CANADA
PROVINCE OF QUÉBEC
DISTRICT OF LAVAL

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

No.: 540-06-

SABRINA IACOVELLI, [redacted];

Petitioner

vs.

LABORATOIRES ABBOTT, LIMITÉE [redacted];

-and-

ABBOTT LABORATORIES, [redacted];

Respondents

MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE THE STATUS OF REPRESENTATIVE
(Art. 1002 C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT OF QUÉBEC, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PETITIONER STATES THE FOLLOWING:

INTRODUCTION:

1. Petitioner wishes to institute a class action on behalf of the following Group of which Petitioner is a member:

SUB-GROUP A:

- All persons in Québec (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Sibutramine drugs, including but not limited to the brand names Meridia, Reductil, Sibutral, Ectiva, Raductil, Reduxade and Zelium, manufactured, marketed or distributed by Respondents and/or any other related companies, or any other Group or Sub-Group to be determined by the Court;

SUB-GROUP B:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Sibutramine drugs, including but not limited to the brand names Meridia, Reductil, Sibutral, Ectiva, Raductil, Reduxade and Zelium, manufactured, marketed or distributed by Respondents and/or any other related companies, or any other Group or Sub-Group to be determined by the Court;

(hereinafter referred to as the "**Class Members**", the "**Class**", the "**Group Members**", the "**Group**", "**Consumers**" or "**Users**");

2. Respondents LABORATOIRES ABBOTT, LIMITÉE and ABBOTT LABORATORIES, including their past and present related companies (hereinafter referred to collectively as "**Respondents**"), are pharmaceutical companies that research, develop, design, test, manufacture, distribute, label, package, supply, market, advertise and sell various healthcare and pharmaceutical products;

3. In 2001, Respondents acquired a pharmaceutical business from BASF Canada Inc. and/or related entities, which included the global operations and branded pharmaceuticals business of "Knoll Pharmaceuticals";

4. Respondents have sold various products containing the active ingredient sibutramine under various brand names including but not limited to the Meridia, Reductil, Sibutral, Ectiva, Raductil, Reduxade and Zelium brands, or any other drug of this type (herein referred to collectively as the "**Sibutramine drugs**"). The Sibutramine drugs had first been marketed and sold by Knoll Pharmaceuticals;

5. Respondents placed their Sibutramine drugs in the streams of commerce in Canada and in over 140 other countries worldwide for the purpose of helping in weight loss and treating obesity;

6. Respondents (or predecessors) started selling the Sibutramine drugs in Canada in December 2000 and have sold said drugs to hundreds of thousands of Consumers across Canada. Sibutramine drugs had been introduced to the US market in or around 1997;

7. Sibutramine drugs can cause increased negative health effects including but not limited to risks of heart attacks and strokes, increase in blood pressure and heart rate, death and/or other risks or side effects, as more fully detailed below;

8. On October 8, 2010, Respondents announced they will voluntarily withdraw Meridia® (sibutramine) from the U.S. and Canadian markets at the request of the U.S. Food and Drug Administration (FDA) and Health Canada's recommendation, as a result of the Sibutramine Cardiovascular OUTcome Trial (hereinafter "**SCOUT study**"), the whole as more fully appears from copies of

Respondents' Press Releases, communicated herewith as **Exhibit R-1, *en liasse***;

9. The SCOUT study is a clinical study undertaken by Respondents, which was launched in 2002, in order to determine the long-term safety of weight loss by using the Sibutramine drugs in patients with a history of cardiovascular disease;

10. While this Scout Study was being completed, Respondents continued to sell the Sibutramine drugs to Class Members;

11. The SCOUT study concluded that rather than reducing cardiovascular risk in this group of patients, Sibutramine drugs increase the risk for cardiovascular events;

12. Respondents explained the withdrawal of Meridia (sibutramine) from the U.S. market in the following terms in its Exhibit R-1 Press Release:

> "The FDA's request is based primarily on the results of the SCOUT (Sibutramine Cardiovascular OUTcome Trial) study, an approximately 10,000 patient, 6-year study requested by European regulatory authorities as a post-marketing commitment to evaluate cardiovascular safety in high-risk patients. The majority of these patients had underlying cardiovascular disease and were not eligible to receive sibutramine under the current labeling.";

13. As for the withdrawal of the Sibutramine drugs from the Canadian market, Respondents declared the following in their Exhibit R-1 Press Release:

> "Health Canada's recommendation was based on a review of results from the SCOUT study (Sibutramine Cardiovascular OUTcome Trial), which became available in November 2009. The approximately 10,000 patient, six-year SCOUT study was requested by European regulatory authorities as a post-marketing commitment to evaluate cardiovascular safety in high-risk patients. The majority of the patients in the SCOUT study had underlying cardiovascular disease and were ineligible to receive sibutramine under the current labeling and prescribing information";

14. On October 8, 2010, Health Canada issued a warning to Consumers about health risks associated with the use of Sibutramine drugs and announcing that Respondents were withdrawing its Sibutramine drugs from the Canadian market in light of data from the Sibutramine Cardiovascular OUTcomes (SCOUT) study. More precisely, Health Canada stated the following:

> "Health Canada is informing healthcare practitioners and Canadians that Abbott Laboratories is voluntarily withdrawing the prescription weight-loss drug sibutramine, which is marketed under the brand name Meridia®, from the Canadian market.
>
> Abbott's decision, in collaboration with Health Canada, comes in light of data from the Sibutramine Cardiovascular OUTcomes (SCOUT) trial, a large study that suggested an increased risk of serious cardiovascular events associated with sibutramine use in patients with heart problems. The purpose of the study was to determine a link between long-term sibutramine use and the risk of cardiovascular events in patients with pre-existing cardiovascular disease, or who were at risk of heart-related adverse events. Nearly 10,000 overweight and obese subjects aged 55 years and older were enrolled in the trial for up to six years.";

the whole as more fully appears from Health Canada's notice, communicated herewith as **Exhibit R-2**;

15. Health Canada also confirmed that the benefits no longer outweigh the risks for the Sibutramine drugs in the following terms (Exhibit R-2):

> "[...] there continues to be concern of an increased risk of heart-related adverse events, <u>particularly as people at risk of cardiovascular disease may not have symptoms</u>. In light of this concern, and the accumulating scientific evidence on the safety and efficacy of Meridia, <u>it has been determined that the benefits no longer outweigh the risks for this drug</u>.";
> (Emphasis Added)

16. Ingestion of Sibutramine drugs materially contributes to the increased risk of serious cardiovascular events associated in patients with heart problems, such as risks of heart attacks and strokes, increase in blood pressure and heart rate, and/or other risks or side effects;

17. Furthermore, and as stated above, people at risk of cardiovascular disease may not have symptoms, making their use of the Sibutramine drugs even more dangerous;

18. It should be noted that the European Medicines Agency (EMA) suspended marketing authorization for all anti-obesity medicines containing sibutramine in January 2010 but Respondents continued to sell these drugs in Canada and the USA until October 2010 as mentioned above;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

15. In or around March 2010, Petitioner was prescribed Meridia (Sibutramine) by her doctor and she purchased the drugs for $158.93;

16. Petitioner took the Meridia pills for approximately three (3) weeks in April – May 2010;

17. Petitioner stopped taking the Meridia pills because she started experiencing heart palpitations;

18. Respondents failed to warn Petitioner and other Class Members, prior to their purchase and consumption, of the health risks posed by the Sibutramine drugs;

19. Had the Respondents warned Consumers, the Petitioner and other Class Members would not have purchased or used the Sibutramine drugs;

20. The Class Members have incurred injuries and losses from the purchase, consumption, and use of the Sibutramine drugs, including expenses relating to medical treatment sought and received, physical injuries, the cost of the product, opportunity costs incurred as a result of illness or visits to medical facilities, loss

of employment income, loss of enjoyment of life, pain and suffering, and anticipated future medical and health costs;

21. The Class Members have suffered and will continue to suffer physical injuries and other losses, or damages due to the use and consumption of the Sibutramine drugs, and claim damages as a result;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

22. Respondents researched, designed, tested, manufactured, marketed, labeled, distributed, promoted and sold Sibutramine drugs in many countries including Canada;

41. At all material times, Respondents have marketed that Sibutramine drugs are safe and beneficial, which is not true;

42. Respondents warranted and represented that the Sibutramine drugs were fit for their use and consumption by Consumers and posed no significant health risks to those Users;

43. Respondents admit that it was only in January 2010 that they submitted label changes to the US Food and Drug Administration ("FDA") to deter use of the Sibutramine drugs by people with heart and blood-pressure problems as a result of the preliminary SCOUT findings. The said label indicates that people with pre-existing cardiovascular disease (i.e. coronary artery disease (heart disease), congestive heart failure (CHF), arrhythmias, or stroke) should not take the medication, as confirmed by Respondents' Press Release of October 2010, **Exhibit R-1**;

44. Sibutramine drugs are associated with increased negative health effects including but not limited to the increase the risk for cardiovascular events, risks of heart attacks and strokes, increase in blood pressure and heart rate, and/or other risks or side effects;

45. Had the Respondents done appropriate scientific research and testing, as well as carried out reviews of related medical journals or studies, they should have known that Sibutramine drugs materially contribute to the risk of serious adverse medical events as described above and should have fully informed the medical professionals and Consumers, including the Petitioner and putative Class Members, of such risks in a timely manner;

46. Respondents knew or should have known of the risks from the use of Sibutramine drugs but portray Sibutramine drugs as a safe and effective solution to helping overweight or obese people lose weight;

47. In fact, as stated above and at the very least, the SCOUT report was issued in November 2009 but Respondents continued to sell the Sibutramine drugs for nearly an additional year to Class Members, including the Petitioner;

48. In its press release of October 8, 2010, Respondents continue to represent Sibutramine drugs as beneficial rather than unsafe, stating that: "Abbott believes sibutramine has a positive risk/benefit profile in the approved patient population, but will comply with the FDA's request", the whole as more fully appears from **Exhibit R-1**;

49. However, Health Canada is of very different opinion. It states the following in its Information Update of October 8, 2010:

> "[...] there continues to be concern of an increased risk of heart-related adverse events, particularly as people at risk of cardiovascular disease may not have symptoms. In light of this concern, and the accumulating

> scientific evidence on the safety and efficacy of Meridia, it has been determined that the benefits no longer outweigh the risks for this drug; *(Emphasis added)*

the whole as more fully appears from **Exhibit R-1**;

50. Had the true facts been disclosed that Sibutramine drugs are associated with devastating side effects, consumers would not have used Sibutramine drugs;

51. Respondents misled or deceived Class Members by representing in written labeling, written marketing materials and advertising that Sibutramine drugs do not pose the aforesaid risks to them during normal use;

52. Respondents warranted that Sibutramine drugs were safe and fit for their intended and foreseeable purpose. However, Sibutramine drugs were not, and are not, safe for their intended use in that they pose an undue risk of harm to the Members of the Class;

53. At all material times, Respondents failed to provide the medical community and the general public with a clear, complete, and current warning of the risks associated with Sibutramine drugs' use, or failed to provide such warning in a timely manner, and Respondents were negligent in that regard;

54. Further, or in the alterative, Respondents did inferior research, design, and tests on Sibutramine drugs and made a defective drug product;

55. Had the true facts been disclosed that the Sibutramine drugs were associated with increased negative health effects including but not limited to risks of heart attacks and strokes, increase in blood pressure and heart rate, the use of said Sibutramine drugs on an objective Class wide basis would not have occurred and the Class Members would not have experienced the aforementioned injuries

or health risks;

56. Consumers reasonably relied and rely upon the Respondents to ensure that the Sibutramine drugs are safe for human consumption;

57. Respondents are liable for the damages suffered by the Petitioner and the Class Members in that Respondents failed to use sufficient quality control, to conduct adequate testing, and to perform proper manufacturing, production, or processing, or failed to take sufficient measures to prevent harmful Sibutramine drugs from being offered for sale, sold or used by Consumers, when they knew or ought to have known about the serious health risks but still sold and distributed their Sibutramine drugs in Canada;

58. As a direct and proximate result of the Respondents' negligence, the Class Members suffered pain, damages, injuries and risks for which the Respondents are solely liable;

59. Each Member of the Group is entitled to claim damages because of the faults committed by the Respondents, which include but are not limited to the reimbursement of the purchase price for the drugs, personal injuries suffered, economic and financial losses (i.e. loss of income and earning capacity), pain and suffering, loss of amenities and enjoyment of life, costs of past and future care and related expenses, such further and other damages, the particular of which may be proven at trial on the merits;

60. Moreover, the Respondents' conduct, through actions, omissions, wrongdoings, and their awareness of the serious hazards of said drugs, and their failure to fully, clearly, and in a timely way disclose and publicize the serious health effects resulting from the use of the Sibutramine drugs (all detailed hereinabove), subject the Respondents to punitive and exemplary damages;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

61. The composition of the Group makes the application of Article 59 or 67 C.C.P. impractical for the following reasons:

a) The number of potential Group Members is so numerous that joinder of all Members is impracticable. While the exact number of Group Members is unknown to Petitioner at the present time and can only be ascertained from sales and distribution records maintained by the Respondents and its agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Canada;

b) Based on the number of potential Group Members, it is impossible for the Petitioner to identify all potential Group Members and obtain a mandate from each of them. Petitioner does not possess the names and addresses of potential Group Members;

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

a) Does the consumption of the Sibutramine drugs cause an increase in negative health effects, and to what extent?

b) As a result of negative health effects, were the Sibutramine drugs unsafe, or unfit for the purpose for which they were intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce in Canada by the Respondents?

c) Were Respondents negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of the Sibutramine drugs to the Group Members?

d) Did Respondents fail to inform the Class Members of the health risks associated with the use of Sibutramine drugs?

e) Are Respondents liable to pay damages to the Group Members as a result of their negligence, or misrepresentations made to them in manufacturing, marketing, distributing or selling of the Sibutramine drugs, or as a result of the use of Sibutramine drugs?

f) Are Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?

g) Are Respondents liable to pay moral damages to the Group Members, and if so in what amount?

h) Are Respondents liable to pay exemplary or punitive damages to the Group Members, and if so in what amount?

63. The majority of the issues to be dealt with are issues common to every Group Member;

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

65. The action that Petitioner wishes to institute for the benefit of the Members of the Group is an action in damages for product liability;

66. The conclusions that Petitioner wishes to introduce by way of a motion to institute proceedings are:

GRANT Petitioner's action against Defendants;

CONDEMN Defendant to reimburse to Petitioner the purchase price paid of $158.93, plus interest as well as the additional indemnity;

CONDEMN Defendants to pay an amount in compensatory damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Defendants to pay an amount in moral damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Defendants to pay an amount in punitive and/or exemplary damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

GRANT the class action of Petitioner on behalf of all the Members of the Group;

ORDER the treatment of individual claims of each Member of the Group in accordance with Articles 1037 to 1040 C.C.P.;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members.

67. Petitioner suggests that this class action be exercised before the Superior Court in the District of Laval for the following reasons:

a) Petitioner resides in the district of Laval;

b) Respondents sell the Sibutramine drugs in the District of Laval;

c) Many Group Members are domiciled or work in the District of Laval;

d) Petitioner's legal counsel practice law in the District of Laval.

68. Petitioner, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the members of the Group since Petitioner:

a) purchased and consumed Sibutramine drugs without being made aware of the health risks associated with the use of said drugs;

b) suffered damages and injuries from using Sibutramine drugs, as detailed above;

c) understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;

d) is available to dedicate the time necessary for the present action before the Courts of Québec and to collaborate with Class attorneys in this regard;

e) is ready and available to manage and direct the present action in the interest of the Class Members that Petitioner wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class;

f) does not have interests that are antagonistic to those of other members of the Group;

g) has given the mandate to the undersigned attorneys to obtain all relevant information to the present action and intends to keep informed of all developments;

h) is, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Members of the Group and to keep them informed;

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

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present Motion;

ASCRIBE the Petitioner the status of representative of the persons included in the Group herein described as:

SUB-GROUP A:

- All persons in Québec (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Sibutramine drugs, including but not limited to the brand names Meridia, Reductil, Sibutral, Ectiva, Raductil, Reduxade and Zelium, manufactured, marketed or distributed by Respondents and/or any other related companies, or any other Group or Sub-Group to be determined by the Court;

SUB-GROUP B:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were prescribed, purchased, used or ingested any Sibutramine drugs, including but not limited to the brand names Meridia, Reductil, Sibutral, Ectiva, Raductil, Reduxade and Zelium, manufactured, marketed or distributed by Respondents and/or any other related companies, or any other Group or Sub-Group to be determined by the Court;

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

a) Does the consumption of the Sibutramine drugs cause an increase in negative health effects, and to what extent?

b) As a result of negative health effects, were the Sibutramine drugs unsafe, or unfit for the purpose for which they were intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce in Canada by the Respondents?

c) Were Respondents negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of the Sibutramine drugs to the Group Members?

d) Did Respondents fail to inform the Class Members of the health risks associated with the use of Sibutramine drugs?

e) Are Respondents liable to pay damages to the Group Members as a result of their negligence, or misrepresentations made to them in manufacturing, marketing, distributing or selling of the Sibutramine drugs, or as a result of the use of Sibutramine drugs?

f) Are Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?

g) Are Respondents liable to pay moral damages to the Group Members, and if so in what amount?

h) Are Respondents liable to pay exemplary or punitive damages to the Group Members, and if so in what amount?

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

GRANT Petitioner's action against Defendants;

CONDEMN Defendant to reimburse to Petitioner the purchase price paid of $158.93, plus interest as well as the additional indemnity;

CONDEMN Defendants to pay an amount in compensatory damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Defendants to pay an amount in moral damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN Defendants to pay an amount in punitive and/or exemplary damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

GRANT the class action of Petitioner on behalf of all the Members of the Group;

ORDER the treatment of individual claims of each Member of the Group in accordance with Articles 1037 to 1040 C.C.P.;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members.

DECLARE that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Members;

ORDER the publication of a notice to the Members of the Group in accordance with Article 1006 C.C.P. and **ORDER** Respondents to pay for said publication costs;

THE WHOLE with costs to follow.

MONTRÉAL, October 12, 2010

MERCHANT LAW GROUP LLP
Attorneys for Petitioner