Court File No. 52030/10

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

ANN SCHWOOB, CODY SCHWOOB by his litigation guardian Ann Schwoob and CHRISTINE LOVELACE

Plaintiffs

- and -

BAYER INC.

Defendant

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF DEFENCE

1. The Defendant, Bayer Inc. ("Bayer") admits the allegations contained in paragraphs 2-4 of the fresh as amended statement of claim (hereinafter the "statement of claim").

2. Except as expressly admitted below, Bayer denies the remaining allegations in the statement of claim and denies that the plaintiffs are entitled to any of the relief claimed in paragraph 1 of the statement of claim.

Bayer Inc.

3. Bayer is a Canadian corporation with its head office in Toronto, Ontario. It is a sales and marketing company that provides health care and material sciences products that improve the health and quality of life of Canadians.

4. Among the important medications in Bayer's health care portfolio are contraceptives, including the combined oral contraceptives known as Yasmin® and YAZ®. Bayer markets, distributes and sells Yasmin and YAZ in Canada.

Yasmin and YAZ

5. Yasmin and YAZ are combination oral contraceptives (COCs). COCs combine both an estrogen and progestin component. They act to inhibit ovulation and change the cervical mucus (which increases the difficulty of sperm entry into the uterus) and the endometrium (which reduces the likelihood of implantation).

6. Yasmin combines the following active ingredients: 0.03 mg of ethinyl estradiol (the estrogen component) and 3 mg of drospirenone (the progestin component). Ethinyl estradiol and drospirenone have both been approved for use in combination as a COC by Health Canada. Yasmin has a 28-day dosing cycle which consists of taking Yasmin for 21 consecutive days followed by seven days of taking either placebo pills or no pills. Yasmin is available in either 21- or 28-day pill combinations.

7. YAZ combines a lower estrogen amount – 0.02 mg ethinyl estradiol – with 3 mg drospirenone. YAZ has a 28-day dosing cycle which consists of taking YAZ for 24 consecutive days, followed by four days of taking placebo pills. YAZ is available in a 28-day pill combination.

Health Canada

8. Prescription drugs, such as Yasmin and YAZ, can only be sold in Canada if they are approved by Health Canada. A Notice of Compliance is issued by Health Canada after the successful completion of the regulatory review process, and certifies that the prescription medicine and its associated Product Monograph, which contains key prescribing information for health care professionals and information for consumers, comply with the *Food and Drugs Act* and the *Food and Drugs Regulations*.

9. Approved drugs can only be sold for indications authorized by Health Canada. Moreover, what Bayer can say about a drug, including the risks and benefits, is determined by Health Canada and set out in the drug's Product Monograph.

Yasmin Was Approved by Health Canada

10. On December 10, 2004, Health Canada issued to Berlex Canada Inc. (the assets and liabilities of which were subsequently acquired by Bayer) a Notice of Compliance for Yasmin for the following indicated use: conception control. Shortly thereafter, Berlex Canada Inc., and subsequently Bayer, began to market, distribute and sell Yasmin in Canada in accordance with the Health Canada-approved Product Monograph.

11. On August 28, 2007, Health Canada issued to Bayer a Notice of Compliance for Yasmin for the following additional indicated use: the treatment of moderate acne vulgaris in women who are 16 years of age or older who have no known contraindications to oral contraceptive therapy, desire contraception and have achieved menarche.

12. Presently, Yasmin is indicated in Canada for: (i) conception control; and (ii) treatment of moderate acne vulgaris in women who are 16 years of age or older who have no known contraindications to oral contraceptive therapy, desire contraception and have achieved menarche.

13. Since Health Canada issued the first Notice of Compliance for Yasmin, it has directed and approved various revisions to the Yasmin Product Monograph.

14. At all material times, Yasmin and its Health Canada-approved Product Monograph complied with the state of scientific and medical knowledge available at the time and conformed to the applicable efficacy and safety principles embodied in the *Food and Drugs Act* and its associated regulations.

YAZ Was Approved by Health Canada

15. On December 23, 2008, Health Canada issued a Notice of Compliance to Bayer for YAZ for the following indicated uses: (i) conception control; and (ii) the treatment of moderate acne vulgaris in women who are 14 years of age or older who have no known contraindications to oral contraceptive therapy, desire contraception, and have achieved menarche.

16. Shortly after its approval, Bayer began to market and sell YAZ in Canada in accordance with the Health Canada-approved Product Monograph.

17. Presently, YAZ remains indicated in Canada for the purposes described in paragraph 15 above.

18. Since Health Canada issued the first Notice of Compliance for YAZ, it has directed and approved various revisions to the YAZ Product Monograph.

19. At all material times, YAZ and its Health Canada-approved Product Monograph complied with the state of scientific and medical knowledge available at the time and conformed to the applicable efficacy and safety principles embodied in the *Food and Drugs Act* and its associated regulations.

The Benefits of Yasmin and YAZ Outweigh Their Risks

20. Yasmin and YAZ are safe in that when used in accordance with the information contained their respective Product Monographs, as determined by Health Canada, the potential risks of their use are acceptable in light of their beneficial effects.

21. As with every prescription medicine, COCs carry risks, including the risk of serious adverse reactions. For example, all COCs increase the risk of venous thromboembolism (VTE) (*i.e.*, blood clots in the veins) and arterial thromboembolism (ATE) (*i.e.*, blood clots in the arteries – as compared to non-use. However, this risk is lower than the risk of blood clots during pregnancy or following childbirth.

22. Since the introduction of Yasmin and YAZ to the Canadian market, Health Canada has required that their product Monographs contain a statement regarding the risks associated with the use of birth control pills including, among others, the risks of VTE, ATE and gallbladder disease.

23. At all material times, Bayer marketed, distributed and sold Yasmin and YAZ in a manner consistent with the Health Canada-approved Product Monographs, which provided appropriate warnings regarding the risks of adverse events, including thrombotic and thromboembolic events, associated with the use of Yasmin and YAZ.

Risk of thromboembolism

24. A thrombotic or thromboembolic event is a rare event in women generally. The increased risk of thrombotic and thromboembolic events associated with the use of COCs is rare, and is smaller than the risk associated with pregnancy and delivery.

25. An increased risk of thrombotic and thromboembolic events is associated with the use of all COCs. This risk is well-established and is reflected in the Health Canada-approved Product Monographs for all COCs.

26. The risk of VTE associated with the use of Yasmin and YAZ is clinically comparable to the risk associated with the use of other COCs, including those described by the plaintiffs as first and second generation COCs.

27. The risk of ATE associated with the use of Yasmin and YAZ is the same as or lower than the risk associated with the use of other COCs.

Risk of gallbladder disease or kidney stones

28. When used in accordance with the information contained in the Product Monograph, neither Yasmin nor YAZ is associated with a risk of gallbladder disease greater than that associated with other COCs. Further, the Product Monographs for Yasmin and YAZ have always included an appropriate warning regarding the potential risk of gallbladder disease.

29. Yasmin and YAZ are not associated with an increased risk of kidney stones.

Adverse events

30. Like all drugs, all COCs approved for use in Canada are associated with reports of spontaneous adverse events, including deaths. Among other important limitations, adverse event reports cannot be used to:

(a) conclude that the event actually occurred;

(b) conclude that the event was caused by the suspected medicine;

(c) conclude which component in a combination medicine was responsible for a particular reaction;

(d) determine the overall incidence of the reaction among users of the medicine; or

(e) determine the comparative risk of the reaction among users of similar medicines.

The Relevant Medical and Scientific Information

31. The risks and benefits of Yasmin and YAZ have been studied extensively, both prior to and after receiving regulatory approval from Health Canada.

32. The Yasmin and YAZ Product Monographs have always reflected, and continue to reflect, the available medical and scientific information regarding the risk of VTE, ATE and gallbladder disease.

Pre-approval clinical trials

33. None of the pivotal Yasmin or YAZ clinical trials reflected any increased risk of thrombotic or thromboembolic events associated with the use of Yasmin or YAZ compared to other COCs.

Post-approval safety studies

34. Several post-approval safety studies have confirmed that the risk of venous thromboembolism associated with the use of Yasmin and YAZ is comparable to the risk associated with other COCs. In addition, seven post-approval studies have concluded that the risk of arterial thromboembolism is the same as or lower in users of Yasmin and YAZ as compared to users of other COCs.

35. Some retrospective post-approval studies published in and after 2009 have *suggested* that the risk of venous thromboembolism associated with the use of Yasmin might be somewhat higher than the risk associated with the use of other COCs. The results of these studies cannot be extrapolated to apply to YAZ. Further, and in any event, the results from these studies are not consistent with the large amount of data generated in the Yasmin and YAZ clinical trials or the prospective post-approval safety studies. The retrospective post-approval studies suffer from significant methodological issues that raise important questions about the validity of the conclusions drawn by the authors. They do not affect the conclusion of the more reliable scientific studies showing that the risk of venous thromboembolism associated with the use of Yasmin and YAZ is comparable to the risk associated with the use of other COCs.

November 2011 Product Monographs

36. In August 2011, as a consequence of the publication of two studies related to the risks associated with Yasmin (which Bayer submitted to Health Canada), Health Canada initiated a safety review with respect to the risk of blood clots associated with Yasmin and YAZ. As a result of its review, Health Canada adopted a "precautionary approach" and required that the Product Monographs for Yasmin and YAZ be revised to include the following information [emphasis added]:

> Part I [For Healthcare Professionals] – Warnings and Precautions – Hematologic (additional information only): Several epidemiological studies have examined the risk of VTE with drospirenone-containing COCs versus other COCs. Two prospective cohort studies *showed* that the risk of VTE with drospirenone-containing COCs is comparable to that of other COCs, including levonorgestrel-containing COCs. One case-control and three retrospective cohort studies suggested that the risk of VTE with drospirenone-containing COCs is higher compared to users of levonorgestrel-containing COCs. Two additional nested case-control studies have reported a two-fold and three-fold increased risk of idiopathic VTE in users of drospirenone-containing COCs as compared with levonorgestrel-containing COCs. These retrospective studies *suggest* a potential 1.5-3 times risk of VTE in users of drospirenone-containing COCs. Epidemiological studies have inherent methodological issues making the interpretation of their results complex. However, prescribers should consider the benefits and risks for specific patients with respect to VTE risk given the current retrospective epidemiological studies suggesting a higher risk of VTE with drospirenone-containing COCs compared to levonorgestrel-containing COCs.
>
> Part III [For Consumers] – Warnings and Precautions (additional information only): It has been reported that drospirenone, the progestogen in [Yasmin/YAZ], may carry a higher risk of blood clots than some other progestogens (including levonorgestrel). You should talk to your doctor about the available options.

Bayer Fulfilled its Duties and Obligations

37. Bayer denies that it breached any duties or obligations owed to the class members, including the Representative Plaintiffs, or to the *Family Law Act* class members.

38. At all material times, the marketing, distribution and sale of Yasmin and YAZ in Canada was regulated by the *Food and Drugs Act* and the *Food and Drugs Regulations* and, in particular, sections 8-15 and section 30 of the *Food and Drugs Act* and part C of the *Food and Drugs Regulations*. Bayer complied with and fulfilled these statutory requirements at all material times. Compliance with these requirements demonstrates that Bayer exercised due care with respect to Yasmin and YAZ, and that Yasmin and YAZ are fit for their intended use, of merchantable quality and did not have the alleged serious side effects.

39. Bayer denies that the facts pleaded in paragraphs 17 and 18 of the statement of claim are relevant to the class members' claims, or that Bayer could depart from the descriptions Health Canada requires of Yasmin and YAZ in their respective Product Monographs on the basis of actions of foreign regulators. In any event, the 2010 U.S. FDA label change to which the plaintiffs refer described the conclusions of large scale studies indicating that the VTE risks of Yasmin and YAZ were comparable to those of other COCs, including those containing levonorgestrel, and that the studies suggesting otherwise contained unreliable risk estimates.

40. Regulatory requirements in other jurisdictions, for example those in Europe and in the United States, differ from Canadian regulatory requirements and are irrelevant to the issue of Bayer's compliance with Canadian regulatory requirements.

41. At all material times, Bayer made timely and adequate disclosure to Health Canada, health care professionals (including physicians and pharmacists) and consumers of, among other things:

(a) known and potential risks associated with the use of Yasmin and YAZ;

(b) contraindicated medical or health conditions;

(c) warnings and precautions;

(d) adverse reactions and side effects;

(e) drug interactions; and

(f) other safety information.

No Detrimental Reliance

42. Bayer denies that before November 30, 2011 the language of the Product Monographs for Yasmin and YAZ inadequately described the risk of Yasmin or YAZ as alleged in paragraph 19 of the statement of claim.

43. Moreover, the description of the risks contained in the Product Monographs properly reflected the state of medical knowledge at the relevant time concerning those risks, and was determined by Health Canada, whose decisions on such descriptions Bayer was obliged to follow.

44. In any event, Bayer denies that any of the class members detrimentally relied on the language of the Product Monographs, or that they or their prescribing physicians would have acted differently if the Product Monographs contained the language added to the Product Monographs by Health Canada in November, 2011.

Bayer Is Not Liable to the Class

45. At all material times, Bayer has acted in good faith and has satisfied all of its duties and obligations.

46. Bayer denies that any of the class members' alleged injuries were a result of the use of Yasmin or YAZ or as a result of any act, omission or negligence on the part of Bayer.

47. The class members' alleged injuries are attributable to causes unrelated to the use of Yasmin or YAZ, including, but not limited to causes:

(a) known to each class member and her medical adviser(s); or

(b) unknown to Bayer and/or medical science at the time.

48. The class members' alleged injuries resulted from an intervening or superseding cause and/or causes and any act or omission on the part of Bayer was not the cause of such alleged injuries and damages.

49. In the alternative, the class members were aware of the benefits, instructions, risks, possible adverse reactions and appropriate responses to any reaction associated with the use of Yasmin or YAZ, which the class members are alleged to have consumed, and, thereby, consented to the use of Yasmin or YAZ with full knowledge of their benefits and potential risks.

50. In the alternative, if the class members' alleged injuries were related to the use of Yasmin or YAZ, which is expressly denied, any such injuries were the result of an idiosyncratic or allergic reaction to Yasmin.

51. In the further alternative, the class members' alleged injuries were caused or contributed to by the class members' own acts and omissions.

52. In further alternative, Bayer is not responsible for the individual acts or omissions of the prescribing and/or treating physicians of the class members as learned intermediaries or other health care providers for any alleged failure:

(a) to recognize or to communicate the risks, possible reactions and appropriate responses to reactions; or

(b) to appropriately diagnose and treat such reactions and related symptoms as and when they occurred.

53. In the further alternative, the class members' alleged injuries arose from, and were caused or contributed to by, the risks, hazards, and dangers knowingly assumed by the class members.

54. Bayer denies that the *Family Law Act* class members have suffered any injuries or damages. In any event, any such damage is excessive and remote and has not been mitigated.

55. Bayer pleads and relies on the *Negligence Act*, R.S.O. 1990, c. N.1.

56. Bayer denies that the statement of claim was issued within the applicable limitation period, and pleads and relies on the *Limitations Act, 2002*, S.O. 2002, c. 24, Schedule B.

Defence to the Individual Claim of Ms. Lovelace

57. Ms. Lovelace was prescribed YAZ in January 2009 for reasons other than birth control.

58. The following information was disclosed in the Product Monograph for YAZ at the time that Ms. Lovelace was prescribed and allegedly used YAZ [emphasis in original]:

(a) Part I: Health Professional Information

(i) **WARNINGS AND PRECAUTIONS – General: Discontinue medication at the earliest manifestation of: A. Thromboembolic and Cardiovascular Disorders** such as thrombophlebitis, pulmonary embolism, cerebrovascular disorders, myocardial ischemia, mesenteric thrombosis, and retinal thrombosis.

(ii) **WARNINGS AND PRECAUTIONS – General**: The use of combination oral contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasia and gallbladder disease, although the risk of serious morbidity and mortality is small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly if associated with the presence of other risk factors, such as hypertension, hyperlipidemias, obesity and diabetes.

(iii) **WARNINGS AND PRECAUTIONS – General: YAZ contains 3 mg of the progestogen drospirenone (DRSP) that has antimineralocorticoid activity, including the potential for hyperkalemia in high-risk patients, comparable to a 25 mg dose of spironolactone.**

(iv) **WARNINGS AND PRECAUTIONS – Hematologic**: Epidemiological studies have shown that the incidence of venous thromboembolism (VTE) in users of oral contraceptives with low estrogen content (<50 µg ethinyl estradiol) (including YAZ) ranges from about 20 to 40 cases per 100,000 woman-years, but this risk estimate varies according to the progestogen. This compares with 5 to 10 cases per 100,000 woman-years for nonusers.

The use of any combined oral contraceptive carries an increased risk of VTE compared with no use. The excess risk of VTE is highest during the first year a woman ever uses a combined oral contraceptive. The increased risk is less than the risk of VTE associated with pregnancy, which is estimated as 60 cases per 100,000 pregnancies. VTE is fatal in 1% to 2% of cases.

Other Risk Factors for Venous Thromboembolism: Other generalized risk factors for venous thromboembolism include but are not limited to a personal history, a family history (the occurrence of VTE in a direct relative at a relatively early age may indicate genetic predisposition), severe obesity (body mass index >30 kg/m^2) and systemic lupus erythematosus. The risk of VTE also increases with age and smoking. The risk of VTE may be temporarily increased with prolonged immobilization, major surgery, or trauma. Also, patients with varicose veins and leg cast should be closely supervised.

If a hereditary or acquired predisposition for venous thromboembolism is suspected, the woman should be referred to a specialist for advice before deciding on any COC use.

(v) **ADVERSE REACTIONS – <u>Adverse Drug Reaction Overview</u>**: An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives:

- benign hepatic tumors
- cerebral hemorrhage
- cerebral thrombosis
- congenital anomalies
- gallbladder disease
- hypertension
- mesenteric thrombosis

- myocardial infarction
- neuro-ocular lesions (eg, retinal thrombosis)
- pulmonary embolism
- thrombophlebitis

(b) Part III: Consumer Information

(i) **When it should not be used**: The birth control pill is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of the birth control pill should always be supervised by your doctor.

(ii) **WARNINGS AND PRECAUTIONS – BEFORE you use YAZ, talk to your doctor or pharmacist if you**:...

- are overweight...
- have high cholesterol...

(iii) **WARNINGS AND PRECAUTIONS** – If you and your doctor decide that, for you, the benefits of YAZ outweigh the risks, then you should be aware of the following: **THE RISKS OF USING YAZ: 1. Circulatory disorders (including blood clots in the legs, lungs, heart, eyes or brain):** Women who use hormonal contraceptives have a higher incidence of blood clots. Blood clots are the most common serious side effects of birth control pills. The risk of developing blood clots is especially high during the first year a woman ever uses a hormonal contraceptive. Clots can occur in many parts of the body.

Be alert for the following symptoms and signs of serious adverse effects. Call your doctor immediately if they occur:

- sharp pain in the chest, coughing blood, or sudden shortness of breath. These symptoms could indicate a possible blood clot in the lung.

- pain and/or swelling in the calf. These symptoms could indicate a possible blood clot in the leg.

- crushing chest pain or heaviness. These symptoms could indicate a possible heart attack.

- sudden severe or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg. These symptoms could indicate a possible stroke.

- sudden partial or complete loss of vision. This symptom could indicate a blood clot in the eye.

Any of these conditions can cause death or disability. Clots also occur rarely in the blood vessels of the eye, resulting in blindness or impaired vision or in a blood vessel leading to an arm or leg, resulting in damage to or loss of a limb.

The risk of clotting seems to increase with higher estrogen doses. It is important, therefore, to use as low a dosage of estrogen as possible.

(iv) **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM: Stop taking drug and call your doctor or pharmacist** if you have any of the listed uncommon symptoms [including crushing chest pain or heaviness, pain or swelling in the leg, sharp pain in the chest, coughing blood, sudden shortness of breath or fainting]

59. Prior to taking YAZ, Ms. Lovelace did not discuss the risks of YAZ with her family physician. Nor did she read the package insert provided in the package of YAZ that she received.

60. Ms. Lovelace now says that if she had been aware of the risks that were described in the Product Monograph for YAZ (including the package insert) she would not have taken it. Therefore, any damage alleged to have resulted from Ms. Lovelace's consumption of YAZ results from her failure to consider the risks of YAZ that were disclosed by Bayer, and her prescribing physician's failure to advise her of those risks.

61. In September 2009, Ms. Lovelace was admitted to the hospital suffering from a transient ischemic attack, which is a kind of mild-stroke. Ms. Lovelace's stroke was found to be "cryptogenic", meaning of unknown cause.

62. Ms. Lovelace's alleged injuries were not caused or contributed to by Bayer. Any injuries sustained by Ms. Lovelace were caused or contributed to by her own acts or omissions, the particulars of which include, but are not limited to, the following:

(a) Ms. Lovelace failed to assess the benefits and risks associated with the use of YAZ or, alternatively, decided to use YAZ after having assessed the benefits and risks associated with its use; and

(b) Ms. Lovelace failed to inform herself of the risks associated with COCs or, in the alternative, was willfully blind to these risks.

Defence to the Individual Claim of Ms. Schwoob

63. In March 2009, Ms. Schwoob began taking Yasmin. At the time Ms. Schwoob was 32 years old and had been a frequent smoker for approximately twenty years. In addition, Ms. Schwoob had several additional known risk factors for venous thromboembolism that were identified in the Product Monograph for Yasmin, including being overweight and having increased anti-cardiolipin antibodies and lupus anticoagulant.

64. The information set out in paragraph 58 above was disclosed in the Product Monograph for Yasmin at the time that Ms. Schwoob was prescribed and allegedly used it. In addition, the following information was disclosed in the Product Monograph [emphasis in the original]:

(a) Part I - Health Professional Information

(i) **WARNINGS AND PRECAUTIONS** [in a separate box for emphasis]:

> **Serious Warnings and Precautions**
>
> Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in oral contraceptive users older than 35 years of age. Women should be counseled not to smoke (see **WARNINGS AND PRECAUTIONS – Cardiovascular** section…).

(ii) **WARNINGS AND PRECAUTIONS – Cardiovascular – *Predisposing Factors for Coronary Artery Disease:*** Cigarette smoking increases the risk of serious cardiovascular side effects and mortality. Birth control pills increase this risk, especially with increasing age. Convincing data, are available to support an upper age limit of 35 years for oral contraceptive use by women who smoke.

(iii) **WARNINGS AND PRECAUTIONS – Hematologic – *Other Risk Factors for Venous Thromboembolism:*** … The risk of VTE also increases with age and smoking….

(iv) **ADVERSE REACTIONS – Post-Market Active Surveillance Study**: A prospective, controlled, noninterventional, active surveillance cohort study (EURAS) was conducted in Europe to compare risks of adverse cardiovascular and other events associated with the use of DRSP-containing OCs (Yasmin) and other OCs. In this study, 58,674 OC users were actively followed for a total of 142,475 woman-years. Loss to follow-up was 2.4%. The hazard ratios for venous thromboembolic (VTE) and for all thromboembolic (TE) events were close to 1 and thus do not suggest a higher risk for Yasmin users. The results exclude a 1.5-fold thromboembolic risk of Yasmin users compared to users of LNG-containing OCs and a 1.2-fold thromboembolic risk compared to users of other OCs. Arrhythmic events that could be suggestive of an increased

serum potassium level (eg, because of the antimineralocorticoid activity of DRSP) were not observed in this Postmarket Surveillance study.

(b) Part III - Consumer Information

(i) **<u>When it should not be used</u> – You should not use YASMIN** if you have or have had any of the following conditions: ...

- heavy smoking (> 15 cigarettes per day) and over age 35

(ii) [Under a black box headed **WARNINGS AND PRECAUTIONS**, and in a separate box for emphasis]:

> **Serious Warnings and Precautions**
>
> **Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in hormonal contraceptive users older than 35 years of age. Women should not smoke.**

65. Ms. Schwoob was aware of and disregarded the repeated warnings given by her physicians and confirmed in the Product Monograph of the significant risks of smoking while consuming Yasmin, or any other COC. Bayer denies that the amendments to the Yasmin Product Monograph introduced by Health Canada in November, 2011, would have changed Ms. Schwoob's decision to take Yasmin.

66. In August 2009, Ms. Schwoob was diagnosed with a pulmonary embolism.

67. Ms. Schwoob's alleged injuries were not caused or contributed to by Bayer. Further, Ms. Schwoob's injuries were caused or contributed to by her own acts or omissions, the particulars of which include, but are not limited to, the following:

(a) Ms. Schwoob failed to assess the benefits and risks associated with the use of Yasmin or, alternatively, decided to use Yasmin after having assessed the benefits and risks associated with its use; and

(b) Ms. Schwoob engaged in activities known to independently and significantly increase her risk of suffering from adverse events, including thrombotic and thromboembolic events, and she failed to control and/or manage medical, health and lifestyle factors that independently and significantly increased her risk of suffering from adverse events, including thrombotic and thromboembolic events.

Remedies

68. Bayer denies that the Representative Plaintiffs and other class members are entitled to any of the relief sought in paragraph 1 of the statement of claim, or any other relief. Bayer further denies that the Representative Plaintiffs and other class members are entitled to punitive damages.

69. Bayer denies that "waiver of tort" exists as an independent cause of action or that a remedy based on "waiver of tort" is available to any of the class members.

70. Bayer requests that this action be dismissed with costs on a substantial indemnity basis.

August 5, 2015

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Proceeding commenced at ST. CATHARINES

STATEMENT OF DEFENCE

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