OLMETEC, effectively usurped their ability to make informed decisions regarding its use and removed their ability to limit and/or control the risk;
21. On November 26, 2009, less than a year after the approval and introduction of OLMETEC in Canada, the first Adverse Reaction was reported to Health Canada, whereby a 58-year-old male complained of diarrhea and nausea. After this, there were weekly and/or monthly reported adverse reactions reported until the present, with a total of 137 adverse events being reported to Health Canada, many of which complained about Gastrointestinal Disorders, as appears from a copy of Health Canada's list of Adverse Reaction Reports and from a copy of the actual reports, produced herein as **Exhibit R-6**;
22. On July 3, 2013, the United States Food and Drug Administration ("FDA") issued a Drug Safety Communication warning that OLMETEC can cause intestinal problems known as sprue-like enteropathy. The FDA mandated changes to the label of these drugs to include this concern. Some of the findings of the FDA include, but are not limited to:
  - (a) Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss,
  - (b) The enteropathy may develop months to years after starting OLMETEC, and sometimes require hospitalization,
  - (c) If patients taking OLMETEC develop these symptoms and no other cause is found, the drug should be discontinued, and therapy with another antihypertensive started;
  - (d) Discontinuation of OLMETEC has resulted in clinical improvement of sprue-like enteropathy symptoms in all patients, and
  - (e) Sprue-like enteropathy has not been detected with ARB drugs other than OLMETEC;

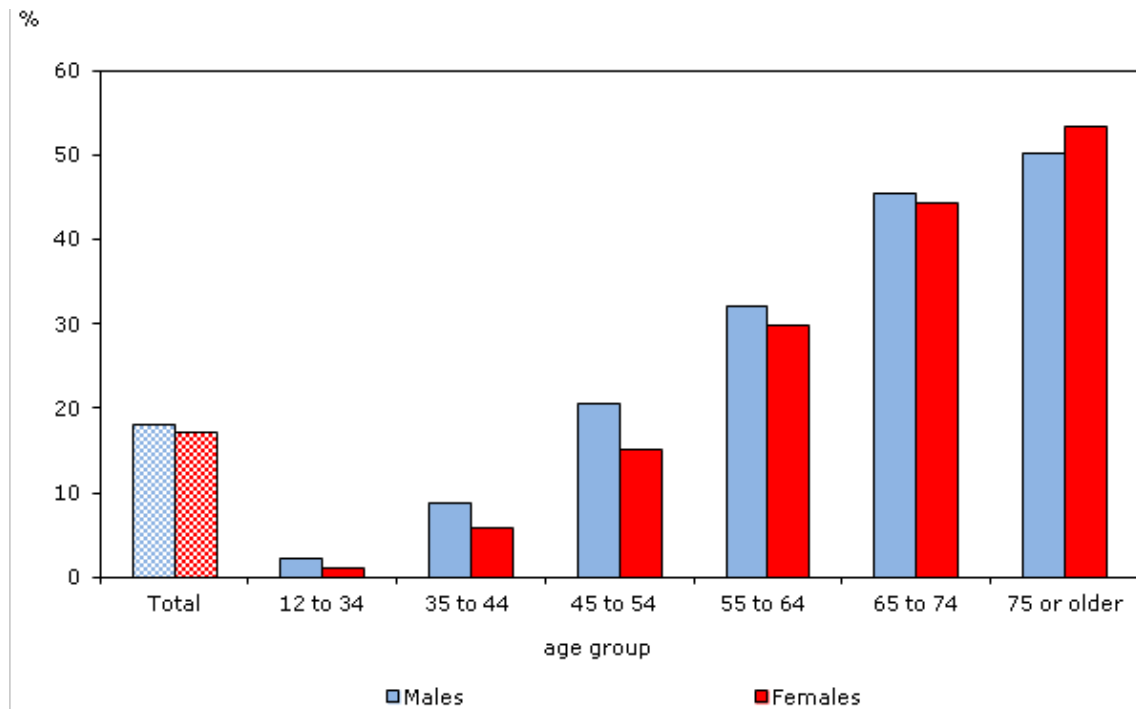
As appears more fully from a copy of the Drug Safety Communication, produced herein as **Exhibit R-7**;

23. Despite this mounting evidence and the growing number of adverse event reports, the Respondents have, to this day, failed to adequately and accurately inform consumers, healthcare professionals and the general public of the

existence of a causal connection between the use of OLMETEC and Class Members injuries, including the Gastrointestinal Disorders;

### III. The Respondents' Practices

24. The Canadian market for hypertension treatment is immense. In 2013, 17.7% (5.3 million) of Canadians aged 12 and older reported being diagnosed with high blood pressure. The incidence of high blood pressure increases with age, with the highest rate of high blood pressure being the 75 and older age group, as appears more fully from a copy of the Statistics Canada publication entitled "High blood pressure, 2013", produced herein as **Exhibit R-8**;



Source: Canadian Community Health Survey, 2013.

25. The Respondents' drug, Olmesartan Medoxomil, was first introduced in the United States in 2002 and Respondent Daiichi (with other non-parties) engaged in an aggressive marketing campaign focussed on convincing physicians that it was the ARB with superior efficacy and more;

26. In 2006, the FDA found these efficacy and safety claims unsubstantiated and false or misleading as there was no evidence that that Olmesartan Medoxomil was superior to or safer than other ARBs. In addition, the FDA found that their marketing materials failed to include risk information necessary to qualify its safety and effectiveness claims. The FDA ordered Respondent Daiichi to discontinue the use of approximately 50 promotional pieces and to disseminate corrective messages to physicians who received the materials;

27. On November 5, 2013, the FDA again found Respondent Daiichi's promotional material misleading, as appears more fully from a copy of the letter dated November 5, 2013, produced herein as **Exhibit R-9**;
28. On March 10, 2010, a former Daiichi sales representative brought suit against Respondent Daiichi alleging that they were using incentive programs to induce physicians to use its pharmaceuticals, including Olmesartan Medoxomil – the case settled five years later for over \$39 million dollars to be paid to the U.S. government, as appears more fully from a copy of the Business Wire article dated January 9, 2015 and from a copy of the settlement agreement, produced herein *en liasse* as **Exhibit R-10**;
29. In spite of the strong indication that OLMETEC was causing Gastrointestinal Disorders, the Respondents failed to inform consumers, health care professionals, and the scientific community and they failed to perform further investigation into its safety;
30. This important information made its first appearance in the Product Monograph on November 5, 2013, years after the drugs had been introduced and years after the Respondents knew or should have known about the associated risks, as appears more fully from a copy of the Product Monograph for OLMETEC last revised on November 5, 2013, from a copy of the Product Monograph for OLMETEC PLUS last revised November 5, 2013, and from copies of eight previous Product Monographs, produced herein as **Exhibit R-11**;
31. Even today, this disclosure is insufficient and many doctors are still unaware of the direct causal relationship between the use of OLMETEC and the development of Gastrointestinal Disorders;
32. There are feasible alternatives to OLMETEC in the form of angiotensin II receptor blockers for which there are no reported Gastrointestinal Disorders. OLMETEC suffers from a defective design, which was a substantial factor in causing the Plaintiff's and Class Members' injuries;

#### IV. The Respondents' Liability

33. Although OLMETEC is marketed, packaged, promoted, advertised, distributed, labelled and/or sold as a safe and effective prescription drug to reduce high blood pressure, it has the serious side effect of the increased risk for Gastrointestinal Disorders;
34. A reasonably prudent drug researcher, designer, developer, formulator, manufacturer, tester, marketer, packager, promotor, advertiser, distributor, labeller and/or seller in the Respondents' position would have adequately warned both doctors and patients of the risks associated with the use of OLMETEC;



35. Despite a clear signal, the Respondents have failed to either alert the public and the scientific and medical community or to perform further investigation into the safety of OLMETEC;
36. The Respondents knew, or by the reasonable and careful employment of known scientific methods should have known, and, in the exercise of reasonable care toward patients who would be expected to ingest OLMETEC, should have known that:
- (a) Studies published in peer-reviewed scientific and medical literature found there may be an association between OLMETEC and Class Members' injuries;
  - (b) These studies represent some of the best scientific evidence available for evaluating the association between OLMETEC and Class Members' injuries;
  - (c) Physicians commonly prescribe OLMETEC as treatment for hypertension for prolonged periods of 6 months to 1 year or more;
  - (d) Clinical trials for the OLMETEC only lasted up to 3 months in duration;
  - (e) Olmesartan-Associated Enteropathy symptoms are typically and often experienced chronically over long periods of time; and
  - (f) Clinical trials over periods greater than 3 months would have demonstrated the effects of longer term cumulative exposure to OLMETEC;
37. The Respondents were negligent in the research, design, development, formulation, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of OLMETEC in one or more of the following respects:
- (a) They knew of should have known that OLMETEC increased the risk of the adverse side effect of Gastrointestinal Disorders;
  - (b) They failed to ensure that OLMETEC was not dangerous to consumers;
  - (c) They failed to conduct appropriate testing to determine whether and to what extent the ingestion of OLMETEC poses serious health risks, including the Gastrointestinal Disorders;
  - (d) They failed to adequately test the product prior to placing it on the market;
  - (e) They failed to adequately test OLMETEC in a manner that would fully disclose the side effect of Gastrointestinal Disorders;

- (f) They failed to use care in designing, developing and manufacturing their products so as to avoid posing unnecessary health risks to users of such products;
- (g) They failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the drug;
- (h) They failed to advise that the consumption of OLMETEC could result in severe and disabling side effects, including but not limited to, the Gastrointestinal Disorders;
- (i) They failed to advise the medical and scientific communities of the potential to increase the risk of Gastrointestinal Disorders;
- (j) They failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks associated with the use of OLMETEC;
- (k) They failed to provide Class Members and their physicians with adequate warnings or sufficient indications of inherent risks associated with OLMETEC;
- (l) They failed to provide adequate updated and current information to Class Members and their physicians respecting the risks of OLMETEC as such information became available;
- (m) They failed to provide prompt warnings of potential hazards of OLMETEC in the products' monograph and in the products' labelling;
- (n) They failed to warn that Class Members and their physicians that the risks associated OLMETEC would exceed the risks of other available angiotensin II receptor blocker medications;
- (o) After receiving actual or constructive notice of problems with OLMETEC, they failed 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 drugs' inherent dangers;
- (p) They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the risks associated with the drug;
- (q) They falsely stated and/or implied that OLMETEC was safe when they knew or ought to have known that this representation was false;

- (r) They disregarded reports of Gastrointestinal Disorders among patients;
- (s) They failed to accurately and promptly disclose to Health Canada information relating to Gastrointestinal Disorders associated with OLMETEC and to adequately modify the OLMETEC product monographs and product labelling accordingly and in a timely manner;
- (t) They failed to monitor and to initiate a timely review, evaluation and investigation of reports of Gastrointestinal Disorders associated with OLMETEC in Canada (and around the world);
- (u) They failed to properly investigate cases of Gastrointestinal Disorders caused by OLMETEC;
- (v) They deprived patients of a chance for safe, effective and/or successful alternative treatments; and
- (w) In all circumstances of this case, they applied callous and reckless disregard for the health and safety of their consumers;

## **II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER**

- 38. On or about the beginning of 2011, Petitioner was prescribed OLMETEC PLUS by his physician in the 40 mg/ 25 mg dosage, which was intended to lower his high blood pressure;
- 39. Petitioner filled his prescription at the Pharmaprix located at 1337 Boulevard Iberville, in Repentigny, Quebec and he took it as directed, namely, once daily in the mornings;
- 40. Within a few months' time, Petitioner began to suffer from cramps in his lower abdomen about once a week and he would need to rush to the toilet shortly thereafter to relieve himself;
- 41. These symptoms increased in frequency being twice a week and then every few days;
- 42. During this time (whether or not he was experiencing cramping), his stools were exceedingly soft and often completely liquid (i.e. diarrhea);
- 43. In addition, he was unable to travel far distances in comfort as he could not predict when the abdominal cramping would begin and when he would need access to a toilet, which interfered with his profession as a travelling union representative;

44. Petitioner has experienced chronic diarrhea, dehydration, weight loss, and abdominal and gastrointestinal pain for approximately 6 years;
45. Petitioner went to see another doctor in the end of 2015 who performed a colonoscopy and opined that there was nothing wrong with his digestive system;
46. Thereafter, Petitioner conducted research online and discovered that OLMETEC can cause the symptoms that he was experiencing;
47. Petitioner stopped taking OLMETEC PLUS around January 2016 and the Gastrointestinal Disorder symptoms disappeared within a few months;
48. At no time was Petitioner made aware of the risks of suffering from Gastrointestinal Disorders associated with taking OLMETEC PLUS;
49. Had the Respondents properly disclosed the risks associated with OLMETEC, Petitioner would have avoided the risk of suffering Gastrointestinal Disorders by not using OLMETEC PLUS at all. Further, had Plaintiff been made aware of the risks of Gastrointestinal Disorders, he would not have had to suffer injury for 6 long years without any explanation of the cause, and instead would have simply discontinued his use of OLMETEC PLUS at the first sign of a Gastrointestinal Disorder;
50. Petitioner is aware that several lawsuits were filed in the United States due to the defects associated with OLMETEC and due to the Respondents' conduct related thereto, as appears more fully from a copy of the In Re Benicar (Olmesartan) Products Liability Litigation Complaint Civil No. 15-2606, produced herein as **Exhibit R-12**;
51. As a result of the Respondents' conduct, Petitioner suffered damages including, but not limited to physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, inflammation, chronic diarrhea, dehydration, weight loss, and abdominal and gastrointestinal pain, and the apportioned cost of the OLMETEC PLUS;
52. Petitioner's damages are a direct and proximate result of his use of the drug OLMETEC PLUS, Respondents' negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug OLMETEC;
53. In consequence of the foregoing, Petitioner is justified in claiming damages;

### **III. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP**

54. Every member of the Class was prescribed and ingested the drug, OLMETEC or is the successor, family member, assign, and/or dependant of a person who was prescribed and/or ingested OLMETEC;

55. The Class Members' damages would not have occurred, but for the acts, omissions and/or negligence of the Respondents in failing to ensure that OLMETEC was safe to use, for failing to provide adequate warning of the unreasonable risks associated with using the drug, for false or misleading representations and for omitting to disclose important information to Class Members and to their physicians;

56. In consequence of the foregoing, each member of the Class is justified in claiming at least one or more of the following as damages:

- a. Physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems;
- 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 OLMETEC side effect services;
- c. Loss of income and loss of future income;
- d. Refund of the purchase price of OLMETEC or alternatively, the incremental costs of OLMETEC as paid for by the class members and/or by the *Régie de l'assurance maladie du Québec*, the Ontario Health Insurance Plan, and other provincial health insurers; and
- e. Punitive damages;

57. As a direct result of the Respondents' conduct, the users' family members and dependants have, had, and/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;

58. All of these damages to the Class Members are a direct and proximate result of the use of OLMETEC and Respondents' conduct, negligence and reckless

failure to adequately disclose necessary information and the risks associated with the drug;

#### **IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION**

A) The composition of the class makes it difficult or impracticable to apply the rules for mandates to sue on behalf of others or for consolidation of proceedings

59. Petitioner is unaware of the specific number of persons who were prescribed and ingested OLMETEC, which information is confidential; however, it is safe to estimate that it is in the thousands. The Respondents, on the other hand, can establish this through their own business records;

60. Class Members are numerous and are scattered across the province and country;

61. Given the costs and risks inherent in an action before the courts, many people will hesitate to institute an individual action against the Respondents;

62. 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;

63. 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;

B) The claims of the members of the Class raise identical, similar or related issues of law or fact

64. Individual questions, if any, pale by comparison to the numerous common questions that will advance the litigation significantly;

65. The damages sustained by the Class Members flow, in each instance, from a common nucleus of operative facts, namely, Respondents' misconduct;

66. The claims of the Class Members raise identical, similar or related issues of fact or law as outlined hereinbelow;

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

#### **V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT**

68. The action that the Petitioner wishes to institute on behalf of the members of the class is an action in damages, injunctive relief, and declaratory judgment;

69. The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings appear hereinbelow.

A) The Petitioner requests that he be attributed the status of representative of the Class

70. Petitioner is a member of the Class;

71. Petitioner is ready and available to manage and direct the present action in the interest of the members of the Class that he wishes to represent and is determined to lead the present file to a final resolution;

72. Petitioner has the capacity and interest to fairly, properly, and adequately protect and represent the interest of the members of the Class;

73. Petitioner has given the mandate to his attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

74. Petitioner, with the assistance of his 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;

75. Petitioner has given instructions to his 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;

76. Petitioner is in good faith and has instituted this action for the sole goal of having his 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 Respondents' conduct;

77. Petitioner understands the nature of the action;

78. Petitioner's interests are not antagonistic to those of other members of the Class;

79. Petitioner is prepared to be examined out-of-court on his allegations (as may be authorized by the Court) and to be present for Court hearings, as may be required and necessary;

80. Petitioner has spent time researching this issue on the internet and meeting with his attorneys to prepare this file. In so doing, he is convinced that the problem is widespread;

B) Petitioner suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal

81. A great number of the members of the Cass reside in the judicial district of Montreal and in the appeal district of Montreal;

82. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

83. The Canadian Respondents' head offices are located in the judicial district of Montreal;

84. 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;

**APPOINT** the Petitioner as representative of the persons included in the class herein described as:

- all persons residing in Canada who were prescribed and have ingested the drug(s) OLMETEC<sup>®</sup> (Olmesartan Medoxomil) and/or OLMETEC PLUS<sup>®</sup> (Olmesartan Medoxomil and Hydrochlorothiazide) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

Alternately (or as a subclass)

- all persons residing in Quebec who were prescribed and have ingested the drug(s) OLMETEC<sup>®</sup> (Olmesartan Medoxomil) and/or OLMETEC PLUS<sup>®</sup> (Olmesartan Medoxomil and Hydrochlorothiazide) and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

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



- a) Does OLMETEC cause, exacerbate or contribute to an increased risk of Gastrointestinal Disorders?
- b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as researchers, designers, developers, formulators, manufacturers, testers, marketers, packagers, promoters, advertisers, distributors, labellers and/or sellers of OLMETEC?
- c) Was OLMETEC researched, designed, developed, formulated, manufactured, tested, marketed, packaged, promoted, advertised, distributed, labelled, and sold with defects that increase a patient's risk of Gastrointestinal Disorders?
- d) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for OLMETEC?
- e) Did the Respondents fail to adequately and properly test OLMETEC before and/or after placing it on the market?
- f) Did the Respondents know or should have known about the risks associated with the use of OLMETEC?
- g) Did the Respondents knowingly, recklessly or negligently breach a duty to warn Class Members and/or their physicians of the risks of harm from the use/ingestion of OLMETEC?
- h) Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks of harm from the use/ingestion of OLMETEC?
- i) Did the Respondents knowingly fail to disclose and warn of OLMETEC's defects?
- j) Did the Respondents adequately and sufficiently warn the members of the Class and/or their physicians about the risks associated with the use of OLMETEC?
- k) Should OLMETEC have been sold with more appropriate warnings?
- l) Were the members of the Class prejudiced by taking OLMETEC instead of other angiotensin II receptor blocker medications, which have similar benefits, but do not pose such an increased risk of Gastrointestinal Disorders?

- m) In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the Class?
- n) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?
- o) Are members of the Class entitled to bodily, moral, and material damages?
- p) 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 Petitioner and each of the members of the class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of OLMETEC;

RESERVE the right of each of the members of the class to claim future damages related to the use of OLMETEC;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner 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 group in accordance with article 579 C.C.P. within sixty (60) days from the judgment to be rendered herein in The Globe and Mail, National Post, La Presse, the Gazette, the Toronto Star, and the Vancouver Sun;

**ORDER** that said notice be available on the Respondents' websites, Facebook page(s), and twitter accounts with a link stating "Notice to OLMETEC and OLMETEC PLUS users";

**RENDER** any other order that this Honourable Court shall determine is in the interest of the members of the Class;

**THE WHOLE** with costs, including all publication fees.

Montreal, November 4, 2016

(S) Andrea Grass

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CONSUMER LAW GROUP INC.

Per: Me Andrea Grass

Attorneys for the Petitioner