CANADA
PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

SUPERIOR COURT OF QUÉBEC
(CLASS ACTION)

No.: 500-06-000656-138

C[redacted] Richards, domiciled and residing at [redacted]

Petitioner

vs.

BAYER INC., a legal person duly constituted according to the laws of Canada, with its principal establishment located at 2820-1250 boul. René-Lévesque Ouest, in the City and District of Montreal, Province of Quebec, H3B 4W8;

-and-

BAYER OY, a legal person constituted according to the laws of the Republic of Finland, having its principal place of business at Pansiontie 47, Turku, Finland, 20210;

-and-

BAYER PHARMA AG, a legal person constituted according to the laws of the Federal Republic of Germany, having its principal place of business at Müllerstrasse 178, Berlin, Germany, 13353;

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:

INTRODUCTION:

1. Petitioner wishes to institute a class action on behalf of the following Group of which Petitioner is a member:

> All residents of Canada (subsidarily in Quebec) (including their estates, executors, personal representatives, dependants and family members), who had the contraceptive device Mirena inserted, which device was manufactured, marketed or distributed by Respondents and/or related companies, or any other Group or Sub-Group to be determined by the Court;

(hereinafter referred to as the "**Class Members"**, the "**Class**", the "**Group Members**", the "**Group**", "**Consumer**" or "**Users**");

2. Respondent Bayer Inc. is a federal corporation with its registered head office located in the City of Toronto, in the Province of Ontario;

3. Respondent Bayer OY is a pharmaceutical company incorporated under the laws of the Republic of Finland, having its principal place of business in Turku, Finland;

4. Respondent Bayer Pharma AG, formerly known as Bayer Schering Pharma AG, and before that known as Schering AG, is a pharmaceutical company incorporated under the laws of the Federal Republic of Germany, having a principal place of business at Berlin, Germany;

5. Respondent Bayer AG is the parent/holding company of all other named Respondents. As such, all of the Bayer Respondents are affiliated with Bayer AG and with one another;

6. At all material times, Respondents were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling and marketing, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena;

7. Mirena is a T-shaped contraceptive device that is inserted inside a woman's uterus by a healthcare provider. It is in a category of devices known as intrauterine systems ("IUSs") or intrauterine devices ("IUDs"). Mirena slowly releases the hormone, levonorgestrel, continuously over a period of five (5) years in order to prevent pregnancy;

8. If continued use is desired after five (5) years, the old system must be removed and a new one inserted;

9. The anticipated means of removing the device is a simple, non-surgical, procedure;

10. Mirena was approved for sale in the United States in December 2000, and subsequently approved for sale in Canada in February 2001;

11. There are risks of serious injury associated with, and caused by, using Mirena. Such injury includes, but is not limited to, migration of the device within the uterus or outside of the uterus into other tissues and organs, sepsis, organ damage, infertility, irregular bleeding and the need for surgical removal of the device ("Gynecological Adverse Events");

12. In Canada, the health risks associated with Mirena are contained within the device's "product monograph", the whole as more fully appears from a copy of the Mirena Product Monograph, communicated herewith as **Exhibit R-1**;

13. The product monograph is a document prepared by a health product's manufacturer. It contains dosage and usage indications, and is intended to provide healthcare professionals and patients with the necessary information for the safe and effective use of a health product;

14. Mirena's product monograph makes no mention of the risk of migration or complications arising out of migration;

15. Migration of Mirena throughout the body is related to uterine perforation. Uterine perforation describes the condition whereby Mirena either partially or completely perforates the uterine wall. Mirena's monograph currently includes a "serious warning and precaution" that uterine perforation may occur; however, perforation is described as an "uncommon" serious side effect;

16. Both perforation and migration can lead to serious complications, which complications are not adequately or at all enumerated in the product monograph. Perforation and migration often require complicated, expensive and painful treatment to correct. If either takes place, Mirena must be removed by a healthcare professional, sometimes by means of surgery;

17. The product monograph makes no mention of the risk that Mirena can migrate to other parts of the body and cause organ damage. This is in contrast with Mirena's U.S. label, which has warned about the risk of migration since as early as 2008;

18. The product monograph and the U.S. label also fail to identify infertility as a possible outcome from perforation and migration;

19. Both the Canadian monograph and the U.S. label for Mirena indicate that perforation can occur "most often" during insertion of the Mirena device. In reality, perforation can occur long after insertion;

20. From the time when it was approved and the date this claim was issued, there have been 201 reports to Health Canada identifying uterine perforation as an adverse reaction associated with Mirena, the whole as more fully appears from a copy of the Health Canada Summary of Reported Adverse Reactions, communicated herewith as **Exhibit R-2**;

21. The monograph continues to describe perforation as an "uncommon" event notwithstanding that a large number of complaints of perforation and migration have been received by Bayer since the product was introduced into the market. Indeed, the volume of these complaints was large enough so as to cause Bayer, at Health Canada's direction, to issue a public communication and a "Dear Healthcare Professional" letter in June 2010 reminding that Bayer continues to receive reports of uterine perforation, the whole as more fully appears from the June 15, 2010 public communication and letter from Bayer to health care professionals, communicated herewith as **Exhibit R-3**, *en liasse*;

22. The Petitioner and other putative class members did not receive the June 2010 public communication or the Dear Healthcare Professional letter;

FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

23. Petitioner had the Mirena contraceptive device inserted by her healthcare professional;

24. A week or so after insertion of the Mirena IUD, Petitioner woke up in terrible pain and went to the clinic, being told that it took a while to get used to the IUD;

25. Several days later, Petitioner went for an ultrasound where she was told that she had an ectopic pregnancy and that the IUD could not be found;

26. Petitioner underwent surgery where doctors had to remove the fallopian tube and discovered that the IUD was near her lung and removed that as well;

27. Petitioner was not made aware by the Respondents of the risks of Gynecological Adverse Events associated with and caused by Mirena ;

28. Petitioner would not have had Mirena IUD inserted had Respondents properly disclosed the full extent of the risks of Gynecological Adverse Events associated with and caused by the device;

29. At the time the Petitioner used Mirena, none of the device's label, the package insert, the package containing the product, or advertisements provided adequate warnings that using Mirena carried a risk of experiencing Gynecological Adverse Events including such injury as experienced by the Petitioner;

30. Accordingly, the Respondents have failed to discharge their duty to warn and inform the Petitioner and other putative class members about the risk of Gynecological Adverse Events;

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

31. As mentioned hereinabove, Respondents were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling and marketing, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena in Canada;

32. At all material times, Respondents have marketed that Mirena is safe which is not true;

33. Mirena is associated with and causes risks of serious injury. Such injury includes, but is not limited to, infertility, perforation of the uterine walls, migration of the device within the uterus or outside of the uterus into other tissues and organs, organ damage, irregular bleeding and the need for surgical removal of the device;

34. Respondents knew or should have known that Mirena is associated with and causes risks of serious injury;

35. Respondents failed in their obligation to adequately warn medical professionals and Canadian Consumers of these effects;

36. Had the Consumers (or Petitioner) been reasonably informed of the risks inherent to the insertion of Mirena, they would not have inserted it or would have had it removed;

37. Respondents committed a fault by putting a dangerous contraceptive on the market, insufficiently tested according to the norms of the trade and by continuing to market the product despite its risks;

38. Consumers reasonably relied and rely upon the Respondents to ensure that the Mirena was safe;

39. Respondents are liable for the damages suffered by the Petitioner and the Class Members in that Respondents were negligent and/or committed a fault when:

(a) It failed to ensure that Mirena was not dangerous to Consumers and that the device was fit for its intended purpose and use;

(b) It failed to conduct appropriate testing to determine whether and to what extent the use of Mirena poses serious health risks;

(c) It failed to adequately test Mirena in a manner that would fully disclose the serious side effects and the magnitude of the risks associated with its use;

(d) It failed to conduct any or adequate follow-up studies on the efficacy and safety of Mirena;

(e) in the alternative to sub-paragraphs (c) and (d) above, it failed to recognize and/or heed the results of studies Respondents conducted or were conducted by others;

(f) It failed to promptly provide the putative class members and their physicians and health regulators with any or adequate warnings of the inherent risks associated with Mirena;

(g) It failed to provide any or adequate updated and current information to the putative class members and their physicians and health regulators

respecting the risks and effects of Mirena as such information became available;

(h) It failed to provide prompt warning of potential risks and adverse side effects associated with Mirena on the product monograph and in the product labeling. More particularly, Respondents, contrary to their marketing campaign, knew that a disproportionally high number of its Mirena products were perforating the uterine wall and harming patients post-insertion. Respondents were aware of many complaints made to the Food and Drug Administration ("FDA") in the U.S. and to Health Canada (Exhibit R-2) regarding the perforation of the uterine wall and migration of their Mirena products from the uterus. The perforation of the uterine wall often results in migration from the uterus and often requires complicated, expensive and/or painful treatment to correct;

(i) Indeed, Respondents deliberately obscured the risks of Gynecological Adverse Events. In March 2009, the FDA sent a warning letter to Bayer, expressing concern that Bayer's sponsored links on internet search engines were misleading because they made representations and/or suggestions about the efficacy of Mirena, but failed to communicate any risk information, the whole as more fully appears from the March 26, 2009 letter from the FDA to Bayer, communicated herewith as **Exhibit R-4**. The FDA letter warned Bayer that advertisements for drugs and medical devices must include risk information. By omitting important risk information, including the most frequently occurring risks and side effects, the ads misleadingly suggested that Mirena is safer than it really is. Canadian putative class members consumed such ads;

(j) In December 2009, the FDA sent a second warning letter to Bayer due to a promotional program for Mirena. The FDA warned that the program overstates the efficacy of Mirena, presents unsubstantiated claims, minimizes the risks of using Mirena, and includes false or misleading representations regarding Mirena. The FDA also pointed out that, contrary to what Bayer was claiming in that program, many women do not "feel better", the whole as more fully appears from a copy of the December 30, 2009 letter from the FDA to Bayer, communicated herewith as **Exhibit R-5**. Canadian putative class members consumed such ads as well;

(k) It failed to warn the putative class members and their physicians and health regulators about the need for comprehensive regular medical monitoring to ensure the device did not migrate post-insertion and cause perforation, and to ensure that, if migration and/or perforation did occur, that these were detected early;

(l) After receiving actual or constructive notice of migration and post-insertion perforation associated with Mirena, it failed to issue adequate or timely warning, withdraw or recall the device, publicize the problems and otherwise act properly and in a timely manner to alert the public, putative class members, and their physicians and health regulators of the device's inherent dangers;

(m) It failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the usage of Mirena and the risks associated with the device;

(n) It falsely stated and or implied that Mirena was safe and fit for its intended purpose when it knew or ought to have known that these statements were false;

(o) It failed to cease the manufacture and or distribution of Mirena when it knew or ought to have known that the device caused or could cause significant injury and death;

(p) It failed to instruct its employees properly to monitor and record complaints of adverse effects of Mirena;

(q) It failed to accurately and promptly disclose to Health Canada information relating to increased risks associated with Mirena and to adequately and/or promptly modify the product monograph and product labeling accordingly in a timely manner and/or at all;

(r) It failed to monitor and to initiate a timely review, evaluation, and investigation of reports of adverse events associated with Mirena in Canada and around the world;

(s) It marketed and sold Mirena without disclosing the device's risks when it knew or ought to have known of the adverse events associated with the device's use;

(t) It failed to warn the Petitioner, putative class members, and health professionals that Mirena was not as safe as other available

contraceptives;

(u) It failed to warn the Petitioner, putative class members, and health professionals that the risks of adverse events with Mirena are higher than those of other available contraceptives;

(v) It failed to provide any or adequate warning to the health profession and to the Petitioner and putative class members;

(w) It failed to properly investigate cases of adverse events and reactions caused by Mirena;

(x) It falsely understated the risks of Mirena, while at the same time falsely overstating the safety and efficacy of the device;

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

41. Each Member of the Group is entitled to claim damages because of the faults committed by the Respondents, which include but are not limited to the reimbursement of the purchase price for the contraceptives, personal injuries suffered, economic and financial losses (i.e. loss of income and earning capacity), pain and suffering, loss of amenities and enjoyment of life, costs of past and future care and related expenses, such further and other damages, the particulars of which may be proven at the trial on the merits;

42. Moreover, Respondents' conduct, through actions, omissions, wrongdoings, and their awareness of the serious hazards of said drugs, and their failure to

fully, clearly, and in a timely way disclose and publicize the serious health effects resulting from the insertion of Mirena (all detailed hereinabove), subject the Respondents to punitive and/or exemplary damages;

43. In fact, Respondents' above detailed actions qualify its fault as intentional which is a result of wild and foolhardy recklessness in disregard for the rights of the Class Members, with full knowledge of the immediate and natural or at least extremely probable consequences that its action would cause to the Class Members;

44. Respondents' negligence has shown a malicious, oppressive and high-handed conduct that represents a marked departure from ordinary standards of decency. In that event, punitive damages should be awarded to Class Members;

CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

45. 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 the joinder of all Members is impracticable. While the exact number of Group Member is unknown to Petitioner at the present time and can only be ascertained from sales and distribution records maintained by the Respondents and their agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Quebec and the rest of Canada;

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

46. The recourses of the members raise identical, similar or related questions of fact or law, namely;

a. Were Respondents negligent or did they commit fault in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of Mirena?

b. Did the Respondents know or should Respondents have known that Mirena posed serious health risks?

c. Did the use of Mirena cause or increase the likelihood of Gynecological Adverse Events in patients?

d. Was Mirena defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Respondents? If so, in what way or ways was Mirena defective or unfit?

e. Did Respondents breach a duty to warn or inform the users of Mirena?

f. Are Respondents liable to pay damages equal to the purchase price of Mirena, or part of the purchase price of Mirena, and if so in what amount?

g. Are Respondents liable to pay damages to the Group Members as a result of their negligence, faults or misrepresentations made to them in manufacturing, marketing, distributing or selling of Mirena or as a result of the use of Mirena?

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

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

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

47. The majority of the issues to be dealt with are issues common to every Group Member;

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

NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

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

50. The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings are:

> **GRANT** Petitioner's action against Respondents;
>
> **CONDEMN** Respondents solidarily to reimburse to Petitioner and the Class Members the purchase price paid, plus interest as well as the additional indemnity;
>
> **CONDEMN** Respondents solidarily to pay an amount in compensatory damages to Petitioner and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;
>
> **CONDEMN** Respondents to pay an amount in moral damages to Petitioner and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to Petitioner and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

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

ORDER the collective recovery of the above amounts;

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

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

a. The only Canadian Respondent, Bayer Inc., has its principal establishment in the District of Montreal;
b. Mirena is sold in the District of Montreal;
c. Many Group Members are domiciled or work in the District of Montreal;
d. Petitioner's legal counsel practice law in the District of Montreal;

52. Petitioner, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the members of the Group since Petitioner:

a. purchased and had Mirena inserted without being made aware of the health risks associated with the use thereof;
b. suffered damages and injuries from inserting Mirena, as detailed above;
c. understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;
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 Petitioner wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class;

f. does not have interests that are antagonistic to those of other members of the 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 Members of the Group and to keep them informed;

53. 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 residents of Canada (subsidarily in Quebec) (including their estates, executors, personal representatives, dependants and family members), who had the contraceptive device Mirena inserted, which device was manufactured, marketed or distributed by Respondents and/or related companies, or any other Group or Sub-Group to be determined by the Court;

IDENTIFY the principle questions of fact and law to be treated collectively

as the following:

a. Were Respondents negligent or did they commit fault in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of Mirena?

b. Did the Respondents know or should Respondents have known that Mirena posed serious health risks?

c. Did the use of Mirena cause or increase the likelihood of Gynecological Adverse Events in patients?

d. Was Mirena defective or unfit for the purpose for which it was intended and designed, developed, fabricated, manufactured, sold, imported, distributed, marketed or otherwise placed into the stream of commerce in Canada by one or more of the Respondents? If so, in what way or ways was Mirena defective or unfit?

e. Did Respondents breach a duty to warn or inform the users of Mirena?

f. Are Respondents liable to pay damages equal to the purchase price of Mirena, or part of the purchase price of Mirena, and if so in what amount?

g. Are Respondents liable to pay damages to the Group Members as a result of their negligence, faults or misrepresentations made to them in manufacturing, marketing, distributing or selling of Mirena or as a result of the use of Mirena?

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

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

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

IDENTIFY the conclusions sought by the action to be instituted as being the following:

GRANT Petitioner's action against Respondents;

CONDEMN Respondents solidarily to reimburse to Petitioner and the Class Members the purchase price paid, plus interest as well as the additional indemnity;

CONDEMN Respondents solidarily to pay an amount in compensatory damages to Petitioner and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

CONDEMN Respondents to pay an amount in moral damages to Petitioner and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

CONDEMN Respondents to pay an amount in punitive and/or exemplary damages to Petitioner and the Class Members, amount to be determined by the Court, plus interest as well as the additional indemnity;

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

ORDER the collective recovery of the above amounts;

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

DECLARE that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Members;

ORDER the publication of a notice to the Members of the Group in accordance with Article 1006 C.C.P. and pursuant to a further hearing to be held, and **ORDER** Respondents to pay for said publication costs;

THE WHOLE with costs, including all costs related to publication of notices to the Class Members.

MONTREAL, July 19, 2013
LEX GROUP INC.

(s) David Assor

Per: David Assor
Attorneys for Petitioner