C A N A D A

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

N° : 500-06-000909-180

S U P E R I O R C O U R T
(Class Action)

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

Applicant

-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

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

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

GENERAL PRESENTATION

1. The Applicant wishes to institute a class action on behalf of the following Class, of which she is a member, namely:

   a. All persons in Canada who, on or after November 2015, purchased or was injected with an EpiPen (0.3 mg epinephrine) auto-injector or EpiPen Jr. (0.15 mg epinephrine) auto-injector (hereinafter, collectively referred to as an "**EpiPen**" or "**EpiPens**") (the "**User Class**"); and,

   b. Spouses, children, grandchildren, parents, grandparents, brothers, sisters and guardians of the User Class who, by reason of their relationship with members of the User Class, are entitled to assert a claim (the "**Family Class**"),

   Henceforth referred to as the "**Class**" or as "**Class Members**".

The Defendants

2. 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;**

3. 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**;

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

5. 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;

6. 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;

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

General Facts**:**

Allergies and Anaphylaxis

8. 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;

9. 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;

10. 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;

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

12. 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;

13. 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;

14. 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;

15. 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

16. 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;

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

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

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

20. 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;

21. 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

22. 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**;

23. 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;

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

25. 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;

26. 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;

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

28. As a consequence of the recall, pharmacies across Canada, including in Saskatchewan, saw a

lowered supply of EpiPens;

29. Individuals at risk for anaphylaxis found themselves in possessions of a device that were intended to save their lives, that may be faulty, with no way to test their efficacy;

30. Others may have experienced personal injuries that could have been prevented, had their EpiPens been working;

Assertions

31. EpiPens which were manufactured, designed, sold, distributed, supplied, or placed in the stream of commerce by the Defendants, were defective in their manufacture when they left the hands of the Defendants;

32. In particular, the product grossly deviated from performance standards expected by the consumer, such that it failed to perform the one critical task that it was expected to perform, placing each and every customer at risk of a serious, potentially life threatening, allergic reaction;

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

34. The EpiPens were in fact incapable of reliably delivering these benefits. Thus, each Class Member has common claims that are founded on the same underlying facts as the Plaintiff's, as they pertain to the acts and omissions of the Defendants;

35. The Defendants did not take appropriate or necessary precautions to ensure that the manufacture, testing, and quality assurance processes used with respect to EpiPens were sufficient to ensure the safety and effectiveness of the EpiPens;

36. The Defendants communicated the purported benefits of EpiPen with the intent that consumers, including the Plaintiff and members of the EpiPen Classes, would purchase and

inject themselves with an EpiPen;

37. The Defendants misled the Plaintiff and members of the Class by and through statements made by the Defendants, their authorized agents, or sales representatives (or through doctors and pharmacists). These representations that EpiPens were safe, effective, and fit and proper for their intended use were made orally and in publications, package inserts, and other written materials to the health care community and the general public;

38. Despite the fact that the Defendants knew or ought to have known prior to the recall that EpiPens failed to perform as expected such that it may not counter severe allergic reactions and therefore posed a serious increased risk of injury, bodily harm, or death to consumers, the Defendants did not take the appropriate and timely steps to notify consumers and EpiPen Class Members or to recall the product. When the Defendants became aware of the defect, they did not act with the timeliness required to minimize the potential damages to the Plaintiff and the Class;

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

40. The Plaintiff and members of the Class did not discover and could not have discovered through the exercise of reasonable diligence the existence of the product defect alleged herein prior to April 2017 when the recall was announced;

41. 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;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE APPLICANT

42. The Applicant, Annie Middleton is a resident of St-Leon Québec and her son Jean-Christophe

Boivin is also a resident of Quebec;

43. The Applicant, and her son have not, to date, had a severe allergic reaction requiring that they use EpiPen;

44. The Applicant has, in the past, been treated at the emergency room, on an emergency basis, for a severe allergic reaction and her son as well has been treated for an allergic treatment;

45. The Applicant has diagnosed food allergies to Latex contact and vaporisation aerosol, which are serious enough to be considered life-threatening while the Applicant's son has an allergy to bee stings;

46. The Applicant was alarmed to learn that, had he had the need to use EpiPen in response to a severe allergic reaction, the product may not have functioned properly or at all;

47. 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;

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

48. Each Member of the Group purchased or used EpiPens, expecting that their EpiPens would provide potentially life-saving benefits should a severe allergic reaction occur;

49. EpiPens were in fact incapable of reliably delivering these benefits. Thus, each Group Member have common claims that are founded on the same underlying facts as the Petitioner's as they pertain to the acts and omissions of the Respondents;

50. Each Member of the Group suffered damages directly related to the purchase or use of the EpiPens;

51. Each Member of the Group was put to the inconvenience of seeking out and obtaining a replacement device;

52. All of these damages to the Class Members are a direct and proximate result of the Defendants' conduct;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

53. **The composition of the Class makes the application of Article 91 or 143 C.C.P. impractical or impossible for the reasons detailed below:**

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 the Petitioner at the present time and can only be ascertained from sales and distribution records maintained by the Respondents and its agents, it is estimated, as indicated in Exhibit P-3, that over 100,000 EpiPen units have been recalled in Canada;

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

c) In addition, given the costs and risks inherent in an action before the Courts, many people will hesitate to institute an individual action against the Defendants. Even if the Group Members themselves could afford such individual litigation, the Court system could not as it would be overloaded. Furthermore, 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 judicial system;

d) Moreover, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province) risks having contradictory judgments on questions of fact and law that are similar or related to all Group Members;

54. **The recourses of the Group Members raise identical, similar, or related questions of fact or law, namely:**

a) Were EpiPens unsound, defective, unsafe or unfit for the purpose for which it was intended?

b) Were the Defendants, or any of them, negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling, or selling of the EpiPens to the Group Members?

c) Did the Respondents know or should they have known that the EpiPens were defective, and if so, from what time?

d) Did the Respondents adequately advise and warn the Group Members of the non-adequacy and risks of the EpiPens?

e) Did the purchase or use of the EpiPens cause physical, moral, or other injuries?

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

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

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

55. The questions of fact and law particular to each member consist of:

a) The amount of damages suffered;

b) The amount of damages that each Group Member can claim from the Respondents;

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

56. The action that the Applicant wishes to institute for the benefit of the members of the Class is an action in damages for latent defect, negligence and product liability;

57. The conclusions that the Applicant wishes to introduce by way of an application to institute proceedings are:

GRANT the Petitioner's action against the Respondents;

AUTHORIZE the Petitioner to commence this action as a class action;

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

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

CONDEMN the Respondents to pay an amount in punitive and/or exemplary damages to every Group Member, in an amount to be determined by the Court, or a lump sum to be apportioned by the Court, plus interest as well the additional indemnity;

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

ORDER the treatment of individual claims of each Group Member 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;

58. Applicant suggests that this class action be exercised before the Superior Court in the District of Montreal for the following reasons:

a) Many Class Members are domiciled in the District of Montreal;

b) The Defendants have a business establishment in the District of Montreal;

c) Many of the EpiPens were purchased by Class Members in the District of the Montreal;

d) The Applicant's counsel is domiciled in the District of Montreal;

59. The Applicant, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the Members of the Class, since Applicant:

a) purchased Epipens, with the expectation that it would be used and relied upon in emergency situations;

b) suffered damages from purchasing and using the Epipens;

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 Class;

d) is available to dedicate the time necessary for the present action before the Courts of Quebec 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 the Applicant 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 Class;

g) has given the mandate to the undersigned attorneys to obtain all relevant information to the present action and intend 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 Class and to keep them informed;

i) The present application 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:

a. All persons in Canada who, on or after November 2015, purchased or was injected with an EpiPen (0.3 mg epinephrine) auto-injector or EpiPen Jr. (0.15 mg epinephrine) auto-injector (hereinafter, collectively referred to as an "EpiPen" or "EpiPens") (the "User Class"); and,

b. Spouses, children, grandchildren, parents, grandparents, brothers, and sisters of the User Class who, by reason of their relationship with members of the User Class, are entitled to assert a claim (the "Family Class"),

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) Were EpiPens unsound, defective, unsafe or unfit for the purpose for which it was intended?
b) Were the Respondents, or any of them, negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling, or selling of the EpiPens to the Group Members?
c) Did the Respondents know or ought to have known that the EpiPens were defective, and if so, from what time?
d) Did the Respondents adequately advise and warn the Group Members of the non-adequacy and risks of the EpiPens?
e) Did the purchase or use of the EpiPens cause physical, moral, or other injuries?
f) Are the Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?

g) Are the Respondents liable to pay moral damages to the Group Members, and if so, in what amount?
h) Are the 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 the Petitioner's action against the Respondents;

AUTHORIZE the Petitioner to commence this action as a class action;

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

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

CONDEMN the Respondents to pay an amount in punitive and/or exemplary damages to every Group Member, in an amount to be determined by the Court, or a lump sum to be apportioned by the Court, plus interest as well the additional indemnity;

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

ORDER the treatment of individual claims of each Group Member in accordance with Articles 1037 to 1040 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 expert's 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 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.;

THE WHOLE with costs to follow.

MONTRÉAL, February __, 2018

MERCHANT LAW GROUP LLP
Attorneys for the Petitioner

MERCHANT
LAW GROUP LLP

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

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

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

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

Content of Answer

In your answer, you must state your intention to:

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

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

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

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

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

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

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

These Exhibits are available upon request.

Notice of presentation of an application

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

Montreal, February__, 2018

_____

Merchant Law Group LLP
10 rue Notre Dame Est, suite 200
Montréal (Québec) H2Y 1B7
Phone : 514-842-7776
Fax : 514-842-6687
Notifications : rdupont@merchantlaw.com
Attorneys for the Applicant

NOTICE OF PRESENTATION

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

TO: **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

TO: 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.

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

PLEASE ACT ACCORDINGLY.

Montreal, February____, 2018.

Commented [JA1]:

Commented [JA2R1]: Missing a word?

Commented [JA3]: Ensure the month is right.

_____

Merchant Law Group LLP
Attorneys for the Applicant