CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Action)

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No.: 500-06-000909-180

ANNIE MIDDLETON, residing and domiciled at 760 rue Principale, in the city of St-Leon-Legrand, Province of Québec, J0K 2W0;

Plaintiff

vs.

MYLAN SPECIALTY L.P. is a company incorporated under the laws of the state of Delaware and is headquartered at 110 Allen Road, 4th Floor in Basking Ridge, New Jersey in the United-States of America, 07920.

-and-

PFIZER CANADA INC. is a company incorporated under the laws of Canada and is headquartered at 17300 Trans-Canada Highway, Kirkland, Quebec, Canada, H9J 2M5.

Defendants

SECOND AMENDED ORIGINATING APPLICATION
(Articles 141 and 583 C.C.P.)

TO THE HONOURABLE ANDRE PREVOST, JUSTICE OF THE SUPERIOR COURT OF QUÉBEC, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PLAINTIFF STATES THE FOLLOWING:

1. On July 9th, 2019, the Honourable Judge André Prévost authorized the bringing of the present class action, as it appears in the Court file;

2. The judgment of authorization grants the Plaintiff the status of representative for the members of the group defined as follows:

> "All persons in Canada who, on or after March 31, 2017 possessed, for their potential individual use, an EpiPen auto-injector lot 5GU763 or lot 5GR765, and/or the legal guardian of those persons when minor or incapable, and who returned their auto-injector EpiPen as a result of the recall of March 31 and April 1, 2017 in return of a replacement."

(**Group Members** or the **Group**)

3. The common questions in fact and in law to be determined collectively at trial have are the following:

a) Was there a shortage of EpiPen auto-injectors at the distribution outlets during the period surrounding the recall of March 31 and April 1, 2017?

b) Did the Group Members encounter delays in obtaining a replacement of their EpiPen auto-injector?

c) Were the Defendants at fault or negligent in providing EpiPen auto-injectors to the distributors during the period surrounding the recall?

d) What damages have been suffered by the Group Members resulting from the delay in obtaining EpiPen auto-injectors replacement?

4. The conclusions sought in relation to the questions of fact and law that must be treated collectively, as mentioned in the judgment rendered on July 9th, 2019, were identified as follows:

CONDEMNS the Defendants to pay damages to every Group Member in an amount to be determined by the Court, plus interest and the additional indemnity;

ORDERS the treatment of individual claims of each Group Member in accordance with Articles 599 to 601 C.C.P.;

as it appears in the Court file;

I. Defendant Pfizer and Mylan

5.The Defendant, Mylan Speciality L.P. ("**Mylan Speciality**"), is a limited partnership organized under the laws of Delaware with its headquarters in Basking Ridge, New Jersey; as it appears on a page of the website of the State of New Jersey Business Records Service, https://www.njportal.com/DOR/businessrecords/EntityDocs/BusinessStatCopies.aspx, communicated herein as **Exhibit P-1;**

6.Defendant, Pfizer Canada Inc. ("**Pfizer Canada**") is incorporated pursuant to the Canada Business Corporations Act, and carries on business in Canada. Mylan Speciality conducts business in Canada, including in Quebec, as it appears in a copy of an extract from the *Registraire des entreprises du Québec*, produced herein as **Exhibit P-2**;

7.The business of Mylan Specialty and Pfizer Canada includes designing, developing, testing, manufacturing, marketing, and sale of EpiPens in Quebec and Canada;

8.The Applicant or Class Members could not reasonably be expected to know which of the Defendants has committed which individual act or omission at this stage;

9.Each of the Defendants are part of a common enterprise, one worldwide corporate entity, acting together for common goals. Each created and executed a common business plan to manufacture and sell the EpiPens throughout the world including in Quebec. The Defendants are therefore solidarily liable for the acts and omissions of the other;

10.Hereinafter Mylan Specialty and Pfizer Canada will be collectively referred to as the "**Defendants";**

General Facts**:**

Allergies and Anaphylaxis

11.Food allergies affect as many as 6% of young children and 3-4% of adults. These are triggered when an individual's immune system mistakes a food protein for something harmful. Exposure to the food protein can cause anaphylaxis. Anaphylaxis can be fatal after exposure to the allergen. Common food allergies include nuts, milk, soy, wheat, and shellfish. Anaphylaxis can also be triggered through insect bites or stings, and medicines;

12.Anaphylaxis has a rapid onset, is severe, and can affect the entire body. The tongue may swell, and blood pressure plummets, and consciousness can be lost. If there is no treatment administered, it can lead to death. Each onset of anaphylaxis is treated as a life-threatening medical emergency;

13.Epinephrine, also known as adrenaline, is a medication and hormone that is used to treat severe allergic reactions in emergency situations. These allergic reactions include anaphylaxis. Epinephrine also treats anaphylaxis caused by unknown substances or triggered by exercise;

14.The EpiPen is the brand name of an epinephrine injection device, or auto-injector;

15.Patients suffering anaphylaxis require the epinephrine to be injected into the muscle of their outer thigh. The EpiPen delivers a pre-measured doze via a spring-loaded needle. This can be done by the individual suffering anaphylaxis, or by a caregiver. It is a first line of defence before seeking additional medical assistance;

16.Patients at risk for anaphylaxis are advised to carry an epinephrine injection device like an EpiPen with them at all times. They are carried because a patient is unlikely to know in advance when or if a serious allergic reaction will occur;

17.Serious allergic reactions, left untreated, can have significant and catastrophic medical consequences, including death. Death can occur in as little as 30 minutes if epinephrine is not administered in a child;

18.The EpiPen Auto-Injector is the number one dispensed epinephrine auto-injector. Food Allergy Canada's National Guidelines include an "Anaphylaxis Emergency Plan" for individuals to file to ensure that they are treated appropriately during anaphylaxis. The first step in case of a reaction is to give an epinephrine auto-injector. EpiPen is listed as the example of an auto-injector;

The Defendants' Roles

19.Mylan Specialty is identified by Health Canada as the market authorization holder, and the entity responsible for producing the product monograph with respect to EpiPens;

20.EpiPens are sold in Canada under the following Drug Identification Numbers ("**DIN**"): 00578657 and 00509558;

21.Pfizer Canada is the Canadian distributor of the EpiPens, and the entity responsible for marketing and distributing the EpiPens in Canada;

22.The business processes, involvement, and individual roles of the Defendants are interwoven and integrated in a manner that is known only to the Defendants;

23.The Defendants shared the common purpose of producing, manufacturing, marketing, selling, or distributing EpiPens in Canada for profit. The business and interests of the Defendants are interwoven and each is the agent of the other;

24.At all material times, the Defendants were involved in producing, manufacturing, marketing, selling, or distributing EpiPens in Canada directly or through agents, affiliates, or subsidiaries; produced herein as **Exhibit P-3 the product monographs**;

Recalls

25.On April 1, 2016, after consultations with Health Canada, the Defendants voluntarily recalled one lot of EpiPen auto-injector and one lot of EpiPen Jr. auto-injector ; produced herein as **Exhibit P-4 the recall notice from Health Canada**;

26.The affected EpiPens were:

a) EpiPen (0.3 mg epinephrine) auto-injector lot 5GU763, expiry date May 2017, 67844 units distributed in Canada; and

b) EpiPen Jr (0.15 mg epinephrine) auto-injector lot 5GR765, expiry date March 2017, 39503 units distributed in Canada;

27.The recall was conducted following two confirmed international reports of EpiPens failing to activate;

28.It was reported that recalled EpiPens may contain a defective part that may result in the auto-injector failing to activate or requiring increased force to activate;

29.Failure of the auto-injector to activate may result in patients not receiving the required dose of adrenaline (epinephrine), resulting in the worsening of symptoms of anaphylaxis or anaphylactic reactions, which could be life threatening;

30.Other countries affected by the EpiPen recall include, but are not limited to Norway, Denmark, Finland, Ireland, Australia, New Zealand, and Japan;

31.As a consequence of the recall, pharmacies across Canada, including in Quebec, saw a lowered supply of EpiPens;

32.After the recall, Group Members including the Plaintiff were unable to obtain a replacement device for a certain period of time calculated in weeks, that delay was cause because of the Defendants negligence;

33.The Defendants should have had enough replacements devices for every consumers who needed an EpiPen after the recall;

34. (…)

35. (…)

Assertions

36. (…)

37. (…)

38.Each Class Member purchased or used an EpiPen, expecting that the EpiPen would provide potentially life-saving benefits should a severe allergic reaction occur;

39. (…)

40. (…)

41. (…)

42.The Defendants were negligent in providing sufficient numbers of replacement devices after the recall. The consequence was that Group Members were unable to obtain a replacement device for weeks;

43.That shortage of Epipens caused Group Members, among other consequences, severe mental distress because Epipen is a product that is created to be an emergency treatment when someone is victim of a life threatening anaphylaxis reaction;

44. (…)

45. (…)

46.As a direct and proximate result of the Defendants' negligence that cause the shortage of EpiPens, the Plaintiff and Class Members suffered injury, economic loss, and damages, for which the Defendants are jointly and severally liable;

47. (…)

48.As a consequence of the recall, EpiPen users, including the Plaintiff, were left without access to a reliable emergency epinephrine device and were exposed to an increased risk of serious physical harm, including death for several weeks ;

II. The Representative Plaintiff, Annie Middleton

49.The Plaintiff, Annie Middleton is a resident of St-Leon Québec~~;~~

50.The Plaintiff has not, to date, had a severe allergic reaction requiring that they use EpiPen;

51.The Plaintiff has, in the past, been treated at the emergency room, on an emergency basis, for a severe allergic reaction;

52.The Plaintiff was diagnosed food allergies to Latex contact and vaporization aerosol, which are serious enough to be considered life-threatening;

53.The Plaintiff was alarmed to learn that, had she had the need to use EpiPen in response to a severe allergic reaction, the product may not have functioned properly or at all and she didn't have in her possession a replacement device after the recall;

54.As a result of the recall, the Plaintiff was put to the trouble of locating and obtaining a replacement device, inconveniencing them, endangering them and causing them to incur out of pocket costs;

55.The Plaintiff did not have a replacement device available at her pharmacy for her safety for several weeks causing her mental distress and other damages;

IV. Defendant's Liability

56.Defendants researched, designed, tested, manufactured, marketed, labeled, distributed, promoted and sold EpiPen in many countries including Canada;

57. ~~(…)~~

58.The Defendants have marketed and developed a product that is possibly affected by a safety defect under the article 1468 of the Civil code that cause the recall;

59. ~~(…)~~

60.The Group Members have incurred injuries and losses from the ~~(…)~~ shortage of the EpiPen, including expenses relating to medical treatment sought and received, physical injuries, 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;

61.The Group Members have suffered and will continue to suffer physical and mental injuries and other losses, or damages due to the shortage of EpiPen, and claim damages as a result;

62. ~~(…)~~

63. ~~(…)~~

64. ~~(…)~~

65.At all material times, Defendants failed to provide the Group Members with a replacement Epipen device after the recall for several weeks, leaving the Group Members without a device that can save their life in emergency situation;

66. ~~(…)~~

67.Consumers reasonably relied and rely upon the Defendants to ensure that the EpiPen were safe for their intended use and that the Defendants had enough replacement devices after the recall to prevent a shortage of Epipen;

68.Defendants are liable for the damages suffered by the Plaintiff and the Group Members in that Defendants ~~(…)~~ failed to replace defective product, failed to have the appropriate number of replacement device available for their client ~~(…);~~

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

70.Each Member of the Group is entitled to claim damages because of the faults and/or negligence of the Defendants, which include but are not limited to 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;

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the Plaintiff's, Annie Middleton, action against the Defendants;

CONDEMNS the Defendants to pay damages to every Group Member in an amount to be determined by the Court, plus interest and the additional indemnity;

ORDERS the treatment of individual claims of each Group Member in accordance with Articles 599 to 601 C.C.P.;

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

Montréal, November 16, 2020

Merchant Law Group

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MERCHANT LAW GROUP LLP

Attorneys for the Plaintiff