CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Action)

No: 500-06-000788-162

JOAN LETARTE residing and domiciled at [redacted], Province of Quebec, [redacted]

Representative Plaintiff

vs.

BAYER INC., legal person duly constituted, having its head office at 2920 Matheson Boulevard East, Mississauga, Ontario, L4W5R6

and

BAYER CORPORATION, having its head offices at 100 Bayer Road in Pittsburgh Pennsylvania, 15205, U.S.A.

and

BAYER HEALTHCARE LLC, legal person duly constituted, having its head office at 1011 McCarthy Boulevard Milpitas, CA, 95035, U.S.A.,

Defendants

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

TO AN HONORABLE JUDGE OF THE SUPERIOR COURT OF QUEBEC, IN SUPPORT OF HER MOTION, THE PLAINTIFF JOAN LETARTE RESPECTFULLY STATES THE FOLLOWING:

1. On March 20, 2019, the Honourable Judge Chantal Lamarche 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 women in Quebec, including their successors, assigns, family members, and dependants, who were implanted with Essure and who were diagnosed with urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia or autoimmune symptoms between July 1, 2011 and date of the judgment authorizing the class action..

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

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

a) Does Essure cause, exacerbate or contribute to a risk of having urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia and autoimmune symptoms?

(b) If so, did the Defendants commit a fault in failing to adequately warn the class members and or their physicians about a risk associated with the use of Essure?

(c) Did the Defendants commit a civil fault by marketing, packaging, promoting, advertising, distributing, labelling and selling Essure the way they did

(d) Are members of the class entitled to damages?

(e) Are members of the class entitled to punitive damages?

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 May 27 2016, were identified as follows:

ALLOW the class action of the members;

DECLARE; that the that the Defendants failed to provide adequate warnings with regards to the dangerous side effects of Essure;

CONDEMN The Defendants to pay to each Member of the class an amount to be established at trial;

CONDEMN The Defendants to pay each Member of the class damages other than punitive;

CONDEMN The Defendants to pay each Member of the class punitive damages;

CONDEMN The Defendants to pay interest and additional indemnity on the above sum according to law from the institution of the proceedings or the date of the judgement;

CONDEMN The Defendants to bear the costs of the present action including expert and notice fees;

THE WHOLE subject to individual recovery of the claims to be ordered in accordance with 599 to 601 C.C.P.;

THE WHOLE with court costs including experts, expert reports and the publication of the notices

as it appears in the Court file;

I. Defendant Bayer and Essure Device

5. In this originating application:

a)The Defendant, **Bayer Inc.**, is a corporation with offices at 2920 Matheson Boulevard East, Mississauga, Ontario,. At all material times, Bayer Inc. was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Essure in Canada. The development of Essure for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Essure and other actions central to the allegations of this lawsuit, were undertaken by Bayer Inc. in Quebec and elsewhere. Bayer Inc. does business throughout Canada, including within the province of Quebec;

b)The Defendant, **Bayer Corporation**, is an Indiana corporation with offices at 100 Bayer Road, Pittsburgh, Pennsylvania, U.S.A., 15205. At all material times, Bayer Corporation was engaged in the business of designing,

manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Essure in Canada. Bayer Corporation does business throughout Canada, including within the province of Quebec;

c)The Defendant, **Bayer Healthcare LLC**, is headquartered at 1011 McCarthy Blvd, Milpitas, CA, 95035 United States. Bayer Health Care LLC is a wholly owned subsidiary of Bayer AG. At all material times, Bayer Health Care LLC was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, Essure in Canada. Bayer Health Care LLC. does business throughout Canada, including within the province of Quebec,

d)**Essure**" is a permanent form of female birth control (female sterilization). In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage;

e)Hereinafter, Bayer Inc., Bayer Corporation, and Bayer Health Care LLC will be collectively referred to as "Bayer" or the "**Defendants**"

6. The Defendants acted through their employees, servants, and agents, and they are directly and vicariously liable. The Defendants are responsible for the actions, faults, omissions, discrimination, violations and/or negligence of their employees, servants and agents;

7. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use ;

8. The micro-inserts are comprised of two metal coils which are placed in a woman's fallopian tubes via Respondent's disposable delivery system and under hysteroscopic guidance which is in essence a camera ;

9. The hysteroscopic equipment needed to place Essure was manufactured by a third party, and is not a part of Essure. However, the Respondents regularly provided this equipment to physicians so they could sell Essure;

10. The coils are comprised of nickel, steel, nitinol, and PET fibers;

11. The Defendants' disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are allowed to visualize this complicated process through the hysteroscopic equipment provided by the Defendants;

12. After placement of the coils in the fallopian tubes by Respondents' disposable delivery system, the micro-inserts expand upon release and anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes;

13. The coils are alleged to remain securely in place in the fallopian tubes for the life of the consumer and not to migrate;

14. After three months following the device being implanted, patients are to receive a "Confirmation" test to determine that the micro-inserts are in the

correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpinogram ("HSG Test" or "Confirmation Test");

15. Regardless of the Confirmation Test, the Defendants also warrants that Essure allows for visual confirmation of each insert's proper placement during the procedure;

16. The Defendants also trained physicians on how to use its device and other hysteroscopic equipment, including Petitioner's implanting physician;

II. The Representative Plaintiff, Joan Letarte

17. The Plaintiff, Joan Letarte, is a resident of Montreal, Quebec;

18. The Plaintiff On or about July 29, 2012 the Petitioner was implanted with Essure at Ville LaSalle Hospital at 1811 avenue Dollard in LaSalle, Quebec;

19. The Plaintiff agreed to be implanted with Essure as a form of permanent birth control and she relied on claims made by the Respondents that Essure was a safe and effective method of permanent birth control;

20. After being implanted with Essure, the Plaintiff was experienced heavy bleeding and blood clots. The bleeding was so sever it impacted her ability to work. She experienced pain in her pelvic region, significant bloating and weight gain;

21. The Plaintiff's symptoms are so bad that her doctors have recommended surgery to remove the Essure implants. The Petitioner has been on a waiting list to have a hysterectomy since May 2015 ;

22. At no time was the Plaintiff made aware of the risks of pain, bleeding, bloating or weight gain associated with taking Essure ;

23. Had the Defendants properly disclosed the risks associated with Essure, the Petitioner would have avoided the risks associated with Essure by not being implanted with Essure and using a different form of birth control;

24. The Plaintiff has recently discovered, while researching online, that several lawsuits were filed in the United States due to the defects associated with Essure and due to the Respondents' conduct related thereto;

25. As a result of the Defendants' conduct, the Plaintiff suffered damages including, but not limited to physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life and increase risk of health problems, and the apportioned cost of the Essure;

26. Plaintiff's damages are a direct and proximate result of her being implanted with Essure, Defendants' negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the medical device Essure;

27. In consequence of the foregoing, Plaintiff is justified in claiming damages;

III. Defendant's Conduct

28. Although Essure is marketed, packaged, promoted, advertised, distributed, labelled and/or sold as a safe and effective medical device for permanent birth control, it has the serious side effects of increased risk of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

29. A reasonably prudent medical device researcher, designer, developer, manufacturer, tester, marketer, packager, promotor, advertiser, distributer, labeller and/or seller in the Defendants' position would have adequately warned both doctors and patients of the risks associated with the use of Essure;

30. There have been several reports of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms reported associated with the use of Essure;

31. Despite a clear signal, the Defendants failed to either alert the public and the scientific and medical community or to perform further investigation into the safety of Essure;

32. Despite the availability of knowledge indicating that Essure use is causally-related to urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms, the Defendants not only failed to provide adequate labelling to warn Class Members of the risks associated with the use of Essure, but instead incongruously promoted and marketed Essure as a safe and effective medical device, effectively appropriating the ability of doctors and patients to make informed decisions regarding their health;

33. The Defendants ignored the association between the use of Essure and the risk of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

34. Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by the Plaintiff and class;

35. At all pertinent times, the Defendants knew or should have known that the Essure was unreasonably dangerous and defective when put to their reasonably anticipated use;

36. As a direct and proximate result of the Defendants' negligence in one or more of the aforementioned ways, the Plaintiff was implanted with Essure and that directly and proximately caused both the Plaintiff and class to suffer injuries, incur medical bills, lost wages, and conscious pain and suffering;

IV. Defendant's Liability

37. The Defendants were negligent in the research, design, development, manufacture, testing, marketing, packaging, promotion, advertising, distribution, labelling and/or sale of Essure in one or more of the following respects;

a. They knew of should have known that Essure increased the risk of the adverse side effect of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

b. They failed to ensure that Essure was not dangerous to consumers;

c. They failed to conduct appropriate testing to determine whether and to what extent the implantation of Essure poses serious health risks, urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

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

e. They failed to adequately test Essure in a manner that would fully disclose the side effect of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

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 medical device;

h. They failed to advise that the implantation of Essure could result in severe and disabling side effects, including but not limited to, urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

i. They failed to advise the medical and scientific communities of the potential to increase the risk of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms;

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

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

l. They failed to provide adequate updated and current information to class members and their physicians respecting the risks of Essure as such information became available;

m. They failed to provide prompt warnings of potential hazards of Essure in the products' monograph and in the products' labelling;

n. They failed to warn that class members and their physicians that the risks associated Essure would exceed the risks of other available permanent birth control procedures;

o. After receiving actual or constructive notice of problems Essure, 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 medical device's inherent dangers;

p. They failed to establish any adequate procedures to educate their sales representatives and implanting physicians respecting the risks associated with the medical device;

q. They falsely stated and/or implied that Essure was safe when they knew or ought to have known that this representation was false;

r. They disregarded reports of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptom complications among patients;

s. They failed to accurately and promptly disclose to Health Canada

information relating to urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms associated with Essure and to modify Essure product monograph and product labelling accordingly in a timely manner;

t. They failed to monitor and to initiate a timely review, evaluation and investigation of reports of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms associated with Essure in Canada and around the world;

u. They failed to properly investigate cases of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms caused by Essure;

v. They deprived patients of a chance for safe, effective and/or successful alternative procedures; and

w. In all circumstances of this case, they applied callous and reckless disregard for the health and safety of their consumers

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT Plaintiff's action against the Defendants;

CONDEMN the Defendants 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 Defendants to pay an amount for costs of the present action including expert and notice fees to every Group Member, in an amount to be determined by the Court, plus interest as well the additional indemnity;

CONDEMN the Defendant to pay an amount in punitive and/or exemplary damages to every Group Member, in an amount to be determined by the

Court, plus interest as well the additional indemnity;

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

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

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

Montréal, August 8th, 2019

Merchant Law Group

MERCHANT LAW GROUP LLP

Attorneys for the Plaintiff

SUMMONS

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

Filing of a Judicial Application

Take notice that the Plaintiff has filed this originating application in the office of the Superior Court of Quebec in the judicial district of Montreal.

Respondents' 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 Plaintiff.

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 originating application, the Plaintiff intends to use the following exhibits:

n/a

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, August 8th, 2019

Merchant Law Group

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Attorneys for the Applicant

NOTICE OF PRESENTATION

TO: **BAYER INC.**,
2920 Matheson Boulevard East,
Mississauga, Ontario
L4W5R6
Canada

-and-

BAYER CORPORATION,
100 Bayer Road,
Pittsburgh, Pennsylvania
15205
U.S.A.

-and-

BAYER HEALTHCARE LLC,
1011 Mccarthy Boulevard,
Milpitas, California
95035
U.S.A.

TAKE NOTICE that the Petitioner has filed this ORIGINATING APPLICATION in the office of the Superior Court of the Judicial District of Montréal.

The Application will be presented before one of the Honourable Judges of the Superior Court of Québec, District of Montréal, on **a date to be fixed**, at Courthouse of Montréal situated at 1 Notre Dame East, Montréal, Québec. On that date, the Court may exercise such powers as are necessary to ensure the orderly progress of the proceeding or the Court may hear the case.

MONTRÉAL, August 8, 2019

Merchant Law Group

MERCHANT LAW GROUP LLP

Attorneys for the Petitioner