CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

SUPERIOR COURT
(Class Actions)

NO: 500-06-000788-162

JOAN LETARTE

Plaintiff

v.

BAYER INC.

and

BAYER HEALTHCARE LLC

Defendants

DEFENCE OF BAYER INC. AND BAYER HEALTHCARE LLC
(Art. 170 CCP)

IN DEFENCE TO THE ORIGINATING APPLICATION, THE DEFENDANTS RESPECTFULLY SUBMIT THE FOLLOWING:

I. THE PLAINTIFF'S ALLEGATIONS

1. With respect to the allegations contained in paragraphs 1 to 4 of the Originating Application, the Defendants Bayer Inc. and Bayer Healthcare LLC ("Bayer LLC") (the **"**Defendants**"**) refer to the judgment of the Honourable Justice Chantal Lamarche rendered on March 20, 2019, authorizing the present class action (the "Authorization Judgment"), and deny everything not in conformity therewith.

2. The Defendants deny the allegations contained in paragraphs 5 and 6 of the Originating Application as drafted.

3. The Defendants deny the allegations contained in paragraphs 7 to 15 of the Originating Application as drafted.

4. With respect to the allegations contained in paragraph 16 of the Originating Application, the Defendants admit that training was provided to Québec physicians who placed the Essure devices on how to use the Essure device but deny that they trained physicians on how to use other hysteroscopic equipment.

5. With respect to the allegations contained in paragraphs 17 to 21 of the Originating Application, the Defendants refer to the Plaintiff's medical records communicated

herewith under seal as **Exhibit D-1**, *en liasse*, and deny anything not in conformity therewith. The Defendants further deny the allegations contained in paragraph 19 of the Originating Application to the effect that the Plaintiff relied on any claims made by the Defendants as to the safety and efficacy of Essure.

6. The Defendants have no knowledge of the allegations contained in paragraphs 22 and 23 of the Originating Application and put the Plaintiff to the strict proof of same.

7. With respect to the allegations contained in paragraph 24 of the Originating Application, the Defendants state that any lawsuits filed in the United States relating to Essure against Bayer LLC are irrelevant to this proceeding.

8. The Defendants deny the allegations contained in paragraphs 25 to 27 of the Originating Application and put the Plaintiff to the strict proof of her alleged damages, which damages are denied.

9. The Defendants deny the allegations contained in paragraph 28 of the Originating Application.

10. With respect to the allegations contained in paragraph 29 of the Originating Application, the Defendants deny the implication that they failed to provide adequate warnings of the potential risks associated with the use of Essure, or that they failed to act in a reasonably prudent manner.

11. With respect to the allegations contained in paragraph 30 of the Originating Application, the Defendants admit that adverse events associated with Essure have been reported but add that any potential risks associated with Essure were properly disclosed at all material times, and that adverse event reports are of limited utility and do not establish medical or legal causation.

12. The Defendants deny the allegations contained in paragraphs 31 to 36 of the Originating Application. In particular, the Defendants deny that Essure was or is unreasonably dangerous and defective when used in accordance with its labelling.

13. The Defendants deny the allegations contained in paragraph 37 and in each of its subparagraphs, adding that these allegations are in any event insufficiently particularized or supported by evidence and are, therefore, irrelevant to the Plaintiff’s claim.

AND FOR FURTHER PLEA TO PLAINTIFF'S ACTION, THE DEFENDANTS SUBMIT THE FOLLOWING:

II. BACKGROUND

A. THE DEFENDANTS[1]

14. Bayer Inc. is a Canadian corporation that provides products that improve the health and quality of life of Canadians. Bayer Inc. did not design, manufacture, develop, distribute, package, label or sell Essure at any time relevant to the present class action.

15. Bayer LLC is a corporation pursuant to the laws of the United States. It is located in that country and carries on business there. Bayer LLC was not involved in the design or development of the Essure devices sold in Canada during the relevant period and did not have any involvement with Essure in Canada prior to June 2013.

16. Starting in approximately July 2013, Bayer LLC became responsible for the distribution and sale of Essure devices in Canada. As set out below, the sale of Essure was voluntarily discontinued in Canada as of August 31, 2017 for commercial reasons.

B. ESSURE

i. Overview of the Essure system

17. Essure is a medical device initially developed by Conceptus, Inc., a U.S. corporation located in California. It was indicated for women who desired permanent contraception.

18. At all relevant times, Essure was the only device licensed in Canada for non-surgical permanent female sterilization. The only other available method of permanent sterilization to Canadian women is laparoscopic tubal ligation ("LTL"). LTL is a surgical procedure performed under general anesthetic in which a woman's fallopian tubes are either clamped and blocked or severed and sealed.

19. The advantage of Essure over LTL was that Essure did not require surgery and typically did not require general anesthetic. The Essure device was placed hysteroscopically[2] in a woman's fallopian tubes. The placement could be

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[1] On November 30, 2021, the Honourable Justice Martin F. Sheehan, J.S.C., declared this class action to be expired (*périmée*) with regard to Bayer Corporation, given the Plaintiff's failure to serve the Originating Application on this entity within the prescribed delay, the whole as appears from the Court record. As a result, Bayer Corporation is no longer a Defendant in the present class action.

[2] Refers to placement via the uterus. Hysteroscopy is performed using a hysteroscope, a thin lighted tube that is inserted into the vagina to examine the cervix and inside of the uterus.

performed on an outpatient basis. As a result, many of the risks known to be associated with LTL were avoided with Essure.[3] Essure offered unique benefits to women who desired permanent sterilization, but who could not or chose not to undergo invasive surgery.

20. The Essure device consisted of two small spring-shaped micro-inserts or coils, as well as disposable delivery tools that assisted the physician in placing the micro-inserts hysteroscopically.

21. The Essure devices are designed to expand upon release to conform to and anchor into each fallopian tube where they caused a benign tissue ingrowth into and around each device. This tissue response holds the devices in place and occludes the fallopian tubes, resulting in permanent contraception.

22. As directed in the Essure labelling, patients implanted with the Essure device were required to use alternative contraception until a confirmation test performed three months post placement (the "Confirmation Test") confirmed that the devices were placed correctly, that the fallopian tubes were completely blocked, and that the patient could rely on Essure for contraception. The Confirmation Test used could include transvaginal ultrasound, pelvic x-ray, and/or hysterosalpingogram (HSG).

ii. Role of healthcare professionals

23. Essure devices were not sold to the general public or provided directly to patients. On the contrary, Essure devices were intended to be placed only by gynecologists who were skilled in hysteroscopy and who had completed Essure training.

24. Physicians in Québec and elsewhere play a key role in advising their patients on an appropriate birth control method, taking into consideration each patient's medical history, contraindications to certain methods, short and long-term contraceptive objectives, preferences, lifestyle factors, and age, as well as the available information about the risks and benefits associated with each contraceptive method.

25. The selection of an appropriate birth control method is thus an inherently individual and subjective decision, involving consideration of whether the benefits of a particular method outweigh its risks in the context of each patient's unique circumstances and preferences.

26. In every case, physicians who recommended, prescribed, and/or placed (as the case may be) any contraceptive method, including Essure, had the obligation to

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[3] Including adverse reactions to general anesthesia (including death), improper wound healing, and infection. LTL is also associated with other risks, including persistent pelvic or abdominal pain. The risks of LTL may be heightened in certain patients, such as those with a history of pelvic or abdominal surgery or adhesions, obesity, or other medical conditions.

discuss the potential risks and benefits of such contraceptive methods with their patients and decide, in each case, whether to recommend the use of any particular method, such as Essure. Physicians who placed the Essure device had the obligation to give clinical advice, information, and appropriate warnings to their patients concerning the benefits and potential risks of, and the alternatives to using the Essure device, and to provide their patients with the opportunity to ask further questions.

27. At all material times, physicians who placed the Essure devices were provided with detailed information about the device, its use, and its benefits and potential risks, including information and warnings concerning possible adverse events, as more fully discussed below at paragraphs 52 to 92.

C. PLAINTIFF'S CAUSE OF ACTION

28. The gist of the Plaintiff's claim is that Essure suffered from a safety defect which resulted from a lack of sufficient indications regarding the risks and dangers of the device and the means to avoid them. This proceeding is therefore not about a design or manufacturing defect.

29. The Defendants deny that Essure had a safety defect.

30. Two of the alleged harms Plaintiff states were associated with Essure – organ perforation and implant migration (e.g., movement to the distal fallopian tube) - are inherent risks associated with all implantable devices. These risks were well-known to physicians in Québec and elsewhere in Canada who placed the Essure devices and fully disclosed in the Essure labelling.

31. The other adverse effects alleged (urinary tract infections, menorrhagia, pelvic pain, and autoimmune symptoms) are all common in the general population of women of reproductive age and can result from numerous causes unrelated to Essure.

32. Despite the fact that adverse effects that occur among certain Essure patients may be attributable to causes unrelated to Essure, the potential risks associated with the use of Essure were disclosed in the Essure labelling at all times material to this proceeding.

33. Given that the causes of the health problems at issue in this case are known to be multifactoral, causation cannot be assessed on a collective basis, as more fully set out in section VII below.

III. THERE IS NO SAFETY DEFECT IN THE ESSURE DEVICES

A. ESSURE WAS APPROVED BY HEALTH CANADA

i. Overview of the medical device regulatory approval process

34. Health Canada regulates the sale of medical devices in Canada pursuant to the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (the "*Act*") and the *Medical Device Regulations*, SOR/98-282 (the "*Regulations*").

35. Pursuant to the *Act* and *Regulations*, Health Canada is charged with the implementation of a stringent regulatory review process which applies to manufacturers seeking to market a medical device in Canada.

36. The process begins with the initial licence application and continues, once a licence has been issued, through annual licence renewal submissions and reporting requirements, as well as through Health Canada's internal post-market safety screening processes.

37. The overall objective of the regulatory process is to ensure that medical devices sold in Canada are safe and effective when used as labelled and of high quality. Compliance with Health Canada's regulatory requirements is strictly enforced.

38. Pursuant to the *Regulations*, there are four classes of medical devices ranging from Class I (lowest risk) to Class IV (highest risk). Classification rules determine the extent of the premarket regulatory requirements for a proposed device prior to the marketing authorization being granted. As the classification of the device goes up, so does the level of premarket regulatory scrutiny.

39. Essure was a Class III medical device. Subject to certain other criteria that may increase risk classification, Class III medical devices are generally those that are intended to remain in the body for at least 30 consecutive days.[4]

40. A submission for a Class III medical device can include hundreds or thousands of pages of information relating to the device's safety and effectiveness. The submission for Essure included, inter alia, laboratory and clinical studies relating to the safety and effectiveness of Essure, as well as copies of the proposed labelling.

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[4] *Medical Device Regulations*, Schedule 1, Rule 2(3).

ii. Essure Medical Device Licence

41. Essure was initially developed by Conceptus, Inc., a U.S. company, as indicated above. Conceptus, Inc. prepared the submission for initial regulatory approval which it submitted to Health Canada on August 9, 2001.

42. In addition to the information contained in the Conceptus, Inc. initial submission, Health Canada requested supplementary or updated safety and efficacy information, as well as labelling revisions from time to time.

43. On November 23, 2001, Health Canada granted Conceptus, Inc. a Medical Device Licence with a condition for Essure (number 34212), as appears from a copy of the Medical Device Licence with a condition communicated herewith as **Exhibit D-2**.

44. The initial licence condition required Conceptus, Inc. to submit regular interim reports summarizing the results of the ongoing pivotal study on Essure until it was completed. Conceptus, Inc. submitted such reports to Health Canada in May and November 2002, as required.

45. On July 14, 2003, Health Canada removed the condition on the Essure Medical Device Licence and granted Conceptus, Inc. an unconditional Medical Device Licence, as appears from a copy of the Medical Device Licence communicated herewith as **Exhibit D-3**.

iii. Sale of Essure in Canada

46. Conceptus, Inc. was responsible for the marketing, distribution, and sale of Essure in Canada from November 2001 until approximately July 2013.

47. As of approximately July 2013, following an acquisition, Bayer LLC became the Medical Device Licence holder of Essure in Canada.

48. As noted above, sales of Essure were discontinued in Canada as of August 31, 2017 for commercial reasons.

49. Since the issuance of the initial Medical Device Licence in November 2001, Health Canada has reviewed and authorized various amendments to the Essure Medical Device Licence, including amendments relating to revisions to the Essure labelling, the whole as will be proved at trial.

50. At all times since the issuance of the initial Medical Device Licence for Essure in 2001, the Essure labelling and any revisions or amendments thereto were reviewed and approved by Health Canada.

51. At all times material to this class action, the distribution, marketing and sale of Essure in Canada was in accordance with the Medical Device Licences issued by

Health Canada and complied with the requirements of the *Act* and *Regulations* as well as the medical and scientific knowledge available at the time.

B. ESSURE HAS A POSITIVE SAFETY PROFILE

52. Essure was and remains a highly effective form of permanent contraception with a positive safety profile for women seeking permanent sterilization. As such, it affords the safety which a person is normally entitled to expect and did not have a safety defect.

53. All contraceptive methods, both temporary and permanent, are associated with potential risks, and some of these risks can be very serious or even fatal. For example, oral contraceptives have been associated with potential risks of myocardial infarction, stroke, and other serious medical complications.

54. In paragraph 28 of the Originating Application, the Plaintiff alleges that Essure carries an "***increased*** *risk of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms*" [emphasis added] but does not identify the relative comparator. When comparing the benefits and potential risks of Essure to other available means of contraception, the only meaningful comparator is another method of permanent sterilization. The only such method generally available to Canadian women is LTL.

55. LTL requires surgery and the administration of general anesthesia. Therefore, it can be associated with severe complications in some patients (e.g., complications from anesthesia, infection, organ or blood vessels damage, etc.). Furthermore, LTL is contraindicated in patients with certain risk factors, including obesity, previous pelvic or abdominal surgeries, and other underlying health problems, since the risk of severe complications in patients with these factors is increased.

56. In contrast, Essure placement was a non-surgical procedure, that could generally be performed using local anesthesia, and did not require abdominal access, since it was accomplished via hysteroscopy.

57. As a result, the types of surgical risks associated with LTL, as well as the time required for patient recovery, are reduced or eliminated for Essure patients.

58. The risks and benefits of Essure have been studied extensively, both prior to and after it received regulatory approval from Health Canada. Clinical and post-approval studies have consistently shown that Essure is highly effective at achieving permanent sterilization and is associated with a high degree of patient satisfaction and comfort.

59. As with every medical device or procedure, Essure has been associated with certain potential risks, including the risk of adverse events during and after placement.

60. The potential risks associated with Essure are less significant than, or in the alternative, no greater than, those associated with LTL.

61. To date there are over one hundred clinical and post-market studies that have been conducted on Essure that involve over 270,000 Essure patients, including to date, 17 studies that compare the safety and efficacy of Essure to LTL. The results of these comparative studies confirm overall that Essure does not result in increased medical issues when compared to LTL.

62. These comparative studies provide a robust body of data that generally shows that Essure use is associated with fewer hysterectomies, less pelvic pain, and comparable rates of abnormal bleeding when compared with LTL.

C. POTENTIAL RISKS OF ESSURE WERE KNOWN AND/OR DISCLOSED

63. At all relevant times during the class period, the potential risks associated with Essure were appropriately disclosed in the Health Canada approved device labelling, all of which conformed to the applicable principles embodied in the *Act* and in the *Regulations*.

64. At all material times during the class period, Essure was marketed, distributed, and sold in Canada in a manner consistent with the Health Canada approved device labelling.

65. In paragraph 28 of the Originating Application, the Plaintiff alleges that Essure carries the "*[…] risk of urinary tract infections, perforated organs, implant migration, pelvic pain and autoimmune symptoms*". The Plaintiff alleges that the Defendants failed to adequately disclose or warn of these risks. In other places in the Originating Application, reference to a risk of menorrhagia is also made. These allegations are addressed in more detail below.

i. Perforated organs and implant migration

66. The potential risks of organ perforation (or damage), implant migration (e.g., movement to the distal fallopian tube) and/or device malposition were at all material times well known and inherent potential risks of any implanted medical device, including Essure. At all material times, these risks would have been understood by physicians in Québec and elsewhere placing the Essure device to be rare, but possible, outcomes.

67. Clinical and post-approval studies have consistently shown that rates of perforation and migration with the Essure device are low.

68. These potential risks are not uniquely associated with Essure. They exist with other implanted medical devices, including other forms of contraception or sterilization.

For example, the Filshie clip, a common medical device used in LTL, also carries a risk of migration.

69. Moreover, these adverse events may be caused or contributed to by various other intervening causes unrelated to the alleged acts or omissions of the Defendants, including the anatomy or physiology of the patient and/or physician error.

70. In any event, these potential risks were adequately disclosed via the Essure labelling at all times material to this class action. Furthermore, the Essure labelling disclosed strategies for mitigating these risks and addressing them when and if they arose, including the risk that surgery including a hysterectomy may be required, at all material times.

71. Thus, the Defendants deny that the potential risk of perforated organs or implant migration constituted a safety defect.

ii. Pelvic pain and menorrhagia

72. The potential risks of pelvic pain and menorrhagia (abnormally heavy or prolonged menstrual bleeding) were also well-known potential adverse events associated with most implantable contraceptive devices, including Essure. At all material times, these risks would have been understood by physicians placing the Essure device to be possible outcomes.

73. Clinical and post-approval studies have consistently shown that rates of pain and abnormal bleeding with the Essure device are low and are lower than, or equivalent to, the rates of these complaints in patients undergoing LTL. Studies confirm that the vast majority of Essure patients report a high rate of satisfaction and comfort with the Essure device.

74. These potential risks are not uniquely associated with Essure. Pelvic pain and menorrhagia are common conditions among women of reproductive age in the general population. These conditions can result from various possible causes unrelated to Essure, including but not limited to: patients' pre-existing or underlying health or medical conditions; and the cessation of hormonal birth control methods concomitantly or shortly after Essure placement.[5]

75. Notably, patients undergoing Essure placement tend on average to be older and have higher rates of comorbidities than patients who undergo LTL, as appears

[5] Discontinuation of hormonal birth control may bring to light pre-existing or underlying conditions that have been previously "masked" by the hormones.

from Plaintiff's exhibit P-10 (*Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*).[6]

76. While some patients have reported resolution of symptoms such as pain and abnormal bleeding following the removal of the Essure device, this does not establish a causal link between Essure and those symptoms since device removal often requires surgical removal of the uterus (hysterectomy), which may independently be the source of the symptoms being experienced. When Essure devices are removed as part of a hysterectomy, it is not possible to determine whether the symptoms resolved due to the removal of the uterus or the Essure device.

77. The current and existing scientific data does not provide any basis to conclude that Essure causes any increased risk of pelvic pain or menorrhagia in patients implanted with the device as compared to LTL.

78. Despite the fact that these adverse events may be attributable to causes other than Essure, the possibility of experiencing abdominal/pelvic pain, cramping, and/or abnormal bleeding both during and after Essure placement were expressly disclosed in the Essure labelling at all times material to this class action.

79. Thus, Essure does not have a safety defect relating to pelvic pain or menorrhagia.

iii. Autoimmune symptoms

80. In the Originating Application, the Plaintiff does not particularize the specific symptoms that are included in the category of "autoimmune symptoms".

81. The Plaintiff communicated as one of her exhibits the Health Canada May 25, 2016 Summary Safety Review regarding Essure (exhibit P-13) which notes that "*some women have reported symptoms including fatigue, depression, mood swings, bloating, nausea, weight gain, headaches and hair loss*".

82. To the extent that "autoimmune symptoms" are defined to include any of the above, such symptoms are highly prevalent in the general population and are associated with various other conditions and disease states, as well as other pharmaceutical products or devices, including other contraceptives. These are common symptoms that are not uniquely associated with autoimmune diseases and are more commonly associated with conditions other than autoimmune disease.

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[6] Compared with the patients undergoing laparoscopic sterilization, a larger proportion of patients undergoing hysteroscopic sterilization (i.e., insertion of the Essure device) were over 40 years old and had one or more comorbidities. Prevalence of previous pelvic inflammatory disease was also higher among patients undergoing hysteroscopic sterilization. Patients in the hysteroscopic group were also more likely to have a history of major abdominal surgery or cesarean section.

83. No definitive or causal link between the use of Essure and the development of these types of non-specific symptoms can be demonstrated. These symptoms may be caused by any number of factors unrelated to Essure.

84. To the extent that the Plaintiff alleges that it is the materials used in the Essure device that cause “autoimmune symptoms”, the Essure device is composed of materials that have a long history of safe and advantageous use in implantable medical devices.

85. There is no basis to conclude that either the Essure device or any of the materials from which it is made cause any increased risk of “autoimmune symptoms” in patients implanted with the device.

86. Notwithstanding the above, the Essure labelling has at all material times disclosed the possibility of an allergic reaction to the device in patients allergic to nickel titanium.

87. Thus, Essure does not have a safety defect relating to “autoimmune symptoms”.

iv. Urinary tract infections

88. The potential general risk of infection is a well-known and inherent risk associated with any invasive gynecological device or procedure, including Essure. At all material times, this risk would have been understood by Québec physicians who placed the Essure device to be a possible outcome of the Essure placement procedure.

89. The Essure device is not introduced through or placed in the urinary tract. The Defendants deny that the Essure device causes any increased risk of urinary tract infections specifically, outside of the general risk of infection associated with any invasive gynecological device or procedure.

90. Neither infections generally, nor urinary tract infections specifically, are risks uniquely associated with Essure. These are common conditions in the general population, including among women of reproductive age. Infections, including urinary tract infections, can result from various possible causes unrelated to Essure.

91. Nevertheless, the possibility of an infection arising from the Essure placement procedure was adequately disclosed in the Essure labelling at all times material to this class action.

92. Thus, Essure does not have a safety defect relating to urinary tract infections.

D. RELIANCE ON ADVERSE EVENTS REPORTS

93. Reporting adverse events associated, or possibly associated, with a medical device is voluntary for the general population but mandatory for market authorization holders, as required by the *Act* and the *Regulations*. There is no requirement upon those who report adverse events voluntarily to investigate whether the device was the cause of the adverse event. Anyone, including patients, caregivers, physicians, nurses, and dentists, can report an adverse event regarding a medical device available on the Canadian market.

94. All medical devices or medications approved for use in Canada are associated with such voluntary reports of spontaneous adverse events. In the case of Essure, such reports of adverse events are rare when considered as a proportion of the women implanted with Essure.

95. Voluntary spontaneous adverse event reports are also subject to significant limitations, including incomplete, inaccurate, untimely, unverified, or biased data. This renders it impossible to draw conclusions about overall incidence rates or causation from these reports. They also do not involve a control group.

96. Among other important limitations, voluntary spontaneous adverse event reports associated with medical devices cannot be used to:

    a) conclude that the event actually occurred;

    b) conclude that the event was actually caused by the device;

    c) conclude that each report reflects a unique event or patient;

    d) determine the overall incidence rate of the reaction or symptom reported among users of the device; or

    e) determine the relative risk of the reaction or symptom among users of the device when compared with users relying on other contraceptive methods.

97. Furthermore, the number of voluntary adverse event reports can be influenced and exaggerated by external events, such as media attention (social or traditional media) or potential or actual litigation. While steps may be taken to identify duplicative reports, it is possible for the same event to be reported by multiple sources.

98. In short, voluntary, spontaneous reports of symptoms or adverse events associated with Essure do not establish any causal relationship between the reported symptom or event and the Essure device. Moreover, they do not indicate that the Essure device is defective or unsafe, or that its clinical benefits do not outweigh any potential risks for any particular patient.

99. As will be proved at trial, there are many alternative and/or confounding causes that can explain or contribute to the development of the types of adverse events and symptoms alleged by the Plaintiff, including a patient's underlying or pre-existing health or medical conditions, or the cessation of oral contraceptives.

100. At all material times, the Defendants complied with Health Canada's requirements in respect of reporting adverse event information that they received.

101. Health Canada completed two safety reviews of the Essure device in 2014 and 2016. At no time has Health Canada ever required that sales of Essure be ceased in Canada or concluded that the potential risks of Essure outweighed its clinical benefits. The decision to stop marketing the device in Canada was made voluntarily in 2017, for commercial reasons.

102. On May 30, 2016, Health Canada published a Notice to Canadian Healthcare Professionals relating to the risks associated with Essure (the "Notice"). A copy of the Notice is communicated herewith as **Exhibit D-4**.

103. The purpose of the Notice was to ensure that Canadian patients were being fully informed by their physicians of the potential risks and complications associated with the Essure device prior to choosing to undergo Essure placement. The potential risks and adverse events, that are referred to in the Notice, were well known to Canadian OB/GYNs at that time.

E. THE DEFENDANTS FULFILLED ALL THEIR DUTIES AND OBLIGATIONS

104. At all material times, the marketing, distribution, and sale of Essure in Canada was regulated by the *Act* and the *Regulations*. To the extent that the Defendants were involved in the marketing, distribution, and/or sale of Essure in Canada, they complied with and fulfilled the statutory requirements at all material times.

105. Compliance with these requirements demonstrates that the Defendants were not negligent with respect to Essure, including with respect to any duty to warn, and that Essure did not have a safety defect.

106. Essure has been fully approved (without conditions) by Health Canada for use in Canadian women since 2003.

107. The safety and efficacy of Essure are demonstrated by an extensive body of pre-clinical, clinical, and post-market scientific research conducted by Conceptus, Inc., Bayer LLC, and independent medical researchers and involving more than 270,000 women over the past two decades.

108. At all material times, the Defendants made timely and adequate disclosure to Health Canada and to Canadian physicians of, among other things:

a) the potential risks associated with the use of Essure;

b) contraindicated medical or health conditions for use of Essure;

c) warnings and precautions related to the use of Essure;

d) up-to-date instructions for the use of Essure;

e) adverse reactions and side effects associated with the use of Essure; and

f) other safety information.

109. The Essure labelling has always reflected the relevant available medical and scientific information regarding the potential risks associated with the device at that time. Such risks were adequately disclosed at all material times in the Essure labelling, which was approved by Health Canada.

110. Essure was always marketed, packaged, promoted, advertised, distributed, labelled, and sold in conformity with Health Canada's requirements and the requirements of the *Act* and *Regulations*.

111. The Defendants have never made any false, misleading, or deceptive statements regarding Essure to Health Canada, Canadian physicians or patients.

VI. CONCLUSION ON THE EXISTENCE OF A SAFETY DEFECT

112. For all the reasons above, the Defendants deny having committed any fault and deny the existence of any safety defects with the Essure devices

113. The indications as to the risks associated with Essure, which is the only type of safety defect that may be at issue in the present case, were sufficient throughout the class period.

VII. INDIVIDUAL ISSUES

114. Even if the Tribunal were to conclude that there was a safety defect in the Essure devices:

a) for a part, or the totality, of the class period; and

b) for a part, or the totality, of the health problems at issue (i.e., urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia and "autoimmune symptoms");

such a conclusion would not be sufficient to establish the Defendants' liability towards any of the class members.

115. Once the existence of a safety defect has been established, two other elements must be proven on a balance of probabilities according to the usual rules of evidence; namely, (1) an injury and (2) causation between the safety defect of the product in question and the injury suffered.

116. Even assuming that it might be possible to assess the existence of a safety defect on a collective basis, injury and individual (specific) causation can only be determined on an individual basis.

A. CLASS MEMBERS' ALLEGED INJURY

117. To establish the existence of an injury, it is not sufficient for a class member to simply allege that she suffered from one of the health problems at issue here (i.e., urinary tract infections, perforated organs, implant migration, pelvic pain, menorrhagia, and "autoimmune symptoms"). Class members cannot simply diagnose themselves and claim that they suffered from the type of injury at issue in this case.

118. The existence of an injury can only be established on the basis of individualized inquiries involving each class member.

119. Thus, the existence of the injury for each class member cannot be established collectively during the trial of the common issues.

B. CAUSATION

i. Medical causation

120. As detailed above at paragraphs 52 to 92, most of the health problems at issue here are common in the general population of women of reproductive age, and all of them may be caused by numerous risk factors, including the anatomy or physiology of the patient**,** and/or by various other unrelated causes, including the fault of another person (for example a medical error from the physician implanting the device).

121. There is no legal or factual presumption of causation in this case. Causation between a safety defect in the Essure devices (the existence of which is denied) and the injury suffered by the members of the class (once proven on an individual basis) also cannot be addressed collectively and requires individualized inquiries.

ii. Knowledge of the risks

122. There is no causation between the safety defect and the alleged injury if the class member knew or could have known of the defect or could have foreseen the injury suffered.

123. Essure is only intended to be placed by a trained physician. The physicians placing Essure were thus learned intermediaries interposed between the Defendants and patients.

124. The Defendants discharged their duty to warn class members regarding the potential risks associated with Essure by providing adequate warnings to physicians.

125. Physicians placing Essure had the duty to inform themselves of the benefits and potential risks associated with the device, and to exercise their independent judgment as medical experts based on their knowledge of their patient and the device. The patients who consented to the placement of Essure relied primarily on their physician's judgment and recommendation.

126. Thus, independent of the warnings included in the Essure labeling, the Plaintiff or any of the class members may have been told about the risks by a competent intermediary or even acquired such knowledge from other sources, in which case the Defendants cannot be held liable.

127. The Plaintiff or any of the class members may not have relied on the Essure labelling or may not have acted differently if the labelling had contained any additional warnings or disclosures.

128. The Defendants cannot be held liable if causation is not established for each class member. Causation cannot be established collectively. It necessarily requires individualized inquiry.

C. PRESCRIPTION

129. In her decision authorizing this proceeding, Justice Chantal Lamarche, J.S.C., deferred the issue of the prescription of the Plaintiff's claim to the merits stage.[7]

130. She also established July 1, 2011 as the starting point of the class period.[8]

131. As a result, establishing whether or not a class member's claim is prescribed also requires an individualized inquiry.

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[7] Authorization Judgment, para. 65-67.

[8] Instead of April 15, 2013, i.e., three years before the filing of the Application to authorize the bringing of a class action and to ascribe the status of representative, because otherwise, the Plaintiff would not have been a class member: Authorization Judgment, para. 65-67 and 81-84.

VIII. DAMAGES

A. COMPENSATORY DAMAGES

132. Despite the fact that the entitlement of class members to damages has been identified as a common question,[9] this question also requires individualized inquiry for each class member. It cannot be answered on a collective or class-wide basis.

133. To be entitled to damages, a class member must first and foremost demonstrate that she suffered from an injury, and that there is medical causation between such injury and the alleged safety defect in the Essure devices (the existence of which is denied). For the reasons detailed above, such a determination can only be made on an individual basis in the present case.

134. Also, the Defendants must have failed to prove that the class member knew or should have known of the defect or have foreseen the injury, or that the class member's claim is prescribed. Again, as detailed above, these assessments can only be made individually.

135. Given that the entitlement to compensatory damages depends on the Defendants' liability regarding each class member's claims, and that such liability can only be assessed on an individual basis, it is simply not possible to determine on a collective or class-wide basis whether class members are entitled to damages.

136. The Plaintiff recognizes this in her conclusions sought when she refers to the treatment of individual claims of each class member to be dealt with pursuant to articles 599 to 601 CCP.

137. This contradicts the conclusions sought with respect to a condemnation in damages for each class member at the conclusion of the common issues trial which this Court cannot do for the reasons detailed above.

138. The nature and quantum of damages to which each class member may be entitled will also necessarily depend on her specific circumstances and injuries.

139. Any entitlement to compensatory damages needs to be addressed individually.

B. PUNITIVE DAMAGES

140. The Plaintiff and the class members have no right to an award of punitive damages since the relevant criteria are not satisfied.

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[9] Authorization judgment, paras 78-80.

141. The Defendants did not unlawfully and intentionally interfere with the right to life, security, and integrity of the members of the class.

142. There are no allegations whatsoever in the Originating Application pertaining to any unlawful and intentional violation to the rights and freedoms protected by the *Charter*.

143. There is simply no statutory basis or factual basis for awarding punitive damages in this case.

144. Moreover, even if there was (which is vigorously denied) the quantum of punitive damages, if any, could only be established after the total quantum of individual claims for compensatory damages (moral and/or pecuniary) has been determined.

IX. THE PLAINTIFF'S PERSONAL CLAIM IS ILL-FOUNDED

145. The Plaintiff's personal situation illustrates the reasons why even if the Plaintiff was able to demonstrate, on a balance of probabilities, that there was a safety defect in the Essure devices, which is denied, the Defendants' liability towards each class member will have to be determined individually.

146. The Defendants submit that the Plaintiff's personal claim is ill-founded for two reasons: i) it is prescribed; ii) the Plaintiff's injuries were not caused by Essure.

i. Plaintiff's case is prescribed

147. The Defendants submit that the Plaintiff's claim is prescribed, as will be established at trial.

148. As appears from the Court record, the Plaintiff filed her Application for Authorization on April 15, 2016.

149. As appears from Plaintiff's medical record (Exhibit D-1, under seal), the Plaintiff had her Essure devices placed on July 29, 2011, and not on July 29, 2012, as alleged at paragraph 18 of the Originating Application.

150. The Plaintiff herself admitted that the health problems she claims to have suffered would have appeared shortly after the Essure devices were installed.

151. The Plaintiff also admitted that as soon as 2011 she was convinced that Essure was the cause of her health problems.

152. Thus, even if the Plaintiff's health problems had been caused by Essure, which is denied for the reasons mentioned below, her claim would be prescribed since her problems would have appeared shortly after the installation of Essure, as of 2011, she was convinced that Essure was the cause of such problems, and it was only

in April 2016, i.e., almost five years after her health problems would have first manifested themselves, that she filed the Application for Authorization.

ii. Plaintiff's injuries were not caused by Essure

153. The Defendants deny that any of the Plaintiff's alleged health problems were caused or contributed to by Essure.

154. The mere fact that the Plaintiff alleges that she suffered from health problems, and that some of these are potential risks that have been associated with the use of Essure, does not establish causation between her health problems and Essure.

155. The Plaintiff's health problems are attributable to other pre-existing comorbidities, pathologies, and/or conditions including, but not limited to, adenomyosis, uterine fibroids, a uterus having a higher than normal weight, and/or irritable bowel syndrome, as appears from her medical records (Exhibit D-1, under seal). These pathologies are typically associated with pelvic pain and/or abnormal uterine bleeding, such as that allegedly experienced by the Plaintiff. Based on current scientific knowledge, these pathologies cannot have been caused or contributed to by Essure.

156. Furthermore, the Plaintiff stopped taking oral hormonal contraception concomitantly with the placement of her Essure devices. As stated above, the cessation of oral contraception can lead to the appearance, reappearance, or unmasking of symptoms like abnormal bleeding or pelvic pain as well as changes in weight and mood.

157. In the alternative, the Plaintiff's health problems arose from some other cause or causes other than Essure, including health, lifestyle, physiological or environmental factors.

iii. Plaintiff's compensatory damages, if applicable, are unknown

158. Even if the Plaintiff was entitled to compensatory damages, which is denied, the Plaintiff does not even allege having suffered from any pecuniary (or "economic") damages.

159. The Plaintiff also does not quantify the alleged moral damages she would have suffered.

160. Consequently, even if the Plaintiff was entitled to compensatory damages, which is denied, the Court would not be in a position to establish the quantum of her damages.

iv. Knowledge of the risks

161. The Defendants reserve their rights to raise any other means of exoneration to the Plaintiff's personal claim following discovery including, but not limited to, with respect to her knowledge of the risks associated with Essure.

X. CONCLUSION

162. The present Defence is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THIS HONOURABLE COURT TO:

GRANT the present Defence.

DISMISS the Plaintiff's Originating Application.

THE WHOLE with costs, including expert fees.

MONTRÉAL, January 31, 2022

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PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL
SUPERIOR COURT
(Class Actions)

JOAN LETARTE

Plaintiff

v.

BAYER INC.

and

BAYER HEALTHCARE LLC

Defendants

DEFENCE OF BAYER INC. AND BAYER HEALTHCARE LLC
(Art. 170 CCP)

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