

CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000484-093

(Class Action)
SUPERIOR COURT

A. PATON

Petitioner

-vs.-

BAYER INC., legal person duly constituted, having its principal place of business at 1250, René-Lévesque West, bureau 2820, City of Montreal, Province of Quebec, H3B 4W8

and

BAYER A.G., legal person duly constituted, having its head office at Postfach D-51368, Leverkusen, Germany

and

BERLEX CANADA INC., legal person duly constituted, having its head office at 1250, René-Lévesque West, bureau 2820, City of Montreal, Province of Quebec, H3B 4W8

Respondents

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

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT,
SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER
STATES AS FOLLOWS:

I. GENERAL PRESENTATION

A) The Action

1. Petitioner wishes to institute a class action on behalf of the following group, of which she is a member, namely:
 - all persons residing in Canada who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since January 12th 2005 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

Alternately (or as a subclass)

- all persons residing in Quebec who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since January 12th 2005 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

B) The Respondents

2. Respondent Bayer A.G. is a German pharmaceutical company;
3. Respondent Bayer Inc. is involved in “marketing, distribution and sale of healthcare and material science products”, the whole as appears more fully from a copy of the Quebec Inspector General of Financial Institutions Report, produced herein as **Exhibit R-1**;
4. Respondent Berlex Canada Inc. is a “distributor of pharmaceutical products”, the whole as appears more fully from a copy of the Quebec Inspector General of Financial Institutions Report, produced herein as **Exhibit R-2**;
5. Respondent Berlex Canada Inc. is an affiliate of Bayer Inc. and as such they have both, either directly or indirectly, performed any one of the commercial activities of designing, testing, manufacturing, labelling, packaging, assembling, advertising, marketing, promoting, branding, distributing, selling, and/or putting Yaz and Yasmin onto the marketplace in Canada, including the province of Quebec;
6. Given the close ties between the Respondents and considering the preceding, both Respondents are solidarily liable for the acts and omissions of the other. Unless the context indicates otherwise, both Respondents will be referred to as “Bayer” for the purposes hereof;

C) The Situation

7. Yasmin and Yaz are birth control pills manufactured and marketed by the Respondents. They are combination oral contraceptives (“COCs”), meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy;
8. Yasmin was approved by Health Canada on January 12th 2005 and Yaz was approved by Health Canada on January 20th 2009;
9. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol and Yaz contains 0.02 milligrams of ethinyl estradiol. Both drugs contain 3 milligrams of drospirenone;
10. The difference between Yaz / Yasmin and other birth control pills on the market is that drospirenone is a new type of progestin and is unlike any other on the market;
11. Since Yasmin and Yaz contain the progestin drospirenone, they present additional health risks not associated with other birth control pills;
12. Drospirenone has been said to cause an increase in potassium level in the blood, which can lead to a condition known as hyperkalemia, if the potassium level becomes too high;
13. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal;
14. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke;
15. Also, Yaz / Yasmin’s use of drospirenone, a diuretic, creates unique risks compared to other oral contraceptives and is known to cause problems with the gallbladder;
16. Further, because of the combination of estrogen and drospirenone found in Yaz and Yasmin, they can affect a woman’s hormonal level in a way that previous classes of birth control pills did not, and can also cause bouts of severe anxiety, depression and other mental health issues;

17. In addition, Respondents market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits;
18. Respondents promoted Yaz as an oral contraceptive which also reduced menstrual symptoms such as headaches, cramps and breast tenderness. In addition, Yaz is promoted as treating acne and counteracting water retention, resulting in less bloating;
19. These supposed characteristics have been the subject of several FDA warning over the years (2003, 2008, and 2009) for overstating the efficacy of Yaz / Yasmin;
20. In view of the foregoing, the Respondents have:
 - a) misrepresented information concerning the safety and efficacy of Yasmin and Yaz to the medical community and the public; and
 - b) failed to provide adequate warning to the medical community and the public about Yasmin and Yaz's increased risk of serious adverse events, including deep vein thrombosis, blood clots, pulmonary embolism, heart attacks, stroke, gallbladder problems and infections, liver failure, kidney failure, severe anxiety, depression, and sudden death;

II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

21. Petitioner had been using Nuvaring as her contraceptive until approximately mid August 2009;
22. She had heard that the drug Yaz had the effect of reducing menstrual symptoms, such as being cranky and weight gain and decided to try it;
23. On or about July 30th 2009, Petitioner was prescribed Yaz at the Clinique Médicale de la Cité on Léo Pariseau, in Montreal, Quebec;
24. She began taking it a few weeks later and for a total of two (2) months thereafter;
25. Almost immediately after taking it, Petitioner began to suffer from nausea, cramps, excessive bleeding, sore/tenderness all over, headaches, lower back pain, pain in her legs (specifically the ankles), bloating, extreme mood swings, anxiousness, shortness of breath, chest pain, dizziness, and light headedness;

26. On or about the beginning of October 2009, Petitioner saw a commercial on television about the side-effects of Yaz and legal actions that were taken in the United States with regard to said side effects;
27. Petitioner immediately stopped taking Yaz;
28. Petitioner specifically began taking Yaz based on the Respondents' promotion of the drugs efficacy to reduce menstrual symptoms, which she has since learned has been overstated and inaccurate in her personal situation;
29. Further, at no time was Petitioner made aware of the true risks associated with taking Yaz;
30. Petitioner would not have taken Yaz if the Respondents had properly disclosed the true risks and benefits of taking this medication;
31. Petitioner is at risk of developing more pronounced health problems in the near future and will be followed by a physician in the coming weeks;
32. Petitioner's damages are a direct and proximate result of her use of the drug Yaz, Respondents' negligence and/or lack of adequate warnings, and Respondents' misrepresentations as to its efficacy;
33. In consequence of the foregoing, Petitioner is justified in claiming damages;

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

34. Every member of the class has either ingested and/or purchased Yaz and/or Yasmin or is the successor, family member, assign, and/or dependant of a person who purchased and/or ingested one of the aforementioned drugs;
35. The class members' damages would not have occurred but for the acts and/or omissions of the Respondents in failing to ensure that the drugs Yaz and Yasmin were safe for use, for failing to provide adequate warning of the risks associated with using them, and for over-promoting (and misrepresenting) their efficacy;
36. In consequence of the foregoing, each member of the class is justified in claiming at least one or more of the following as damages:
 - a. physical and mental injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, and increased risk of health problems;

- b. out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of Yaz and Yasmin side effect services;
 - c. loss of income and loss of future income;
 - d. refund of the purchase price of Yaz and Yasmin or alternately, the incremental costs of Yaz and Yasmin as paid for by class members and/or by the *Régie de l'assurance maladie du Québec*, the Ontario Health Insurance Plan, and other provincial health insurers;
 - e. disgorgement of all profits earned by the Respondents from the sale of the drugs Yaz and Yasmin;
 - f. punitive damages;
37. As a direct result of the Respondents' conduct, the users' family members, and dependants have, had, and/or will suffer damages and loss, including:
- a. out of pocket expenses, including paying or providing nursing, housekeeping and other services;
 - b. loss of income and loss of future income;
 - c. loss of support, guidance, care, consortium, and companionship that they might reasonably have expected to receive if the injuries had not occurred;
38. Some of the expenses related to the medical treatment that the class members have undergone or will undergo, will have been borne by the various provincial health insurers, including the *Régie de l'assurance maladie du Québec* and the Ontario Health Insurance Plan. As a result of the Respondent's conduct, these various provincial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect to all past and future insured services. These subrogated interests are asserted by the Petitioners and the class members;
39. All of these damages to the class members are a direct and proximate result their use of the drug Yaz and/or Yasmin, Respondents' negligence and/or lack of adequate warnings, and Respondents' misrepresentations as to its efficacy;

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

- A) The composition of the class renders the application of articles 59 or 67 C.C.P. difficult or impractical
40. Petitioner is unaware of the specific number of persons who took and/or purchased these drugs, however, it is safe to estimate that it is in the tens of thousands (if not hundreds of thousands);
41. Class members are numerous and are scattered across the entire province and country;
42. Petitioner has no way of knowing the names and addresses of potential class members due to the confidential nature of medical and pharmacy records;
43. In addition, given the costs and risks inherent in an action before the courts, many people will hesitate to institute an individual action against the Respondents. Even if the class members themselves could afford such individual litigation, the court system could not as it would be overloaded. Further, individual litigation of the factual and legal issues raised by the conduct of Respondents would increase delay and expense to all parties and to the court system;
44. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory judgements on questions of fact and law that are similar or related to all members of the class;
45. These facts demonstrate that it would be impractical, if not impossible, to contact each and every member of the class to obtain mandates and to join them in one action;
46. In these circumstances, a class action is the only appropriate procedure for all of the members of the class to effectively pursue their respective rights and have access to justice;
- B) The questions of fact and law which are identical, similar, or related with respect to each of the class members with regard to the Respondents and that which the Petitioner wishes to have adjudicated upon by this class action
47. Individual questions, if any, pale by comparison to the numerous common questions that predominate;
48. The damages sustained by the class members flow, in each instance, from a common nucleus of operative facts, namely, Respondents' misconduct;

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

- a. Do Yaz and Yasmin cause, exacerbate, or contribute to serious adverse events, including deep vein thrombosis, blood clots, pulmonary embolism, heart attacks, stroke, gallbladder problems and infections, liver failure, kidney failure, severe anxiety, depression, and sudden death?
- b. Were the Respondents negligent and/or did they fail in their duty of safety, duty of care, and/or duty to inform imposed upon them as manufacturers, distributors and/or sellers of Yaz and Yasmin?
- c. Do Yaz and Yasmin possess a superior efficacy over other contraceptives available on the market?
- d. Did the Respondents knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use of Yaz and Yasmin?
- e. Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks and benefits from the use of Yaz and Yasmin?
- f. Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that Yaz and Yasmin were safe?
- g. Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that Yaz and Yasmin had a superior efficacy over other contraceptives?
- h. In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the class?
- i. If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the class can claim?
- j. Are members of the class entitled to bodily, moral, and material damages?
- k. Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking Yaz and Yasmin?

- l. Are the members of the class entitled to recover as damages an amount equal to the purchase price of Yaz and Yasmin or any part of the purchase price?
 - m. Should Respondents be ordered to disgorge all or part of its ill-gotten profits received from the sale of Yaz and Yasmin?
 - n. Are members of the class entitled to aggravated or punitive damages?
50. The interests of justice favour that this motion be granted in accordance with its conclusions;

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

51. The action that Petitioner wishes to institute on behalf of the members of the class is an action in damages;
52. The conclusions that Petitioner wishes to introduce by way of a motion to institute proceedings are:

GRANT the class action of Petitioner and each of the members of the class;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the class;

CONDEMN the Defendants to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to reimburse to each of the members of the class, the purchase price of the product, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

RESERVE the right of each of the members of the class to claim future damages related to the use of Yaz and Yasmin;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to an amount sufficient to compensate the various provincial health insurers for the medical treatments and expenses that the class members have undergone and will continue to undergo in the future, and ORDER the Defendants to deposit in the office of this court these sums so as to establish a fund to be administered as this Honourable Court deems fit;

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

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

A) The Petitioner requests that she be attributed the status of representative of the Class

53. Petitioner is a member of the class;

54. Petitioner is ready and available to manage and direct the present action in the interest of the members of the class that she wishes to represent and is determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the class, as well as, to dedicate the time necessary for the present action before the Courts of Quebec and the *Fonds d'aide aux recours collectifs*, as the case may be, and to collaborate with her attorneys;

55. Petitioner has the capacity and interest to fairly and adequately protect and represent the interest of the members of the class;

56. Petitioner has given the mandate to her attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

57. Petitioner, with the assistance of her attorneys, are ready and available to dedicate the time necessary for this action and to collaborate with other members of the class and to keep them informed;

58. Petitioner is in good faith and has instituted this action for the sole goal

of having her rights, as well as the rights of other class members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Respondents' conduct;

59. Petitioner understands the nature of the action;

60. Petitioner's interests are not antagonistic to those of other members of the class;

B) The Petitioner suggests that this class action be exercised before the Superior Court of justice in the district of Montreal

61. A great number of the members of the class reside in the judicial district of Montreal and in the appeal district of Montreal;

62. Respondent Bayer Inc. has its principal place of business in the judicial district of Montreal;

63. Respondent Berlex Canada Inc. has its head office in the judicial district of Montreal;

64. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

65. The present motion is well founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the bringing of a class action in the form of a motion to institute proceedings in damages;

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

- all persons residing in Canada who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since January 12th 2005 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

Alternately (or as a subclass)

- all persons residing in Quebec who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since January 12th 2005 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

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

- a. Do Yaz and Yasmin cause, exacerbate, or contribute to serious adverse events, including deep vein thrombosis, blood clots, pulmonary embolism, heart attacks, stroke, gallbladder problems and infections, liver failure, kidney failure, severe anxiety, depression, and sudden death?
- b. Were the Respondents negligent and/or did they fail in their duty of safety, duty of care, and/or duty to inform imposed upon them as manufacturers, distributors and/or sellers of Yaz and Yasmin?
- c. Do Yaz and Yasmin possess a superior efficacy over other contraceptives available on the market?
- d. Did the Respondents knowingly, recklessly or negligently breach a duty to warn class members and/or their physicians of the risks of harm from the use of Yaz and Yasmin?
- e. Did the Respondents knowingly, recklessly or negligently misrepresent to class members and/or their physicians the risks and benefits from the use of Yaz and Yasmin?
- f. Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that Yaz and Yasmin were safe?
- g. Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that Yaz and Yasmin had a superior efficacy over other contraceptions?
- h. In the affirmative to any of the above questions, did Respondents conduct engage their solidary liability toward the members of the class?
- i. If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the class can claim?

- j. Are members of the class entitled to bodily, moral, and material damages?
- k. Are members of the class entitled to recover the medical costs incurred in the screening, diagnosis and treatment of medical conditions caused by taking Yaz and Yasmin?
- l. Are the members of the class entitled to recover as damages an amount equal to the purchase price of Yaz and Yasmin or any part of the purchase price?
- m. Should Respondents be ordered to disgorge all or part of its ill-gotten profits received from the sale of Yaz and Yasmin?
- n. Are members of the class entitled to aggravated or punitive damages?

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

GRANT the class action of Petitioner and each of the members of the class;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the class;

CONDEMN the Defendants to pay to each member of the class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to reimburse to each of the members of the class, the purchase price of the product, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the class, punitive damages, and ORDER collective recovery of these sums;

RESERVE the right of each of the members of the class to claim future damages related to the use of Yaz and Yasmin;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual class members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to an amount sufficient to compensate the various provincial health insurers for the medical treatments and expenses that the class members have undergone and will continue to undergo in the future, and ORDER the Defendants to deposit in the office of this court these sums so as to establish a fund to be administered as this Honourable Court deems fit;

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

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

DECLARE that all members of the class that have not requested their exclusion, be bound by any judgement to be rendered on the class action to be instituted in the manner provided for by law;

FIX the delay of exclusion at thirty (30) days from the date of the publication of the notice to the members, date upon which the members of the class that have not exercised their means of exclusion will be bound by any judgement to be rendered herein;

ORDER the publication of a notice to the members of the group in accordance with article 1006 C.C.P. within sixty (60) days from the judgement to be rendered herein in LA PRESSE and the NATIONAL POST;

ORDER that said notice be available on the Respondent Bayer Inc.'s website with a link stating "Notice to Yaz and Yasmin users";

RENDER any other order that this Honourable court shall determine and that is in the interest of the members of the class;

THE WHOLE with costs including publications fees.

Montreal, October 22, 2009

(S) Jeff Orenstein

CONSUMER LAW GROUP INC.

Per: Me Jeff Orenstein
Attorneys for the Petitioner