

CANADA  
PROVINCE OF QUEBEC  
DISTRICT OF MONTREAL

NO: 500-06-000484-093

(Class Action)  
SUPERIOR COURT

ALEXANDRA PATON, domiciled and  
residing at 1230 Doctor Penfield, Apt.  
705, City of Montreal, Province of  
Quebec, H3G 1B5

and

JANIE GUINDON, domiciled and  
residing at 278, rue Lyse-Daniels, City  
of Gatineau, Province of Quebec, J9J  
3Y5

and

GENEVIÈVE GLADU, domiciled and  
residing at 1-4586, boul. Décarie, City  
of Montreal, Province of Quebec, H3X  
2H5

and

SERGE BOUCHARD, domiciled and  
residing at 4960, rue Blain, City of  
Trois-Rivières, Province of Quebec,  
G8Y 7G7

*Petitioners*

-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

ADDITION

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SUBSTITUTION



and

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

and

**BAYER SCHERING PHARMA A.G.**, legal person duly constituted, having its principal establishment at Müllestrasse 178 – 13353, Berlin, Germany;

and

**BAYER CORPORATION**, legal person duly constituted, having its principal establishment at 100, Bayer Road, Building 4, Pittsburgh, PA, United States of America, 15205;

and

**BAYER HEALTHCARE, LLC**, legal person duly constituted, having its principal establishment at 555, White Plains Road, Tarrytown, NY, United States of America, 10591;

and

**BAYER HEALTHCARE PHARMACEUTICALS INC.**, legal person duly constituted, having its principal establishment at 6, Westbelt, Wayne, NJ, United States of America, 07470;

Respondents

ADDITION



SUBSTITUTION


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

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SUBSTITUTION

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT,  
SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR  
PETITIONERS STATE AS FOLLOWS.

**I. GENERAL PRESENTATION**

**A) The Action**

SUBSTITUTION

1. Petitioners wish to institute a class action on behalf of the following group,  
of which they are (...) members, namely:

- all persons residing in Canada who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since December 10<sup>th</sup> 2004 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

Alternately (or as a subclass)

SUBSTITUTION

- all persons residing in Quebec who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since December 10<sup>th</sup> 2004 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

**B) The Respondents**

SUBSTITUTION

2. Respondent Bayer A.G. is a German pharmaceutical company. At all times relevant herein Bayer A.G. either directly or indirectly through an agent, affiliate, predecessor or subsidiary, was in the business of designing, testing, manufacturing, distributing and promoting Yasmin and Yaz. Bayer A.G. is the parent/holding company of all other named Defendants;



SUBSTITUTION

3. Respondent Bayer Inc. is a Federal corporation with its head office in Etobicoke, Ontario. Bayer Inc. is a wholly owned subsidiary of Bayer A.G. 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. At all material times, Bayer Inc. was engaged in the business of designing, manufacturing, developing the formula for, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate, predecessor or subsidiary, Yasmin and Yaz in Canada. The development of Yasmin and Yaz for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Yasmin and Yaz, and other actions central to the allegations of this lawsuit, were undertaken by Bayer Inc. in Quebec and elsewhere;
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;

ADDITION

- 5.1 Respondent Bayer Schering Pharma A.G., formerly known as Schering A.G., is a German corporation with its principle place of business in Berlin, Germany. Bayer Schering Pharma A.G. is the successor to Schering A.G. Bayer Schering Pharma A.G. is the current owner of the Canadian patents relating to Yasmin and Yaz. At all times relevant herein Bayer Schering Pharma A.G. either directly or indirectly through an agent, affiliate, predecessor or subsidiary, was in the business of designing, testing, manufacturing, distributing and promoting Yasmin and Yaz;
- 5.2 Respondent Bayer Corporation is a U.S. corporation formed in the State of Indiana with its principle place of business located in Pittsburgh, Pennsylvania. Bayer Corporation is a wholly owned subsidiary of Bayer A.G. At all material times, Bayer Corporation was engaged in the business of designing, manufacturing, developing the formula for, preparing, processing, inspecting, testing, packaging, promoting, marketing,



## ADDITION

distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate, predecessor or subsidiary, Yasmin and Yaz in Canada including the Province of Quebec;

- 5.3 Respondent Bayer Healthcare, LLC is a U.S. corporation formed in the State of Delaware with its principle place of business located in Montville, New Jersey. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. At all material times, Bayer Healthcare, LLC was engaged in the business of designing, manufacturing, developing the formula for, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate, predecessor or subsidiary, Yasmin and Yaz in Canada including the Province of Quebec;
- 5.4 Berlex Laboratories International, Inc. was a U.S. corporation formed in the State of Delaware with its principle place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Prior to being integrated with Bayer Healthcare to create Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories International Inc. was engaged in the business of designing, manufacturing, developing the formula for, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate, or subsidiary, Yasmin and Yaz in Canada including the Province of Quebec;
- 5.5 Respondent Bayer Healthcare Pharmaceuticals Inc., as successor in interest of Bayer Pharmaceuticals Corporation, is a wholly owned subsidiary of Bayer Corporation, incorporated in the state of Delaware, with its principal place of business located in Wayne, New Jersey. Prior to January 1, 2008, Bayer Pharmaceuticals Corporation was a wholly owned subsidiary of Bayer Corporation. Bayer Healthcare Pharmaceuticals Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Bayer Pharmaceuticals Corporation's principal place of business was located in West Haven, Connecticut. At all material times, Bayer Healthcare Pharmaceuticals was engaged in the business of designing, manufacturing, developing the formula for, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate, predecessor or subsidiary, Yasmin and Yaz in Canada including the Province of Quebec.



- ADDITION 5.6 The business of each of the Respondents are inextricably interwoven with that of the other and each is the agent of the other for the purposes of designing, manufacturing, developing the formula for, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit Yasmin and Yaz in Canada and in Quebec.
- SUBSTITUTION 6. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other. Unless the context indicates otherwise, all Respondents will be referred to as "Bayer" for the purposes hereof;
- C) The Situation
- ADDITION 6.1 Yasmin and Yaz are oral contraceptives manufactured by Bayer, indicated in Canada for the prevention of pregnancy and treatment of moderate acne vulgaris in women (16 years of age or older for Yasmin and 14 years of age or older for Yaz) who have no known contraindications to oral contraceptive therapy, desire contraception, and have achieved menarche;
- SUBSTITUTION 6.2 Yasmin was approved by Health Canada on December 10<sup>th</sup> 2004 and Yaz was approved by Health Canada in late 2008;
- ADDITION 6.3 Yasmin and Yaz are two of the largest selling contraceptives worldwide. Yasmin was the third most prescribed oral contraceptive in Canada in 2008. Worldwide sales of Yasmin and Yaz in 2008 were approximately \$1.8 billion;
- SUBSTITUTION 7. Yasmin and Yaz (...) 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;
- DELETED 8. (Paragraph displaced at paragraph 6.2)
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;

**SUBSTITUTION** 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. Drospirenone is considered to be a fourth generation progestin;

**ADDITION** C.1) THE RISKS

11. Since Yasmin and Yaz contain the progestin drospirenone, they present additional health risks not associated with other birth control pills;

**ADDITION** 11.1 Drospirenone is a spironolactone analog and can cause elevation of potassium levels (hyperkalemia) and a decrease in sodium levels (hyponatremia) due to its potassium-sparing diuretic effects. Potassium is a key control in the electrical system of the heart and elevated levels can cause arrhythmias which can lead to stroke, deep vein thrombosis, pulmonary embolism, heart attack, or sudden death. Because drospirenone can act like a diuretic, it can also cause dehydration which can lead to kidney stones and gall bladder disease and/or removal;

11.2 Because drospirenone is used as the progestin component, the risk of suffering from stroke, deep vein thrombosis, pulmonary embolism, heart attack, or gall bladder disease and/or removal, is substantially higher among women who use Yasmin or Yaz compared to women who use second generation oral contraceptives with a first or second generation progestin component;

**DELETED** 12. (...);

13. (...);

14. (...);

15. (...);

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;

**ADDITION** 16.1 During the brief time that Yasmin and Yaz have been sold, hundreds of reports of injury and death have been reported to health regulatory agencies in association with these products;

ADDITION

- 16.2 On or about April 13<sup>th</sup> 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that second generation birth control pills be prescribed in lieu of Yasmin, due to the adverse event reports of 40 women who experienced venous thrombosis associated with their use of Yasmin;
- 16.3 On or about February 1<sup>st</sup> 2003, the British Medical Journal published a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin*. This paper stated that the Dutch spontaneous reporting system for adverse drug reactions received five reports of thromboembolism (including death) as a suspected adverse drug reaction to the new oral contraceptive Yasmin;
- 16.4 On or about August 13<sup>th</sup> 2009, the British Medical Journal published a study stating that oral contraceptives containing drospirenone (Yasmin and Yaz) carry a 6.3 times increased risk of deep vein thrombosis or pulmonary embolism. When compared to women taking some other type of birth control, the increased risk was nearly four times more among users of Yasmin and Yaz;
- 16.5 Notwithstanding the well documented safety hazards associated with using Yasmin and Yaz, Bayer failed to conduct meaningful post-market surveillance;
- 16.6 Bayer aggressively marketed Yasmin and Yaz without adequately disclosing the increased safety hazards associated with using Yasmin and Yaz as compared to second generation oral contraceptives;
- 16.7 At all material times, Bayer knew or should have known that the risks of using Yasmin and/or Yaz included severe and life threatening complications and side effects;
- 16.8 At all material times, Bayer, through its servants and agents, failed to adequately warn physicians and consumers, including the Plaintiffs and putative class members, that the risk of developing adverse events including stroke, deep vein thrombosis, pulmonary embolism, heart attack, gall bladder disease and/or removal, liver failure, kidney failure, severe anxiety, depression or sudden death associated with using Yasmin and/or Yaz is significantly higher compared to the risk of developing stroke, deep vein thrombosis, pulmonary embolism, heart attack, gall bladder disease liver failure, kidney failure, severe anxiety, depression or sudden death associated with the use of second generation oral contraceptives;



ADDITION

16.9 Bayer did not provide adequate safety data to Health Canada with respect to Yasmin and Yaz. Bayer knew or should have known that Yasmin and Yaz were unsafe, defective, unreasonably dangerous, and not fit for their intended purpose;

16.10 At all material times, Bayer, through its servants and agents, negligently and/or carelessly marketed, distributed and/or sold Yasmin and Yaz without adequate warnings of the products' serious side effects and unreasonably dangerous risks;

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;

DELETED

19. (...)

ADDITION

19.1 The Food and Drug Association ("FDA") in the United States sent Bayer warning letters regarding their aggressive and controversial marketing efforts. Bayer has been warned at least three times by the FDA, in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of Yasmin and Yaz, and minimize serious risks associated with the drugs. Most recently, the FDA issued Bayer a warning letter for overstating Yaz' ability to improve women's moods and clear up acne in television commercial advertisements. In addition, the FDA required Bayer to run a multi-million dollar television advertisement campaign to correct these misleading claims, as well as disclose the risks of hyperkalemia and other health problems associated with Yaz use. The FDA also directed Bayer to address false claims that Yasmin and Yaz were approved to treat Premenstrual Syndrome and all forms of acne;

19.2 A Bayer press release dated January 20<sup>th</sup>, 2009, issued in Canada, which targeted "Gen Yers", states that Yaz may help reduce the symptoms experienced around the time of their period, although Yaz is not indicated for that use and has not been shown to be effective for that use. The press release includes a quote from a family physician stating "The availability of this new low-dose pill provides women with the benefits of reduced menstrual symptoms." Similar to the advertising in the U.S. that the FDA took issue with, the Canadian press release also states that Yaz treats acne, but does not specify the type of acne it is indicated to treat. The press release also states that Yaz was found to be safe and well

ADDITION

tolerated without warning of the increased risks associated with Yaz use compared to second generation oral contraceptives;

19.3 On March 26<sup>th</sup> 2010, Bayer announced it would be updating the Yasmin label in the European Union to include the results of recent epidemiological studies with respect to venous thromboembolism;

19.4 On April 7<sup>th</sup> 2010, the FDA approved new label changes for Yasmin and Yaz in the United States with respect to the risk of blood clots;

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;

SUBSTITUTION

**II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONERS**

**Petitioner Alexandra Paton**

21. Petitioner Alexandra Paton 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 30<sup>th</sup> 2009, Petitioner Alexandra Paton 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 Alexandra Paton 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;

SUBSTITUTION

26. On or about the beginning of October 2009, Petitioner Alexandra Paton 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 Alexandra Paton immediately stopped taking Yaz;
28. Petitioner Alexandra Paton 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 Alexandra Paton made aware of the true risks associated with taking Yaz;
30. Petitioner Alexandra Paton would not have taken Yaz if the Respondents had properly disclosed the true risks and benefits of taking this medication;
31. Petitioner Alexandra Paton 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;

SUBSTITUTION

33. In consequence of the foregoing, Petitioner Alexandra Paton is justified in claiming damages;

ADDITIONPetitioner Janie Guindon

- 33.1 On or about August 1<sup>st</sup> 2009, Petitioner Janie Guindon began using the oral contraceptive Yaz;
- 33.2 Petitioner Janie Guindon was 22 when she began using the oral contraceptive Yaz;
- 33.3 Petitioner Janie Guindon used the oral contraceptive Yaz in accordance with the manner it was intended to be used;
- 33.4 Shortly after her first use of the oral contraceptive Yaz, on or about October 14<sup>th</sup> 2009, Petitioner was told she had developed gallstones;
- 33.5 On or about November 14<sup>th</sup> 2009, Petitioner Janie Guindon had her gallbladder removed;



ADDITION

- 33.6 On or about December 30<sup>th</sup> 2009, Petitioner Janie Guindon suffered from deep vein thrombosis;
- 33.7 On or about January 1<sup>st</sup> 2010, Petitioner Janie Guindon suffered from multiple pulmonary embolism;
- 33.8 On or about January 1<sup>st</sup> 2010, Petitioner Janie Guindon stopped taking Yaz;
- 33.9 Petitioner Janie Guindon was in good health prior to her use of Yaz;
- 33.10 In the period before and during the use of Yaz by the Petitioner Janie Guindon, she received no or inadequate warnings about the increased risk of developing stroke, deep vein thrombosis, pulmonary embolism, heart attack, or gall bladder disease and/or removal associated with Yaz use as compared to use of second generation oral contraceptives;
- 33.11 Petitioner Janie Guindon would not have taken Yaz if the Respondents had properly disclosed the true risks and benefits of taking this medication;
- 33.12 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;
- 33.13 In consequence of the foregoing, Petitioner Janie Guindon is justified in claiming damages;

Petitioner Geneviève Gladu

- 33.14 Petitioner Geneviève Gladu was prescribed the oral contraceptive Yasmin shortly after it was approved by Health Canada in 2004;
- 33.15 Petitioner Geneviève Gladu used the oral contraceptive Yasmin until June of 2009;
- 33.16 Petitioner Geneviève Gladu used Yasmin in accordance with the manner it was intended to be used;
- 33.17 On or about June 2009, Petitioner Geneviève Gladu experienced abdominal pains;
- 33.18 Between June 7<sup>th</sup> 2009 and July 7<sup>th</sup> 2009, when she was 30, Petitioner Geneviève Gladu was hospitalized for gallstones, gallbladder removed, pancreatitis and pulmonary embolism;

ADDITION

- 33.19 On or about June 7<sup>th</sup> 2009, Petitioner Geneviève Gladu stopped taking Yasmin;
- 33.20 Petitioner Geneviève Gladu was in excellent health prior to her use of Yasmin;
- 33.21 In the period before and during the use of Yasmin by the Petitioner Geneviève Gladu, she received no or inadequate warnings about the increased risk of developing stroke, deep vein thrombosis, pulmonary embolism, heart attack, or gall bladder disease and/or removal associated with Yasmin use as compared to use of second generation oral contraceptives;
- 33.22 Petitioner Geneviève Gladu would not have taken Yasmin if the Respondents had properly disclosed the true risks and benefits of taking this medication;
- 33.23 Petitioner's damages are a direct and proximate result of her use of the drug Yasmin, Respondents' negligence and/or lack of adequate warnings, and Respondents' misrepresentations as to its efficacy;
- 33.24 In consequence of the foregoing, Petitioner Geneviève Gladu is justified in claiming damages;

Petitioner Serge Bouchard

- 33.25 Petitioner Serge Bouchard is the father of Julie Bouchard;
- 33.26 Julie Bouchard was a consumer of the oral contraceptive Yasmin;
- 33.27 Julie Bouchard began using the oral contraceptive Yasmin on or about March 10<sup>th</sup> 2009;
- 33.28 Shortly after her first use of the oral contraceptive Yasmin, on or about August 5<sup>th</sup> 2009, Julie Bouchard suffered from a stroke;
- 33.29 On or about August 26<sup>th</sup> 2009, Julie Bouchard suffered from multiple strokes;
- 33.30 Julie Bouchard was 28 when she suffered from these strokes;
- 33.31 Julie Bouchard was in excellent health prior to her use of Yasmin;

ADDITION

- 33.32 Julie Bouchard is currently, and will probably be for the rest of her life, unable to work;
- 33.33 Julie Bouchard's damages are a direct and proximate result of her use of the drug Yasmin, Respondents' negligence and/or lack of adequate warnings, and Respondents' misrepresentations as to its efficacy;
- 33.34 Following the strokes suffered by her daughter Julie Bouchard, Petitioner Serge Bouchard suffered pecuniary damages and other damages such as stress, fear of losing his daughter and worry about the health of his daughter;

**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;

## II. 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

### SUBSTITUTION

40. Petitioners are 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;

SUBSTITUTION

42. Petitioners have 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 Petitioners wish to have adjudicated upon by this class action

SUBSTITUTION

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 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?

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

### III. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

#### SUBSTITUTION

51. The action that Petitioners wish to institute on behalf of the members of the class is an action in damages;

52. The conclusions that Petitioners wish to introduce by way of a motion to institute proceedings are:

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

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioners 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;

SUBSTITUTION A) The Petitioners request(...) the status of representative of the Class

53. Petitioners are members of the class;

54. Petitioners are ready and available to manage and direct the present action in the interest of the members of the class that they wish to represent and are 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 their attorneys;

55. Petitioners have the capacity and interest to fairly and adequately protect and represent the interest of the members of the class;

56. Petitioners have given the mandate to their attorneys to obtain all relevant information with respect to the present action and Intend to keep informed of all developments;

57. Petitioners, with the assistance of their 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. Petitioners are in good faith and have instituted this action for the sole goal of having their 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. Petitioners understand the nature of the action;

SUBSTITUTION 60. The interests of the Petitioners 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;

SUBSTITUTION 64. The Petitioners' co-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;

SUBSTITUTION **ASCRIBE** the Petitioners the status of representatives of the persons included in the class herein described as:

SUBSTITUTION

- all persons residing in Canada who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since December 10<sup>th</sup> 2004 and their successors, assigns, family members, and dependants or any other group to be determined by the Court.

Alternately (or as a subclass)

SUBSTITUTION

- all persons residing in Quebec who have taken and/or purchased the drugs YAZ and/or YASMIN (drospirenone and ethinyl estradiol) since December 10<sup>th</sup> 2004 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 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?

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

SUBSTITUTION

GRANT the class action of Petitioners 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;

SUBSTITUTION

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 the JOURNAL DE QUÉBEC, the JOURNAL DE MONTRÉAL, 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.

Québec, August 19, 2010

Montreal, August 19, 2010

  
SISKINDS, DESMEULES  
Co-Attorneys for the Petitioners

  
CONSUMER LAW GROUP INC.  
Co-Attorneys for the Petitioners

N°: 500-06-000484-093

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(Class Action)  
SUPERIOR COURT  
DISTRICT OF MONTREAL

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ALEXANDRA PATON and JANIE GUIDON and  
GENEVIEVE GLADU and SERGE BOUCHARD  
*Petitioners*

-vs.-

BAYER INC. and BAYER A.G. and BERLEX  
CANADA INC. and BAYER SCHERING PHARMA  
A.G. and BAYER CORPORATION and BAYER  
HEALTHCARE, L.L.C. and BAYER HEALTHCARE  
PHARMACEUTICALS INC.

*Respondents*

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

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ORIGINAL

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