Amended this 11 day of Oct 2017
pursuant to order of J. Lococo
dated the 5th day of Oct 2017

Court File No.: 52030\10

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

ANN SCHWOOB, CODY SCHWOOB, and KRISTY BISHOP

Plaintiffs

- and -

BAYER INC.

Defendant

Proceeding under the *Class Proceedings Act, 1992*

SECOND FRESH AS AMENDED STATEMENT OF CLAIM

TO THE DEFENDANT

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date March 10, 2010

Issued by _____
Local registrar

Address of court office
St. Catharines Court House
59 Church Street
St. Catharines, ON L2R 7N8

TO: **BAYER INC.**
77 Belfield Road
Etobicoke, ON
M9W 1G6

CLAIM

1. The Plaintiffs, Ann Schwoob, Cody Schwoob and Kristy Bishop, claim on behalf of themselves and others similarly situated in Ontario:

(a) an order certifying this proceeding and appointing them representative plaintiffs for the classes;

(b) pecuniary and special damages in the amount of $500,000 for each person prescribed Yasmin and/or Yaz or as aggregated following a trial on the common issues;

(c) non-pecuniary damages in an amount to be assessed for each person who was prescribed Yasmin and/or Yaz;

(d) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from their sales of Yasmin and Yaz;

(e) damages pursuant to the *Family Law Act*, R.S.O. 1990, c F.3 s.61, in the amount of $100,000 for each such plaintiff;

(f) punitive damages in the amount of $20,000,000;

(g) the costs of distributing all monies received to class members;

(h) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;

(i) costs on a substantial indemnity basis, plus applicable taxes; and

(j) such further and other relief as this Honourable Court may deem just.

THE PLAINTIFFS

2. The Plaintiffs Ann Schwoob and Cody Schwoob are individuals residing in St. Catharines, Ontario.

3. Cody is the son of Ann and is pursuing his claim in that capacity.

4. The Plaintiff Kristy Bishop is an individual residing in London, Ontario.

THE DEFENDANTS

5. Bayer Inc. ("Bayer") is a Federal corporation with its head office in Etobicoke, Ontario. Bayer Inc. is a wholly owned subsidiary of Bayer A.G. 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 Ontario and elsewhere.

6. In bringing this action on behalf of a class of people in Ontario who were prescribed and ingested Yasmin and/or Yaz, between December 10, 2004 and November 30, 2011, the Plaintiffs plead and rely upon the provisions of the *Class Proceedings Act, 1992*, S.O. 1992, c.6, the *Negligence Act*, R.S.O. 1990, c. N-1, as amended, and regulations thereunder, and the *Food and Drugs Act,* R.S.C. 1985, c. F.27 and regulations thereunder.

THE DRUG

7. Yasmin and Yaz are oral contraceptives manufactured by Bayer, indicated in Ontario 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.

8. Yasmin was approved by Health Canada on December 10, 2004 and Yaz was approved by Health Canada in late 2008. 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.

9. Yasmin and Yaz are combination oral contraceptives, containing both an estrogen and progestin component. The estrogen component, ethinyl estradiol, is common to many combination oral contraceptives. The progestin component used in Yasmin and Yaz, drospirenone, is unique in Canada to these two oral contraceptives. Drospirenone containing oral contraceptives are considered to be fourth generation combination oral contraceptives[1].

10. Yasmin contains 3.0 mg of drospirenone and 0.030 mg of ethinyl estradiol. Yaz contains 3.0 mg of drospirenone and 0.020 mg of ethinyl estradiol. Yasmin is taken for 21 days followed by 7 days of placebo. Yaz is taken for 24 days followed by 4 days of placebo.

THE RISKS

11. 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

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1 So called "first generation" combination oral contraceptives utilized the progestin lynestrenol, which is no longer in wide use today. So called "second generation" and "third generation" combination orcal contraceptives use levonorgestrel or norgestrel and desogestrel or gestodene, respectively. These are the most widely used progestins in combination oral contraceptives today. Drospirenone is considered part of the "fourth generation" combination oral contraceptive, and is unique in Canada to Yasmin and Yaz.

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.

Negligent Design and Testing

12. Because drospirenone is used as the progestin component, the risk of suffering from side effects including stroke, deep vein thrombosis, pulmonary embolism, heart attack, or gall bladder disease and/or removal ("Injuries"), is substantially higher among women who use Yasmin or Yaz compared to women who use other available combination oral contraceptives.

13. During the brief time that Yasmin and Yaz have been sold, hundreds of reports of Injuries and death have been reported to health regulatory agencies in association with these products.

14. In April 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.

15. An August 2008 study published in the British Medical Journal stated 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 than experienced by women taking other types of combination oral contraceptives.

16. Notwithstanding the well documented safety hazards associated with using Yasmin and Yaz, Bayer failed to conduct meaningful post-market surveillance.

Failure to Warn

17. On March 26, 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. This was not included in the Canadian product monograph at that time.

18. On April 7, 2010, the FDA approved new label changes for Yasmin and Yaz in the United States with respect to the risk of blood clots. This was not included in the Canadian product monograph at that time.

19. Prior to the Canadian product monographs for Yasmin and Yaz dated November 30, 2011, the language in the product monographs for both Yasmin and Yaz were inadequate because they failed to reference studies showing increased risk with Yasmin and Yaz as compared to other available oral contraceptives and instead simply relied on a generic warning with respect to combination oral contraceptives in general.

Negligent Distribution, Marketing and Sale

20. Bayer marketed Yasmin and Yaz as providing the same safety and efficacy as other available combination oral contraceptives in preventing pregnancy, with the additional benefits of treating acne and/or menstrual symptoms.

21. Bayer aggressively marketed Yasmin and Yaz without adequately disclosing the increased safety hazards associated with using Yasmin and Yaz as compared to other available combination oral contraceptives.

22. Bayer hired *The Hills* reality star Lo Bosworth to promote Yaz in Canada. A Bayer press release dated January 20, 2009, issued in Canada, which targeted "Gen Yers" (persons born in the 1980s and 1990s), 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 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 tolerated without warning of the increased risks associated with Yaz use compared to other available combination oral contraceptives.

23. At all material times, Bayer, through its servants and agents, failed to adequately warn physicians and consumers, including the Plaintiffs and putative class members, of significantly increased risk of Injuries associated with using Yasmin and/or compared to using other available combination oral contraceptives.

24. 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 purposes.

25. At all materials 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.

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

THE PLAINTIFFS' EXPERIENCES

27. The Plaintiff, Ann Schwoob, was prescribed Yasmin by her family physician and commenced using Yasmin in or about June 2009.

28. In or about August 2009, Ann began suffering from intense chest pains. On August 10, 2009, Ann went to the emergency department of West Lincoln Memorial Hospital in Grimsby, Ontario. The treating physician at West Lincoln Memorial Hospital believed Ann may have been suffering from pneumonia. Still experiencing intense chest pains, Ann returned to the emergency department of West Lincoln Memorial Hospital again two days later where she was again told she was suffering from pneumonia.

29. Ann's condition failed to improve and as a result, she attended a walk-in clinic on or about August 14, 2009. The walk-in clinic physician advised Ann to immediately go to Hamilton General Hospital. At Hamilton General Hospital, Ann was diagnosed as having suffered from a pulmonary embolism. Ann ceased using Yasmin shortly thereafter.

30. Ann was required to remain in Hamilton General Hospital for approximately one week. While in hospital, Ann received blood thinner injections every day. When she was released from hospital, Ann was required to continue to take blood thinner injections twice daily for an additional week as well as commence warfarin[2] therapy. Ann continues to take warfarin and attend specialists with respect to this incident.

31. Ann used Yasmin in accordance with the package label and consumer information pamphlet, and in the manner it was intended to be used.

32. Ann was in excellent health prior to her use of Yasmin.

33. In the time period before and during Ann's use of Yasmin, she received no or inadequate warnings about the increased risk of Injuries associated with Yasmin use as compared to use of other available combination oral contraceptives.

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2 anticoagulant medication

34. Had Ann been aware of the increased risk of developing Injuries from using Yasmin as compared to using other available combination oral contraceptives, she would never have used Yasmin. But for Bayer's wrongful conduct, Ann would not have incurred her damages.

35. The Plaintiff, Kristy Bishop, was prescribed Yaz by her physician and commenced using Yaz in or about June 2010.

36. On or about October 2, 2010, Kristy began suffering from pain and swelling in her left calf. On or about October 9, 2010, Kristy was diagnosed as having suffered a deep vein thrombosis in her left leg. Kristy was advised by a doctor to immediately cease using Yaz, which she did.

37. Kristy used Yaz in accordance with the package label and consumer information pamphlet, and in the manner it was intended to be used.

38. Kristy was in excellent health prior to her use of Yaz.

39. In the time period before and during Kristy's use of Yaz, she received no or inadequate warnings about the increased risk of developing Injuries associated with Yaz use as compared to use of other available combination oral contraceptives.

40. Had Kristy been aware of the increased risk of developing Injuries from using Yaz as compared to using other available combination oral contraceptives, she would never have used Yaz. But for Bayer's wrongful conduct, Kristy would not have incurred her damages.

41. Cody Schwoob and other class members have suffered and continue to suffer damages including loss of care, guidance and companionship as well as financial expenses and special damages due to the wrongful conduct of Bayer.

CAUSES OF ACTION

Duty of Care and Breach of Duty

42. Bayer at all material times owed a duty of care to the Plaintiffs to:

(a) ensure that Yasmin and Yaz were safe and fit for their intended or reasonably foreseeable use, as compared to other available combination oral contraceptives;

(b) conduct appropriate testing to determine whether and to what extent use of Yasmin and Yaz posed serious health risks, including the risk of Injuries;

(c) properly, adequately, and fairly warn the Plaintiffs and their physicians that use of Yasmin and Yaz carry an increased risk of developing Injuries compared to other available combination oral contraceptives;

(d) ensure that prescribing physicians were kept fully and completely warned and informed regarding all risks associated with Yasmin and Yaz;

(e) monitor, investigate, evaluate and follow up on adverse reactions to the use of Yasmin and Yaz; and

(f) properly inform Health Canada and other regulatory agencies of the increased risks of developing Injuries associated with the use of Yasmin and Yaz, particularly as compared to other available combination oral contraceptives.

43. Bayer negligently breached its duty of care.

Negligence

44. The Plaintiffs state that their damages were caused by the negligence of Bayer. Such negligence includes but is not limited to the following:

(a) Bayer failed to ensure that Yasmin and Yaz were not dangerous to recipients during the course of their use and that the drugs were fit for their intended purpose and of merchantable quality;

(b) Bayer failed to adequately test Yasmin and Yaz in a manner that would fully disclose the magnitude of the risks associated with their use, including but not limited to the increased risk of developing Injuries, particularly as compared to use of other available combination oral contraceptives;

(c) Bayer, both before and after Yasmin and Yaz were approved by Health Canada, failed to give Health Canada complete and accurate information as it became available;

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

(e) Bayer failed to conduct any or any adequate long-term studies of the increased risks of continued use of Yasmin and Yaz;

(f) Bayer failed to provide the Plaintiffs, their physicians and Health Canada with proper, adequate, and/or fair warning of the increased risks associated with use of Yasmin and Yaz, including but not limited to the increased risk of developing Injuries as compared to other available combination oral contraceptives;

(g) Bayer failed to warn the Plaintiffs, their physicians and Health Canada about the need for comprehensive regular medical monitoring to ensure the early discovery of side effects related to using Yasmin and Yaz;

(h) Bayer failed to adequately monitor, evaluate and act upon reports of adverse reactions to Yasmin and Yaz in Ontario and elsewhere in Canada;

(i) Bayer failed to provide any or any adequate updated and/or current information to the Plaintiffs, their physicians and/or Health Canada respecting the increased risks of Yasmin and Yaz as such information became available from time to time;

(j) Bayer failed to provide adequate warnings of the potential increased risks of Yasmin and Yaz, as compared to other available combination oral contraceptives on package labels;

(k) Bayer failed to provide adequate warnings of the increased risks associated with Yasmin and Yaz, including the increased risk of Injuries in all persons using Yasmin and/or Yaz, on the customer information pamphlets in Canada;

(l) Bayer, after noticing problems with Yasmin and Yaz, failed to issue adequate warnings, timely recall the drugs, publicize the problem and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiffs and their physicians of the drugs' inherent dangers, including but not limited to the danger of developing Injuries in all persons using Yasmin and/or Yaz as compared to other available combination oral contraceptives;

(m) Bayer failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the increased risks associated with using Yasmin and Yaz as compared to other available combination oral contraceptives;

(n) Bayer represented that Yasmin and Yaz were as safe as other available combination oral contraceptive products and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(o) Bayer misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Yasmin and Yaz and their associated risks, including the increased risk of developing Injuries in all persons using Yasmin and/or Yaz, particularly as compared to other available combination oral contraceptives;

(p) the misrepresentations made by Bayer were unreasonable in the face of the risks that were known or ought to have been known by Bayer;

(q) Bayer failed to timely cease the manufacture, marketing and/or distribution and/or sale of Yasmin and Yaz when they knew or ought to have known that these drugs caused an increased risk of developing Injuries;

(r) Bayer failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

(s) Bayer failed to properly supervise its employees, its subsidiaries and its affiliated corporations;

(t) Bayer actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Yasmin and Yaz;

(u) Bayer breached other duties of care to the Plaintiffs and putative class members, details of which breaches are known only to Bayer; and

(v) in all of the circumstances of this case, Bayer applied callous and reckless disregard for the health and safety of the Plaintiffs and putative class members.

45. Yasmin and/or Yaz were defective because they were unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Plaintiffs, putative class members, or their physicians. Any benefit from using Yasmin and/or Yaz was

outweighed by the serious and undisclosed risks of their use when used as Bayer intended. There are no individuals for whom the benefits of Yasmin and/or Yaz outweigh the risks, given that there are many alternative products that are at least as efficacious as Yasmin and Yaz and carry far less and/or less serious risks than Yasmin and Yaz.

46. The risks associated with use of Yasmin and Yaz, including increased risk of developing Injuries in all persons using Yasmin and Yaz, were in the exclusive knowledge and control of Bayer. The extent of the risks were not known and could not have been known to the Plaintiffs. The Plaintiffs' injuries would not have occurred but for the negligence of the Defendants in failing to ensure that Yasmin and Yaz were safe for use or, in the alternative, for failing to provide an adequate warning of the increased risks associated with using Yasmin and/or Yaz to the Plaintiffs, class members and to prescribing physicians.

DAMAGES

47. The Plaintiffs' and other putative class members' injuries and damages were caused by the negligence of Bayer, their servants and agents.

48. As a result of Bayer's negligence, the Plaintiffs have suffered and continue to suffer serious personal injuries and pain and suffering.

49. As a result of the conduct of Bayer, the Plaintiffs and other class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

50. Some of the expenses related to the medical treatment that the Plaintiffs and class members have undergone, and will continue to undergo, have been borne by the Ontario provincial health insurer, namely the Ontario Health Insurance Plan ("OHIP").

As a result of the negligence of Bayer, OHIP has suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services. These subrogated interests are asserted by the Plaintiffs and the putative class members pleading and relying upon the *Health Insurance Act*, R.S.O. 1990, c. H.6.

51. The Plaintiffs claim punitive damages for the reckless and unlawful conduct of Bayer.

WAIVER OF TORT

52. In the alternative to damages, in all of the circumstances, the Plaintiffs plead an entitlement to "waive the tort" and claim an accounting or other such restitutionary remedy for disgorgement of the revenues generated by Bayer as a result of their sale of Yasmin and Yaz, due to the drugs' unfitness for purpose and/or Bayer's failure to properly bring the increased risks associated with Yasmin and Yaz, as compared to other available combination oral contraceptives, to the attention of the Plaintiffs, putative class members, and their physicians, as well as other wrongful conduct as laid out in paragraphs 45-47.

53. As a direct, proximate, and foreseeable result of Bayer's acts and otherwise wrongful conduct, the Plaintiffs and putative class members were economically harmed by purchasing and using an oral contraceptive that had increased risks but was no more efficacious than other available oral contraceptive products. Bayer profited and benefited economically from the sale of Yasmin and Yaz prescribed to the Plaintiffs and putative class members who suffered corresponding harm, and as a result Bayer was unjustly enriched by the monies they received from selling the drugs.

54. Bayer voluntarily accepted and retained these profits and benefits with full knowledge and awareness that, as a result of their wrongdoing, the Plaintiffs and putative class members were not treated with a product of the safety quality, nature, fitness, or value

that Bayer had represented or that the Plaintiffs and putative class members could reasonably expect.

55. It would be unreasonable for Bayer to retain the profits or money received from the sale of Yasmin and Yaz because the Plaintiffs and putative class members did not, in fact, receive a safe and effective product.

PLACE OF TRIAL

56. The Plaintiffs propose that this action be tried in St. Catharines, Ontario.

March 10, 2010

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Solicitors for the Plaintiffs

Ann Schwoob et al. v. Bayer Inc. et al. Court File No: 52030\10

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