CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000688-149

(Class Action)
SUPERIOR COURT

M. HAMELIN

Petitioner

-vs.-

PFIZER CANADA INC., legal person duly constituted, having its head office at 17300 Trans-Canada Highway, City of Kirkland, Province of Quebec, H9J 2M5

and

PFIZER INC., legal person duly constituted, having its head office at 235 East 42nd Street, City of New York, State of New York, 10017, U.S.A.

Respondents

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

TO ONE OF THE HONOURABLE JUSTICES 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 she is a member, namely:

    - all persons residing in Canada who have taken and/or purchased the drug, ATORVASTATIN CALCIUM (sold under the brand name LIPITOR®) since March 5th 1997, 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 have taken and/or purchased the drug, ATORVASTATIN CALCIUM (sold under the brand name LIPITOR®) since March 5th 1997, and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

2. "LIPITOR" is a brand of drug that is prescribed to patients in order to prevent cardiovascular disease (heart disease)[1] by reducing the amount of cholesterol and other fatty substances in the blood;

3. Petitioner contends that Respondents designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labelled and/or sold LIPITOR as a safe and effective drug despite a wealth of existing knowledge that the drug had dangerous side effects including, but not limited to, an increased risk of developing type 2 diabetes, particularly so in postmenopausal women[2];

4. Ironically, while the Respondents were labelling LIPITOR as a drug that prevents cardiovascular disease, its side effect of type 2 diabetes has been recognized by the Public Health Agency of Canada as a major risk factor in developing cardiovascular disease. Thus, the Respondents designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labelled and/or sold LIPITOR as a preventative drug, without so much as mentioning that it was also a catalyst;

5. Respondents continue to design, develop, manufacture, test, package, promote, market, distribute, label and/or sell LIPITOR throughout Canada, including within the province of Quebec, with inadequate warnings as to its serious and adverse side effect of the increased risk of developing type 2 diabetes which has severe and life-threatening complications and described in more detail below;

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[1] Heart and blood vessel disease — cardiovascular disease also called heart disease — includes numerous problems, many of which are related to a process called atherosclerosis. Atherosclerosis is a condition that develops when a substance called plaque builds up in the walls of the arteries. This buildup narrows the arteries, making it harder for blood to flow through. If a blood clot forms, it can stop the blood flow. This can cause a heart attack or stroke. (*What is Cardiovascular Disease (Heart Disease)?* American Heart Association at www.heart.org).

[2] The average age of a woman having her last period, menopause, is 51. But, some women have their last period in their forties, and some have it later in their fifties. Smoking can lead to early menopause. So can some types of operations. For example, surgery to remove your uterus (called a hysterectomy) will make your periods stop, and that's menopause. (*Menopause*, National Institute on Aging at www.nia.nih.gov).

B) The Respondents

2. Respondent Pfizer Canada Inc. ("Pfizer Canada") is a federally-incorporated Canadian pharmaceutical company, with its head office in Kirkland, Quebec. It is a wholly-owned subsidiary of Respondent Pfizer Inc. ("Pfizer") that does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the *Registraire des enterprises*, produced herein as **Exhibit R-1**;

3. Respondent Pfizer Canada, as the manufacturer of LIPITOR, patented LIPITOR as a "Lipid Metabolism Regulator" under four (4) Drug Identification Numbers ("DIN") according to its four (4) strengths being: 10 mg (DIN: 02230711[3]), 20 mg (DIN: 02230713[4]), 40 mg (DIN: 02230714[5]), and 80 mg (DIN: 02243097[6]), the whole as appear more fully from a copy of Health Canada's Patent Register for the Medicinal Ingredient "atorvastatin calcium" and the Brand Name "LIPITOR", from a copy of the Patent Form IV Summaries for DIN: 02230711, and from a copy of an original Form IV: Patent List for Patent Number 2220018, produced herein *en liasse* as **Exhibit R-2**;

4. Respondent Pfizer is an American multinational company with its head office in New York, New York. It is one of the world's largest pharmaceutical companies and it operates within Canada, including within Quebec, through its Canadian subsidiary, Pfizer Canada;

5. Both Respondents have either directly or indirectly designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, imported, labelled and/or sold LIPITOR to distributors and retailers for resale to or, directly to physicians, hospitals, medical practitioners and to the general public throughout Canada, including within the Province of Quebec;

6. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other. Unless the context indicates otherwise, all Respondents will be referred to as "Pfizer" for the purposes hereof;

C) The Situation

I. What is LIPITOR?

[3] Associated patent numbers for DIN (02230711): 2220018, 2220455, 2220458, 2450111, 2521776, 2521792, 2521828, 2521833, 2521887, 2521891, 2521908, 2521933, 2521953, 2521956, and 2522899.
[4] Associated patent numbers for DIN (02230713): 2220018, 2220455, 2220458, 2450111, 2521776, 2521792, 2521828, 2521833, 2521887, 2521891, 2521908, 2521933, 2521953, 2521956, and 2522899.
[5] Associated patent numbers for DIN (02230714): 2220018, 2220455, 2220458, 2450111, 2521776, 2521792, 2521828, 2521833, 2521887, 2521891, 2521908, 2521933, 2521953, 2521956, and 2522899.
[6] Associated patent numbers for DIN (02243097): 2220018, 2220455, 2220458, 2450111, 2521776, 2521792, 2521828, 2521833, 2521887, 2521891, 2521908, 2521933, 2521953, 2521956, and 2522899.

7. LIPITOR is a member of the drug class known as "statins" (or HMG-CoA reductase inhibitors) which are a class of drugs used to lower blood cholesterol levels by inhibiting the enzyme, HMG-CoA reductase, a liver tissue enzyme that plays a central role in the production of cholesterol in the body;

8. LIPITOR is prescribed as a "Lipid Metabolism Regulator" to reduce the amount of cholesterol and other fatty substances in the blood thereby preventing the onset of cardiovascular disease (heart disease);

9. On December 17th 1996, Parke-Davis Pharmaceutical Research, a division of Warner-Lambert Company (hereinafter, "Warner-Lambert"), obtained approval from the United States Food and Drug Administration (hereinafter, the "US FDA") to market LIPITOR in the United States. On March 5th 1997, it obtained approval from Health Canada to market LIPITOR in Canada. Warner-Lambert entered into a co-marketing agreement with Pfizer to sell LIPITOR and thereafter, they began distributing and selling LIPTOR throughout the United States and throughout Canada. On June 19th 2000, Pfizer merged and/or acquired Warner-Lambert and all rights to the drug brand, LIPITOR, the whole as appears more fully from a copy of an extract from the Respondents' website at www.pfizer.com, produced herein as **Exhibit R-3**;

10. Since LIPITOR's approval in 1996, it became the "most widely used branded prescription treatment for lowering cholesterol and the best-selling prescription pharmaceutical product of any kind in the world." It was or "is the world's biggest-selling drug, with global annual sales of more than $12 billion". In 2009, LIPITOR had Canadian sales of over $1.1 billion, the whole as appears more fully from a copy of the Respondents' 2009 Financial Report and from a copy of the National Post article entitled "Lipitor generic reaches Canada, Pfizer vows fight", dated May 19th 2010, produced herein *en liasse* as **Exhibit R-4**;

11. In recent years, although still its best-seller, Pfizer has suffered lower sales of LIPITOR due the significant increase in generic competition following the Respondents' loss of exclusivity or loss of patent protection in various countries, including Canada, which officially lapsed on July 19th 2010 (see National Post article Exhibit R-4);

12. A one-month supply of 40 mg strength LIPITOR costs approximately $91.00 CAN;

II. Type 2 Diabetes – Explained

13. In recent years, scientists have discovered that while LIPITOR is an effective medication against heart disease, one of its side effects is that the drug significantly increases the risk of developing non-insulin-dependent diabetes mellitus (hereinafter "type 2 diabetes");

14. Type 2 diabetes is a chronic (incurable) progressive metabolic disorder that is characterized by high blood glucose levels and insulin resistance and deficiency. It is the most common form of diabetes in Canada – 90% to 95% of Canadians with diabetes have type 2 diabetes. An estimated 2 million Canadians and approximately 285 million people worldwide are living with the disease. Each year approximately 60,000 Canadians and 1.2 million Americans are diagnosed with type 2 diabetes, the whole as appears more fully from a copy of the Public Health Agency of Canada report entitled "Diabetes in Canada: Facts and figures from a public health perspective" dated 2011, produced herein as **Exhibit R-5**;

15. Diabetes occurs when the pancreas does not produce enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. When this occurs, sugar (glucose) builds up in the blood which can lead to serious medical problems including, but not limited to, heart disease, strokes, kidney failure, poor circulation, loss of limbs, and blindness. The main management objective of diabetes is to lower a patient's blood sugar to a normal level;

16. In the long-term, diabetes can induce macrovascular disease, which is a disease of the large blood vessels in the body, most commonly affecting the heart, the brain and the limbs. Type 2 diabetes is associated with a ten-year shorter life expectancy due to its long-term degenerative effects;

17. Diabetes can cause many health difficulties, including, but not limited to cardiovascular disease (as mentioned above), loss of vision/ blindness, nerve damage, kidney failure, pregnancy issues, oral disease and depression. The most significant long-term risk associated with diabetes is cardiovascular disease. Individuals with diabetes are two (2) to four (4) times more likely to develop cardiovascular disease than those without and cardio vascular disease is the most common cause of death in individuals with type 2 diabetes (Exhibit R-5 at page 31);

18. According to Statistics Canada, type 2 diabetes is the sixth leading cause of death by disease in Canada with 7,194 Canadians dying of the disease in 2011, the whole as appears more fully from a copy of the Statistics Canada Summary Table entitled "Leading causes of death, by sex (Both sexes)", produced herein as **Exhibit R-6**;

19. It should be noted that this statistical data may be significantly underestimated due to the fact that diabetes is not usually recorded as the primary cause of premature death; instead, it is its associated complications that are recorded on the death certificate. While, type 2 diabetes has been recorded as the cause of three (3%) percent of deaths in Canada (Exhibit R-6), a more accurate indicator of the mortality trend associated with diabetes would be in

the 25% to 30% range, which would include "death from diabetes complications" (Exhibit R-5 at page 37);

III. The Scientific Studies

20. The studies that follow demonstrate that taking LIPITOR significantly increases blood sugar levels and the risk of developing type 2 diabetes, especially in postmenopausal women;

21. In 2008, a systematic literature review was conducted to determine whether individual statins had different effects on insulin sensitivity in patients without pre-existing diabetes mellitus. It was concluded that results show a worsening of insulin sensitivity with the combination of atorvastatin, rosuvastatin and simvastatin, which is consistent with the increase that had been previously reported, the whole as appears more fully from a copy of the Diabetes Research and Clinical Practice journal article entitled "Differing effect of statins on insulin sensitivity in non-diabetics: A systematic review and meta-analysis" dated November 12th 2009, produced herein as **Exhibit R-7**;

22. Through a meta-analysis of clinical studies conducted between 1994 to 2009, it was determined that statin therapy was associated with 9% increased risk for incident diabetes[7], the whole as appears more fully from a copy of the Lancet journal article entitled "Statins and risk of incident diabetes: a collaborative meta-analysis of randomised statin trials" dated February 27th 2010, produced herein as **Exhibit R-8**;

23. Another study published by the Journal of the American College of Cardiology concluded that atorvastatin (statin) treatment resulted in increased risk of developing diabetes[8], the whole as appears more fully from a copy of the American College of Cardiology article entitled "Atorvastatin Causes Insulin Resistance and Increases Ambient Glycemia in Hypercholesterolemic Patients" dated March 23rd 2010, produced herein as **Exhibit R-9**;

24. The British peer-reviewed medical journal, QJM: An International Journal of Medicine[9], published a study that concluded that there was a "significantly increased rate of diabetes" associated with statin use and a "harmful effect associated with diabetes incidents"[10], the whole as appears more fully from a copy of said journal article entitled "Efficacy and safety of statin treatment for

[7] The findings are based on 13 statin trials with 91 140 participants, of whom 4278 (2226 assigned statins and 2052 assigned control treatment) developed diabetes during a mean of 4 years.
[8] Despite beneficial reductions in LDL cholesterol and apolipoprotein B, atorvastatin treatment resulted in significant increases in fasting insulin and glycated hemoglobin levels consistent with insulin resistance and increased ambient glycemia in hypercholesterolemic patients, which a trending towards developing diabetes
[9] At the time of publication, this paper was the "largest evaluation of statins to date".
[10] The authors combined evidence from all previous randomized controlled trials comparing a statin with placebo or usual care among patients with and without prior coronary disease to determine clinical outcomes.

cardiovascular disease: a network meta-analysis of 170 255 patients from 76 randomized trials" dated October 7th 2010, produced herein as **Exhibit R-10**;

25. Another study published in the American Journal of Cardiology concluded that blood sugar levels were increased in subjects who took LIPITOR over 2-3 weeks preceding the test. Furthermore, this study suggests that statins "cause worsening of glycemic control and increase insulin resistance"[11], the whole as appears more fully from a copy of said journal article entitled "Effects of Maximal Atorvastatin and Rosuvastatin Treatment on Markers of Glucose Homeostasis and Inflammation" dated February 1st 2011, produced herein as **Exhibit R-11**;

26. In 2011, the Journal of American College of Cardiology published a study that concluded that an 80mg dose of atorvastatin was associated with an increased risk of type 2 diabetes when compared with a placebo[12]. The study also concluded that "any potential increased risk of new-onset [type 2 diabetes] with atorvastatin might warrant careful monitoring" , the whole as appears more fully from a copy of said journal article entitled "Predictors of New-Onset Diabetes in Patients Treated With Atorvastatin: Results From 3 Large Randomized Clinical Trials", dated April 5th 2011, produced herein as **Exhibit R-12**;

27. In 2012, the Archives of Internal Medicine published a study that indicated that postmenopausal women of an average age of 63 years old who were on a statin at the beginning of the study had almost a 50% greater risk of diabetes than those who were not on the drug [13], the whole as appears more fully from a copy of said journal article entitled "Statin Use and Risk of Diabetes Mellitus in Postmenopausal Women in the Women's Health Initiative" dated January 23rd 2012, produced herein as **Exhibit R-13**;

28. In August 2012, Atherosclerosis Supplements published a review assessing current available evidence of statin use and diabetes and offered a clinical perspective regarding the claims that the use of statins increases the risk of type 2 diabetes. The conclusions of the study confirm that:

> "the balance of evidence now available suggests that statins are associated with an increased risk of diabetes and that there does appear to be a dose effect, with the risk of new-onset diabetes increasing with higher doses of statin therapy".

[11] The results of this study showed that both statins examined, rosuvastatin and atorvastatin (LIPITOR), significantly increased the median insulin levels by 8.7% and 5.2%, respectively, from baseline. Only atorvastatin was found to increase the glycated albumin levels from baseline.

[12] Results showed that 351 of 3,798 patients randomized to 80mg of atorvastatin and 308 of 3,797 randomized to 10mg developed new-onset T2DM, representing 9.24% and 8.11%, respectively

[13] Results show that 10,242 incident cases of self-reported [type 2 diabetes] over 1,004,466 person-years of follow-up, which indicates that Statin use at baseline was significantly associated with an increased risk of DM when compared with nonuse.

> …
> "In the meantime, whilst statin prescribing practice is unlikely to change due to the modest effects on diabetes risk, it is clear that patients being prescribed statins should be informed of potential diabetes risks (which the recent FDA label will facilitate), giving an additional incentive to undertake lifestyle changes. Such advice could help mitigate diabetes risk as well as further lower their CVD risks. Moreover, the recent statin-diabetes links further justify the need for combined CVD and diabetes risk assessments in many patients".

The whole as appears more fully from a copy of said journal article entitled "Statins are diabetogenic- Myth or Reality?" dated August 2012, produced herein as **Exhibit R-14**;

29. Again in April 2013, the American Journal of Cardiology published an article that analysed a meta-analysis of randomized controlled trials which concluded that high-dose atorvastatin is associated with type 2 diabetes, the whole as appears more fully from a copy of said journal article entitled "Meta-Analysis of Impact of Different Types and Doses of Statins on New-Onset Diabetes Mellitus" dated April 15th 2013, produced herein as **Exhibit R-15**;

30. In May 2013, the British Medical Journal published a study that performed a population-based retrospective cohort study in patients aged 66 and older in Ontario who started treatment with a statin from August 1st 1997 to 31 March 2010. The results of this study showed that patients treated with atorvastatin were at an increased risk of type 2 diabetes compared with the reference drug (Pravastatin). Notably, the researchers concluded:

> "After adjustment for known confounders, and compared with patients treated with pravastatin, those treated with faced a 22% increase in the risk of new onset diabetes.
> …
> Overall, we observed a 10-22% increased risk of diabetes for some statins that is consistent with findings from previously published meta-analyses of clinical trials.
> …
> Our population based assessment adds to the discussion of risk when doctors are considering starting statin treatment in a patient for primary versus secondary prevention."

The whole as appears more fully from a copy of said journal article entitled "Risk of incident diabetes among patients treated with statins: population based study" dated May 23rd 2013, produced herein as **Exhibit R-16**;

31. In summary, these studies confirm that there is indeed a significant increased risk of heightened blood sugar levels and of developing type 2 diabetes when taking LIPITOR and that the risk is most pronounced among postmenopausal women;

32. Many of these studies specify the importance of informing both patients, especially those most at risk, and healthcare professionals of these adverse side-effects so that they may make informed decisions regarding this medication. In addition, should the patient make an informed decision to take LIPITOR in spite of the serious risks, knowledge of these risks would allow their blood-sugar levels should be closely and consistently monitored;

33. The Respondents, in failing to advise doctors and patients of the increased risks associated with LIPITOR, effectively appropriated their ability to make informed decisions regarding its use and removed their ability to limit and/or control the risk through engaging in precautionary monitoring measures;

IV. The Associated Labelling Changes

34. On August 11th 2011, the Division of Metabolism and Endocrinology Products of the US FDA requested that Pfizer make labeling changes for LIPITOR based on the US FDA's comprehensive review of available data, including clinical trials;

35. On February 28th 2012, the Respondents responded to the US FDA request and added the following language to its "Warnings and Precautions" Section:

> "Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including LIPITOR";

36. Following the release of the FDA's comprehensive review and request for labeling changes, several federal lawsuits were filed against Pfizer Inc. in various United States courts, the whole as appears more fully from a copy of the complaints, produced herein *en liasse* as **Exhibit R-17**;

37. On September 4th 2012, the following language was added to LIPITOR's Product Monograph in Canada:

> "PART I: HEALTH PROFESSIONAL INFORMATION
> …
> **Endocrine and Metabolism**
> …
> Endocrine Function
> …

> Increases in fasting glucose and HbA1c levels have been reported with inhibitors of HMG-CoA reductase as a class. For some patients, at high risk of diabetes mellitus, hyperglycemia was sufficient to shift them to the diabetes status. The benefit of treatment continues to outweigh the small increased risk. Periodic monitoring of these patients is recommended.
>
> PART III: CONSUMER INFORMATION
> …
> Slightly increased blood sugar can occur when you take LIPITOR. Discuss with the doctor your risk of developing diabetes",

The whole as appears more fully from a copy of the September 4th 2012 Product Monograph for LIPITOR, produced herein as **Exhibit R-18**;

38. On January 24th 2013, Health Canada issued an advisory, informing Canadians of a labelling update for six (6) statins, including LIPITOR regarding the risk of increased blood sugar levels and the risk of developing diabetes, the whole as appears more fully from a copy of the Health Canada advisory entitled "New statins labeling update: Risk of increased blood sugar levels and diabetes" dated January 24th 2013, produced herein as **Exhibit R-19**;

39. Until the September 4th 2012 change (above in paragraph 37), LIPITOR's label had never warned patients of any potential relationship between changes in blood sugar levels and taking LIPITOR;

40. On the website, under the heading "Contraindications, Warnings and Precautions", only the following are listed:

> "You should not take LIPITOR if you:
> - Are allergic to any ingredient of this medication (click here to see what the medicinal ingredient is and what the important non-medicinal ingredients are)
> - Have active liver disease or unexplained increases in liver enzymes
> - Are pregnant or breast-feeding"

The whole as appears more fully from a copy of the "Contraindications, Warnings and Precautions" section of the website at www.lipitor.ca, produced herein as **Exhibit R-20**;

41. In the "Contraindications, Warnings and Precautions" section of the Respondents' website, the risk of developing type 2 diabetes is not even

mentioned among those listed, the whole as appears more fully from a copy of the Respondents' website at www.lipitor.ca, produced herein as **Exhibit R-21**;

42. Despite the labelling changes, LIPITOR's label continues to fail to warn consumers, healthcare professionals and the public:

    a) Of the serious and significant risk of developing type 2 diabetes;

    b) That postmenopausal women are particularly at risk of developing type 2 diabetes; and

    c) That people taking LIPITOR should closely and frequently monitor their blood sugar levels;

V. The Respondents' Liability

43. Although LIPITOR is designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labelled and/or sold as a safe and effective prescription drug that reduces cholesterol, it has the serious side effect of the increased risk of developing type 2 diabetes, especially in postmenopausal women;

44. A reasonably prudent drug designer, developer, manufacturer, tester, packager, promoter, marketer, distributer, labeller and/or seller in the Respondents' position would have adequately warned both doctors and patients of the risks associated with the use of LIPITOR;

45. Pfizer failed to exercise reasonable care and/or was negligent in the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labelling and/or sale of LIPITOR in one or more of the following respects:

    a) They knew of should have known that LIPITOR increased the risk of the adverse side effect of developing type 2 diabetes, which has severe and life-threatening complications;

    b) They failed to ensure that LIPITOR was not dangerous to consumers;

    c) They failed to conduct appropriate testing to determine whether and to what extent the ingestion of LIPITOR poses serious health risks, including the onset of type 2 diabetes;

    d) They failed to adequately test the product prior to placing it on the market;

    e) They failed to adequately test LIPITOR in a manner that would fully disclose the side effect of type 2 diabetes and the magnitude of the long-

term degenerative effects including heart disease, strokes, kidney failure, poor circulation, loss of limbs, and blindness;

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 LIPITOR could result in severe and disabling side effects, including but not limited to, type 2 diabetes and the magnitude of the long-term degenerative effects including heart disease, strokes, kidney failure, poor circulation, loss of limbs, and blindness;

i) They failed to advise the medical and scientific communities of the potential to increase the risk of type 2 diabetes and the magnitude of the long-term degenerative effects including heart disease, strokes, kidney failure, poor circulation, loss of limbs, and blindness;

j) They failed to provide adequate and timely warnings or sufficient indications about the increased potential health risks associated with the use of LIPITOR;

k) They failed to provide Class Members and their physicians with adequate warnings or sufficient indications of inherent risks associated with LIPITOR;

l) They failed to warn Class Members and their physicians about the need to undergo regular medical monitoring to ensure early discovery of elevated blood sugar levels to prevent the onset of type 2 diabetes;

m) They failed to provide adequate updated and current information to class members and their physicians respecting the risks of LIPITOR as such information became available;

n) They failed to provide prompt warnings of potential hazards of LIPITOR in the products' monograph and in the products' labelling;

o) They failed to warn that class members and their physicians that the risks associated LIPITOR would exceed the risks of other available cholesterol-lowering medications;

p) After receiving actual or constructive notice of problems LIPITOR, 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;

q) They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the risks associated with the drug;

r) They falsely stated and/or implied that LIPITOR was completely safe when they knew or ought to have known that this representation was false;

s) They disregarded reports of symptoms of elevated blood glucose levels and the onset of type 2 diabetes among patients who participated in clinical trials of LIPITOR;

t) They failed to accurately and promptly disclose to Health Canada information relating elevated blood glucose levels and the onset of type 2 diabetes associated with LIPITOR and to modify LIPITOR product monograph and product labelling accordingly in a timely manner;

u) They failed to monitor and to initiate a timely review, evaluation and investigation of reports of elevated blood glucose levels and the onset of type 2 diabetes associated with LIPITOR in Canada and around the world;

v) They failed to properly investigate cases of type 2 diabetes caused by LIPITOR;

w) They deprived patients of a chance for safe, effective and/or successful alternative treatments to reduce cholesterol; and

x) In all circumstances of this case, they applied callous and reckless disregard for the health and safety of their consumers;

46. Despite the vast availability of knowledge clearly indicating that LIPITOR use is causally-related to the development of type 2 diabetes and/or blood glucose levels diagnostic for type 2 diabetes, especially amongst postmenopausal women, Respondents not only failed to provide adequate labelling to warn Class Members of the risks associated with the use of LIPITOR, but instead incongruously promoted and marketed LIPITOR as a safe and effective drug, effectively usurping the ability of doctors and patients to make informed decisions regarding their health;

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

47. Petitioner was prescribed LIPITOR by her doctor and used it as directed beginning on or about February 26th 2008. She was 67 years old at the time;

48. Petitioner was prescribed and ingested LIPITOR in various strengths, including 80 mg, 40 mg and 20 mg;

49. Petitioner was prescribed LIPITOR to lower her levels of low-density lipoprotein ("LPL") and as a primary prevention measure in an effort to reduce her cholesterol and the risk of developing heart disease;

50. While on LIPITOR, Petitioner developed type 2 diabetes. On or about December 10th 2010, Petitioner began taking Metformin and on or about June 27th 2011, she starting taking Diabeta, all to control her type 2 diabetes;

51. Petitioner stopped taking LIPITOR on or about March 22nd 2012;

52. Petitioner recently become aware of the many individual personal injury actions against LIPITOR going on in the U.S. (referred to above) from their television advertisements, which led her to realize the direct causal relationship between her having taken LIPITOR and developing type 2 diabetes herself;

53. At no time was the Petitioner made aware of the risks of developing diabetes associated with taking LIPITOR;

54. Had Respondents properly disclosed the risks associated with LIPTOR, Petitioner would have avoided the risk of developing diabetes by either not using LIPITOR at all or by closely monitoring her blood sugar levels to see if the drug was adversely affecting her metabolism;

55. As a result of the Respondent's conduct, the Petitioner must, for the rest of her life, undergo regular testing of her blood sugar levels, adhere to a restrictive diet, and take medication to control her diabetes. Due to her diabetes, she is now at markedly increased risk of heart disease, blindness, neuropathy, and kidney disease;

56. Petitioner's damages are a direct and proximate result of her use of the drug LIPITOR, Respondent's negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug LIPITOR;

57. 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

58. Every member of the class has purchased and/or ingested the drug, LIPITOR or is the successor, family member, assign, and/or dependant of a person who purchased and/or ingested LIPITOR;

59. The class members' damages would not have occurred, but for the acts, omissions and/or negligence of the Respondents in failing to ensure that LIPITOR 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;

60. 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 LIPITOR side effect services;

    c. Loss of income and loss of future income;

    d. Refund of the purchase price of LIPITOR or alternatively, the incremental costs of LIPITOR 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;

    e. Punitive damages;

61. 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;

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

62. Some of the expenses related to the medical treatment that the class members have undergone or will undergo, will have been borne by the various

provincial health insurers, including the *Régie de l'assurance maladie du Québec* and the other provincial health plans such as the Ontario Health Insurance Plan. As a result of the Respondents' conduct, these various provincial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect to all past and future insured services. These subrogated interests are asserted by the Petitioners and the class members;

63. All of these damages to the class members are a direct and proximate result of the use of LIPITOR 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 renders the application of articles 59 or 67 C.C.P. difficult or impractical

64. Petitioner is unaware of the specific number of persons who ingested and/or purchased LIPITOR; however, it is safe to estimate that it is in the tens of thousands (if not hundreds of thousands);

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

66. 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 Respondents. Even if the class members themselves could afford such individual litigation, the court system could not as it would be overloaded. Further, individual litigation of the factual and legal issues raised by the conduct of the Respondents would increase delay and expense to all parties and to the court system;

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

68. 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;

69. 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 Respondents and that which the Petitioner wishes to have adjudicated upon by this class action</u>

70. Individual questions, if any, pale by comparison to the numerous common questions that predominate;

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

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

    a) Does LIPITOR cause, exacerbate or contribute to an increased risk of type 2 diabetes?

    b) Were the Respondents negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as designers, developers, manufacturers, testers, packagers, promoters, marketers, distributers, labellers and/or sellers of LIPITOR?

    c) Was LIPITOR designed, developed, manufactured, packaged and sold with defects that increase a patient's risk of type 2 diabetes?

    d) Does LIPITOR increase a patient's risk of developing type 2 diabetes as a result of its defects?

    e) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for LIPITOR?

    f) Did the Respondents fail to adequately and properly test LIPITOR before and/or after placing it on the market?

    g) Did the Respondents know or should have known about the risks associated with the use of LIPITOR?

    h) 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 LIPITOR?

    i) Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks of harm from the use/ingestion of LIPITOR?

j) Did the Respondents knowingly fail to disclose and warn of LIPITOR's defects?

k) Did the Respondents adequately and sufficiently warn the members and/or their physicians of the class about the risks associated with the use of LIPITOR?

l) Should LIPITOR have been sold with more appropriate warnings?

m) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that LIPITOR was safe or omitted to disclose material facts regarding LIPITOR's safety?

n) Did the Respondents fail in their duty to inform class members and/or their physicians about the importance of frequently monitoring blood sugar levels for patients taking LIPITOR so as to prevent the consequences that could result?

o) Were the members of the class prejudiced by taking LIPITOR instead of other cholesterol-lowering therapies, which have similar benefits, but do not pose an increased risk of developing type 2 diabetes and/or reduce such risk?

p) In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the class?

q) 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?

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

s) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking LIPITOR?

t) Are the members of the class entitled to recover as damages an amount equal to the purchase price of LIPITOR or any part of the purchase price?

u) Should Respondents be ordered to disgorge all or part of their ill-gotten profits received from the sale of LIPITOR?

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

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 Petitioner wishes to institute on behalf of the members of the class is an action in damages for the product liability of a drug manufacturer-distributer-seller;

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

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

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;

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

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 an amount sufficient to compensate the various provincial health insurers for the medical treatments and expenses that the class members have undergone and will continue to undergo in the future, and ORDER the Defendants to deposit in the office of this court these sums so as to establish a fund to be administered as this Honourable Court deems fit;

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 Petitioner requests that she be attributed the status of representative of the Class</u>

76. Petitioner is a member of the class;

77. Petitioner is ready and available to manage and direct the present action in the interest of the members of the class that she wish to represent and is 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 her attorneys;

78. Petitioner has the capacity and interest to fairly and adequately protect and represent the interest of the members of the class;

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

80. Petitioner, with the assistance of her 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. Petitioner has given instructions to her 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. Petitioner is 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 Respondents' conduct;

83. Petitioner understands the nature of the action;

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

85. Petitioner's interests are not antagonistic to those of other members of the class;

B) <u>The Petitioner suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal</u>

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

87. The Respondent Pfizer Canada Inc.'s head office is located in the judicial district of Montreal;

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

89. 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;

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

- all persons residing in Canada who have taken and/or purchased the drug, ATORVASTATIN CALCIUM (sold under the brand name LIPITOR®) since March 5th 1997, 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 have taken and/or purchased the drug, ATORVASTATIN CALCIUM (sold under the brand name LIPITOR®) since March 5th 1997, and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

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

a) Does LIPITOR cause, exacerbate or contribute to an increased risk of type 2 diabetes?

b) Were the Respondents negligent and/or did they fail in their duty of safety, and/or duty to inform imposed upon them as designers, developers, manufacturers, testers, packagers, promoters, marketers, distributers, labellers and/or sellers of LIPITOR?

c) Was LIPITOR designed, developed, manufactured, packaged and sold with defects that increase a patient's risk of type 2 diabetes?

d) Does LIPITOR increase a patient's risk of developing type 2 diabetes as a result of its defects?

e) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for LIPITOR?

f) Did the Respondents fail to adequately and properly test LIPITOR before and/or after placing it on the market?

g) Did the Respondents know or should have known about the risks associated with the use of LIPITOR?

h) 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 LIPITOR?

i) Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks of harm from the use/ingestion of LIPITOR?

j) Did the Respondents knowingly fail to disclose and warn of LIPITOR's defects?

k) Did the Respondents adequately and sufficiently warn the members and/or their physicians of the class about the risks associated with the use of LIPITOR?

l) Should LIPITOR have been sold with more appropriate warnings?

m) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that LIPITOR was safe or omitted to disclose material facts regarding LIPITOR's safety?

n) Did the Respondents fail in their duty to inform class members and/or their physicians about the importance of frequently monitoring blood sugar levels for patients taking LIPITOR so as to prevent the consequences that could result?

o) Were the members of the class prejudiced by taking LIPITOR instead of other cholesterol-lowering therapies, which have similar benefits, but do not pose an increased risk of developing type 2 diabetes and/or reduce such risk?

p) In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the class?

q) 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?

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

s) Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking LIPITOR?

t) Are the members of the class entitled to recover as damages an amount equal to the purchase price of LIPITOR or any part of the purchase price?

u) Should Respondents be ordered to disgorge all or part of their ill-gotten profits received from the sale of LIPITOR?

v) 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 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;

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

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 an amount sufficient to compensate the various provincial health insurers for the medical treatments and expenses that the class members have undergone and will continue to undergo in the future, and ORDER the Defendants to deposit in the office of this court these sums so as to establish a fund to be administered as this Honourable Court deems fit;

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 judgement to be rendered herein;

ORDER the publication of a notice to the members of the group in accordance with article 1006 C.C.P. within sixty (60) days from the judgement to be rendered herein in LA PRESSE and the GLOBE & MAIL;

ORDER that said notice be available on the Respondents' website with a link stating "Notice to LIPITOR prescribers and users";

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, March 24th 2014

(S) Jeff Orenstein

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CONSUMER LAW GROUP INC.
Per: Me Jeff Orenstein
Attorneys for the Petitioner