CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

No.: 500-06-000772-158

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

FRANÇOIS MICHAUD, [redacted];

The Petitioner

vs.

SANOFI-AVENTIS CANADA INC., a legal person duly constituted, with its principal establishment located at 2905 Place Louis-R.-Renaud, Laval, Quebec, H7V 0A3;

- and -

SANOFI-AVENTIS U.S. LLC, a legal person duly constituted with its principal establishment located at 55 Corporate Drive, Bridgewater, NJ, 08807-5925, United States of America;

- and -

SANOFI S.A., a legal person duly constituted with its principal establishment located at 54 rue La Boétie, 75008, Paris, France;

- and -

SANOFI WINTHROP INDUSTRIE, a legal person duly constituted with its principal establishment located at 20, avenue Raymond Aron, 92165, Antony Cedex, France;

- and -

MEDIVATIVE TECHNOLOGIES LLC, a legal person duly constituted with its principal establishment located at 2950 North Catherwood Avenue, Indianapolis, Indianapolis, 46219, United States of America;

The Respondents

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

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

1) The Petitioner wish to institute a class action on behalf of the following Group, of which they are members, namely:

All persons in Canada who, on or after December 11th, 2012, purchased or ingested "Allerject", also known as "Auvi-Q", including DIN02382059/0.15mg/0.15mL epinephrine and DIN02382067/0.3mg/0.3mL epinephrine ("**Allerject**")

(hereinafter referred to as the "Group Members" or the "Group");

THE RESPONDENTS

2) The Respondent Sanofi-aventis Canada Inc. ("**Sanofi Canada**") is incorporated pursuant to the *Canada Business Corporations Act*, and carries on business in Canada, with offices at 2905 Place Louis-R.-Renaud, Laval, Quebec, H7V 0A3, as it appears from a copy of a report from the Registre des Enterprises, to be filed as **Exhibit P-1**, and a copy of a report from Corporations Canada, to be filed as **Exhibit P-2;**

3) The Respondent Sanofi S.A. ("**Sanofi SA**") is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue

La Boétie, 75008 Paris, France, as it appears from a copy of a report from the Registre du Commerce et des Societies (Greffe de Tribunal de Commerce de Paris), to be filed as Exhibit **P-3;**

4) The Respondent Sanofi-aventis U.S. LLC ("**Sanofi USA**") is incorporated pursuant to the laws of the State of Delaware, and is a wholly owned subsidiary of Sanofi SA, having its principal place of business at 55 Corporate Drive, Bridgewater, NJ, 08807-5925, United States of America. Sanofi USA has appointed Corporation Service Company as a registered agent for service, with offices at 2711 Centerville Rd, Suite 400, Wilmington, Delaware, 19808, United States of America, as it appears from a copy of a report from the Department of State, Division of Corporations, to be filed as Exhibit **P-4**;

5) The Respondent Sanofi Winthrop Industrie, also referred to by Sanofi as the *Commercial & External Partnership Industrial Affairs* organization ("**Sanofi CEPIA**") a legal person duly constituted with its principal establishment located at 20, avenue Raymond Aron, 92165, Antony Cedex, France, as it appears from a copy of a report from the Registre du Commerce et des Societies (Greffe de Tribunal de Commerce de Paris), to be filed as Exhibit **P-5**;

6) The Respondent Medivative Technologies LLC ("**Medivative**") is a legal person duly constituted pursuant to the laws of the State of Indiana, having its principal place of business at 2950 N Catherwood Avenue, Indianapolis, Indiana, 46219, United States of America. Medivative has named David M. Berry, at 6205 E 30th Street, Indianapolis, Indiana, 46219, United States of America, as its registered agent for the service of documents, all of which appears on a report from the Indiana Secretary of State, to be filed as Exhibit **P-6**;

7) The business processes, involvement, and individual roles of Sanofi Canada, Sanofi SA, Sanofi USA, and Sanofi CEPIA are interwoven and integrated in a manner that is known only to the Respondents. As such, Sanofi Canada, Sanofi SA, Sanofi USA, and Sanofi CEPIA are henceforth referred to collectively as "**Sanofi**";

8) Sanofi and Medivative shared the common purpose of producing, manufacturing, marketing, selling, or distributing Allerject in Canada for profit. The business and interests of the Respondents are interwoven and each is the agent of the other, as evidenced by the description of their collaboration which appears on Sanofi CEPIA's web site (as at October 31st, 2015), to be filed as Exhibit **P-7**. In particular:

> **March 2013**
>
> On January 28, 2013 Sanofi launched AuviQ™ in the US and Allerject in Canada for the emergency treatment of life threatening allergic reactions in people who are at risk for anaphylaxis.
>
> Sanofi US has licensed the rights to AuviQ™ in North America from Intelliject who had developed this drug/device combination. Under this license agreement Sanofi was responsible to develop and manage the industrialization of the AuviQ™ product for commercial use. This involved oversight and management by Sanofi's Commercial & External Partnership Industrial Affairs (CEPiA) organization, External Manufacturing (EM) North America. EM North America was assisted in this highly complex process through consultation and support from Frankfurt Devices, SME consultants, Industrial Development & Innovation (ID&I) and the main Contract Manufacturing Organization (CMO) for assembly, Medivative.
>
> Challenges for this project included working through 20+ individual device design changes, creating a robust trainer device, fine-tuning the supply chain process with 19 suppliers in 6 countries and 3 continents, developing unique packaging for 5 SKUs for the US, 6 SKUs in Canada and creating a specialized state of the art final assembly line and auxiliary equipment at a cost of USD17 million.

> This flexible manufacturing line takes 17 assembled parts and performs the final assembly and is built concurrently with final product design which includes 17 in process cameras checking each step of assembly and the use of 20 robots with overall capability of assembling 6 million active devices per year. Sophisticated inline systems check for correct audio script, LED indicators, amount of drug dispensed, needle length at time of dispense, dispense time, and needle retraction time.

9) At all material times, the Respondents were involved in producing, manufacturing, marketing, selling, or distributing Allerject in Canada directly or through agent(s), affiliate(s), or subsidiaries;

10) Allerject (also known in the United States as “Auvi-Q”) is described in Exhibit P-7 by Sanofi CEPIA as “the first and only compact epinephrine autoinjector with audio and visual cues that guide patients and caregivers step by step through the injection process. Auvi-Q is the size and shape of a credit card, the thickness of a cell phone. In addition to being an autoinjector, Auvi-Q features an automatic retractable needle mechanism to help prevent accidental needle sticks”.

11) Sanofi Canada is identified by Health Canada as the market authorization holder, and the entity responsible for producing the product monograph (the “**PM**”) with respect to Allerject, a copy of which is to be filed as Exhibit **P-8**;

12) Medivative was, in conjunction with Sanofi or under contract with Sanofi, responsible for the production of Allerject units, as referenced in Exhibit P-7 and as demonstrated by Medivative’s web site as it appeared on October 23rd, 2015, a copy of which is to be filed as Exhibit **P-9**;

13) At some point between October 23rd, 2015 at 14:35:38 GMT and October 31st, 2015, the references on Medivative's web site to their involvement with Allerject were removed. The Medivative web site as it appeared on October 31st, 2015 is to be filed as Exhibit **P-10**;

ALLERJECT

14) As described in the product monograph, the active ingredient in an Allerject dispenser is epinephrine. Allerject is intended to be used as a first-line response to severe allergic reactions, including reactions to foods, insects, medications, latex, and other allergens;

15) Patients prescribed this medication are to self-inject, or have a caregiver inject, as soon as an allergic reaction is identified, as a first line of defence before seeking additional medical assistance;

16) Patients typically use Allerject in emergency situations, and are expected to carry it with them at all times in circumstances where they are 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;

18) According to the PM:

> Research shows that fatalities from anaphylaxis are often associated with failure to use epinephrine or a delay in the use of epinephrine treatment. Epinephrine should be administered as early as possible after the onset of symptoms of a severe allergic response. Patients requiring epinephrine will not always have predictable reactions. Adequate warning signs are not always present before serious reactions occur. … Epinephrine may prove to be life saving when used as directed immediately following exposure to an allergen.

19) Allerject is marketed as a safe and easy means of injecting epinephrine to counteract allergic reactions. Typically, only four steps are required (see p. 20 of the PM): removal of the Allerject injector from its outer protective casing, removal of a red plastic safety guard, pressing the injector firmly against the middle of the outer thigh for approximately five seconds, and then seeking emergency medical care;

20) On June 13th, 2013, Sanofi Canada recalled two lots of the pediatric (0.15mg/0.15mL) variant of Allerject (lot nos. 2857505 and 2857508) (the "**First Recall**"), due to an unspecified "manufacturing defect", as indicated in their press release to be filed as Exhibit **P-11**;

21) Health Canada reported that the manufacturing defect affected the needle, and as a result of the defect "the device may not deliver the epinephrine needed for emergency treatment of serious allergic reactions" and warned particularly of the risk that anaphylaxis could result in death, in their recall alert posted June 16th, 2015 and to be filed as Exhibit **P-12**;

22) On October 28th, 2015, Sanofi Canada recalled <u>all</u> Allerject products (the "**Second Recall**"), because "the products have been found to potentially have inaccurate dosage delivery", as indicated in their press release to be filed as Exhibit **P-13**;

23) A parallel recall of all Allerject products in the United States, there known as Auvi-Q, was commenced on October 28th, 2015;

24) Health Canada characterized this as a product safety issue, as evidenced by the recall alert posted October 28th, 2015 and to be filed as Exhibit **P-14**;

FAULTS COMMITTED BY THE RESPONDENTS

25) Allerject which was manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by the Respondents, was defective in its manufacture when it left the hands of the Respondents. 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 serious, potentially life threatening, allergic reactions;

26) The Respondents did not take appropriate or necessary precautions to ensure that the manufacture, testing, and quality assurance processes used with respect to Allerject were sufficient to ensure the safety and effectiveness of Allerject;

27) The Respondents communicated the purported benefits of Allerject with the intent that consumers, including the Petitioner, would purchase and ingest Allerject;

28) The Respondents misled the Petitioner by and through statements made by the Respondents, their authorized agents, or sales representatives (or through doctors and pharmacists). These representations that Allerject was safe, effective, and fit and proper for its intended use were made orally and in publications, package inserts, and other written materials to the health care community and the general public;

29) In purchasing and using Allerject, the Petitioner relied on the representations made by the Respondents to the healthcare community and the public. As a direct result of the Respondents' faults, the Petitioner and other Group Members suffered physical and moral damages, and are entitled to be compensated;

30) Despite the fact that the Respondents knew or ought to have known prior to the First Recall that Allerject 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 Respondents did not take the appropriate and timely steps to notify consumers and Group Members or to recall the product. When the Respondents became aware of the defect, they did not act with the timeliness required to minimize the potential damages to the Petitioner and the Group Members;

31) Despite the fact that the Respondents knew or ought to have known prior to the Second Recall that Allerject 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 Respondents did not take the appropriate and timely steps to notify consumers and Group Members or to recall the product. When the Respondents became aware of the defect, they did not act with the timeliness required to minimize the potential damages to the Petitioner and the Group Members;

32) As a direct and proximate result of the Respondents' negligence, the Petitioner and Group Members suffered injury, economic loss, and damages, for which the Respondents are jointly and severally liable;

33) Each Member of the Group is entitled to claim compensatory damages directly caused by the faults of the Respondents, as well as moral damages;

34) Moreover, pursuant to the *Consumer Protection Act*, R.S.Q., c. P-40.1, each Member of the Group is entitled to punitive damages due to the gravity of the faults committed by the Respondents;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

35) The Petitioner, François Michaud, is a resident of Montréal, Québec.

36) Mr. Michaud was prescribed and initially obtained Allerject (0.3mg/0.3mL, DIN 02382067) on or about December 2014;

37) Mr. Michaud has not, to date, had a severe allergic reaction requiring that he use Allerject;

38) Mr. Michaud has, in the past, been treated at the emergency room, on an emergency basis, for a severe allergic reaction;

39) Mr. Michaud has diagnosed food allergies to pink fish and shellfish, which are serious enough to be considered life-threatening;

40) Mr. Michaud was alarmed to learn that, had he *had* the need to use Allerject in response to a severe allergic reaction, the product may not have functioned properly or at all;

41) As a result of the recall, Mr. Michaud was put to the trouble of locating and obtaining a replacement device;

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

42) Each Member of the Group purchased or used Allerject, expecting that Allerject would provide potentially life-saving benefits should a severe allergic reaction occur;

43) Allerject was 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;

44) Each Member of the Group suffered damages directly related to the purchase or use of Allerject;

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

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

46) The composition of the Group makes the application of Articles 59 or 67 C.C.P. impractical for the following reasons:

a) The number of potential Group Members is so numerous that joinder of all Members is impracticable. While the exact number of Group Members is unknown to 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-9, that at least 492,000 Allerject units have been distributed 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 Petitioner 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 Respondents. 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;

47) The recourses of the Group Members raise identical, similar, or related questions of fact or law, namely:

a) Was Allerject 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 Allerject to the Group Members?

c) Did the Respondents know or ought to have known that Allerject was 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 Allerject?

e) Did the use of Allerject 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?

48) 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;

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

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

51) The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings are for the Court to:

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;

52) The Petitioner suggest that this class action be exercised before the Superior Court in the District of Montréal for the following reasons:

a) The Respondents have sold Allerject in the District of Montréal;

b) The Petitioner reside in the District of Montréal;

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

d) The Petitioner's legal counsel practise law in the District of Montréal.

53) The Petitioner, who are requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the members of the Group since the Petitioner:

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

b) suffered damages from purchasing and using Allerject;

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

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 Petitioner wish to represent, and are determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Group;

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

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

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

54) The present motion is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present Motion;

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

All persons in Canada who, on or after December 11th, 2012, purchased or ingested “Allerject”, also known as “Auvi-Q”, including DIN02382059/0.15mg/0.15mL epinephrine and DIN02382067/0.3mg/0.3mL epinephrine

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) Was Allerject 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 Allerject to the Group Members?
c) Did the Respondents know or ought to have known that Allerject was 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 Allerject?
e) Did the use of Allerject 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 Québec* and with full costs and expenses including experts' fees and publication fees to advise members;

MONTRÉAL, November 2, 2015

(s) Merchant Law Group LLP

MERCHANT LAW GROUP LLP
Attorneys for the Petitioner