

Form 4.02A

2010

Hfx. No. 330493

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

NATASHA PAULEY

- and -



BAYER CORPORATION; HEALTH CARE PHARMACEUTICALS, INC; BAYER PHARMACEUTICALS CORPORATION; BAYER HEALTH CARE, LLC; BAYER INC; BAYER SCHERING PHARMA AG, a body corporate, BAYER AG, a body corporate

Defendants

Notice of Action

Proceeding under the *Class Proceedings Act*, S.N.S. 2007, c. 28

TO: BAYER CORPORATION

TO: BAYER HEALTH CARE PHARMACEUTICALS, INC

TO: BAYER PHARMACEUTICALS CORPORATION

TO: BAYER HEALTH CARE, LLC

TO: BAYER INC

TO: BAYER SCHERING PHARMA AG

TO: BAYER AG

Action has been started against you

The plaintiff takes action against you.

The plaintiff started the action by filing this notice with the court on the date certified by the prothonotary.

The plaintiff claims the relief described in the attached statement of claim. The claim is based on the grounds stated in the statement of claim.

Deadline for defending the action

To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

- 15 days if delivery is made in Nova Scotia.

- 30 days if delivery is made elsewhere in Canada.
- 45 days if delivery is made anywhere else.

Judgment against you if you do not defend

The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

You may demand notice of steps in the action

If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

If you file a demand for notice, the plaintiff must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

Rule 57 - Action for Damages Under \$100,000

Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the plaintiff states the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the plaintiff.

This action is not within Rule 57.

Filing and delivering documents

Any documents you file with the court must be filed at the office of the Prothonotary, The Law Courts, 1815 Upper Water Street, Halifax, Nova Scotia (telephone #902-424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

Contact information

The plaintiff designates the following address:

Wagners Law Firm
1869 Upper Water Street
Halifax, Nova Scotia
B3J 1S9

Documents delivered to this address are considered received by the plaintiffs on delivery.


Further contact information is available from the prothonotary.

Proposed place of trial

The plaintiff proposes that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Signature
Signed

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RAYMOND F. WAGNER
Solicitor for Plaintiff

Prothonotary's certificate

I certify that this notice of action, including the attached statement of claim, was filed with the court on

June 10, 20 *10*



Prothonotary

BONNIE MACMULLIN
Deputy Prothonotary

FORM 4.02B

STATEMENT OF CLAIM

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

I. OVERVIEW

- 1) Yasmin, which contains drospirenone and ethinyl estradiol, is a combination birth control pill originally developed by Berlex Laboratories, Inc and/or Berlex, Inc containing the hormones oestrogen and progestin.
- 2) In 2006, Bayer acquired Berlex Laboratories, Inc and/or Berlex, Inc and began marketing an almost identical drug, Yaz.
- 3) The difference between both Yasmin/Yaz and other birth control pills on the market is that drospirenone has never before been marketed in Canada and is unlike other progestin available in Canada.
- 4) Shortly after the introduction of combined oral contraceptives in the 1960s, doctors and researchers found that women using birth control pills had a higher risk of blot clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of oestrogen. As the amounts of oestrogen levels reduced, so did the risks of blood clots, heart attacks, and strokes.
- 5) During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of oestrogen (ethinyl estradiol) helped to reduce the risk of blood clots, heart attacks and strokes and were considered safer for women.
- 6) During the 1990s, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA and Health Canada have required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

- 7) Yasmin and Yaz contain the same oestrogen component, ethinyl estradiol, which has been used in the lower dose birth control pills for decades.
- 8) However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.
- 9) Since drospirenone in birth control is new, there are not decades of data available to support its safe use as there are with second generation progestins.
- 10) One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.
- 11) Hyperkalemia can cause various medical complications, including heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.
- 12) Drospirenone increases the risk of and permits blood clots to form - including deep vein thrombosis. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.
- 13) If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form - including deep vein thrombosis. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lung, where they can cause pulmonary embolism, or travel to the brain where they can cause a stroke.
- 14) During the time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.
- 15) During the brief time that Yasmin and Yaz have been available for sale in Canada, a total of over 120 reports of injury and death have been submitted to Health Canada in association with Defendants' products.
- 16) In April 2002, the British Medical Journal reported that the Dutch College of Medical Practitioners recommended that older second generation birth control pills be prescribed

instead of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

- 17) In February 2003, a paper entitled *Thromboembolism Associated with the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism, including two deaths, where Yasmin was suspected as the cause.
- 18) In August 2009, the British Medical Journal published the result of a national follow-up study which concluded that oral contraceptives containing drospirenone, such as Yasmin and Yaz, are associated with a significantly higher risk of venous thromboembolism than other oral contraceptives.
- 19) Yasmin and Yaz were approved for sale in Canada in 2004 and 2008 respectively.
- 20) Yasmin and Yaz are among the top selling pharmaceuticals produced by the Bayer Group.
- 21) Sales of Yasmin were as high as \$616 million in 2008.

II. REPRESENTATIVE PLAINTIFF AND CLASS

- 22) The Plaintiff, Natasha Pauley, resides at 53 Ainslie Crescent, Eastern Passage, Nova Scotia.
- 23) The Plaintiff seeks to certify this action as a class proceeding and pleads the *Class Proceedings Act*, S.N.S. 2007, c. 28 as providing the basis for such certification. The Plaintiff, as the Representative Plaintiff, does not have any interest adverse to any of the members of the proposed class. The Plaintiff states that there is an identifiable class that would be fairly and adequately represented by the Plaintiff; that the Plaintiff's claims raise common issues; and that a class proceeding would be the preferable procedure for the resolution of such common issues.
- 24) The Plaintiff proposes to bring a class proceeding on behalf of herself and a class of other residents of Canada who claim to have suffered personal injuries as a result of ingesting Yasmin or Yaz. The proposed class, which will include Injury Class Members, and Family Class Members will be further defined in the Application for Certification.
- 25) In this action the Plaintiff seeks on her own behalf and on behalf of the Class:
 - (a) compensation for the personal injuries and other costs incurred as a result of having taken Yasmin or Yaz;

- (b) disgorgement of the benefits that accrued to the Defendants as a result of their wrongful acts; and
 - (c) damages in the form of total funds required to establish a medical monitoring process for the benefit of the Class Members.
- 26) Class Members have all been prescribed Yasmin or Yaz. Deceased individuals through Class Members who are lawfully entitled claimants under the *Fatal Injuries Act*, R.S.N.S. 1989, c. 163 in this proceeding had been prescribed Yasmin or Yaz.
- 27) Living Class Members have been continuously harmed by their use of the medication Yasmin or Yaz as hereinafter described. Deceased individuals had been harmed by the use of Yasmin or Yaz that caused or materially contributed to their death.
- 28) The Plaintiff and Class Members have suffered pain, loss of enjoyment of life, a probable shortening of life, loss of earnings and earning capacity, and therefore, claim both special damages and general damages as a result of ingesting Yasmin or Yaz.

III. DEFENDANTS

- 29) Defendant Bayer Corporation is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is the sole member of Bayer Health Care LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of the Defendant Bayer Health Care Pharmaceuticals, Inc. As such, Defendant Bayer Corporation is the parent of Defendant Bayer Health Care Pharmaceutical, Inc.
- 30) Defendant Bayer Healthcare Pharmaceuticals, Inc, is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Health Care Pharmaceuticals, Inc was created by the integration of Bayer Health Care and Berlex Laboratories. Bayer Health Care Pharmaceuticals, Inc is the U.S. based pharmaceutical unit of Schering Berlin, Inc and is a division of Bayer AG.
- 31) Defendant Bayer Healthcare Pharmaceuticals, Inc was formerly known as Berlex, Inc, which was formerly known as Berlex Laboratories, Inc and is the same corporate entity as Berlex, Inc and Berlex Laboratories, Inc.

- 32) Defendant Bayer Healthcare Pharmaceuticals, Inc is the holder of approved New Drug Application ("NDA") for Yaz.
- 33) Defendant Bayer Pharmaceuticals Corporation is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.
- 34) As of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.
- 35) Defendant Bayer Healthcare, LLC is, and at all times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 555 White Plains Road, Tarrytown, New York 10591.
- 36) Defendant Bayer Inc is a Canadian subsidiary of Bayer AG which operates the Bayer Group's Healthcare and Material Science businesses in Canada. Defendant Bayer Inc has its principal place of business located at 77 Belfield Road, Toronto, Ontario, M9W 1G6.
- 37) Defendant Bayer Schering Pharma AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Mullerstrasse 178, 13353 Berlin, Germany.
- 38) Defendant Bayer Schering Pharma AG is the current owner of the patent(s) relating to the oral contraceptive Yaz.
- 39) Defendant Bayer AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.
- 40) Defendant Bayer AG is the third largest pharmaceutical company in the world.
- 41) Defendant Bayer AG is the parent/holding company of all other named Defendants.
- 42) Defendants Bayer Corporation; Bayer Healthcare Pharmaceuticals, Inc; Bayer Pharmaceuticals Corporation; Bayer Healthcare, LLC; Bayer Inc; Bayer Schering Pharma AG; and Bayer AG shall be referred to herein individually by name or jointly as the "Defendants."
- 43) During the Class Period, the Defendants were engaged in, involved in, and/or were responsible for the research, development, designing, testing, manufacturing,

distributing, packaging, promoting, and/or marketing of Yasmin or Yaz in the United States and Canada.

- 44) The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the research, development, designing, testing, manufacturing, distributing, packaging, promoting, and/or marketing and/or selling of Yasmin or Yaz in the United States and Canada.
- 45) At all material times, the Defendants, all or any one of them, were carrying on business as, inter alia, the researchers, developers, designers, testers, manufacturers, distributors, packagers, promoters, marketers and/or sellers of Yasmin or Yaz in the United States and Canada.

V. NATURE OF THE ACTION

- 46) During the applicable times within the class period, the Defendants marketed Yasmin and Yaz as providing the same efficacy as other oral contraceptive used for the prevention of pregnancy but with additional benefits.
- 47) As a result, the Defendants were warned by the FDA on at least three occasions (in 2003, 2008, & 2009) about misleading the public through the use of ads which overstated the efficacy of Yaz and/or its predecessor Yasmin and which minimize the serious risks associated with the drug(s).
- 48) Bayer had to subsequently air new TV advertisements to correct the previous misleading Yaz advertisements.
- 49) Bayer agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.
- 50) The Plaintiff and Class Members allege that the Defendants ignored the correlation between the use of Yasmin and Yaz and increased thrombosis formation despite the wealth of scientific information available.
- 51) The Plaintiff and Class Members further allege that the Defendants knew or should have known about the correlation between the use of Yasmin and Yaz and blood clots, heart attacks, and strokes.
- 52) The Plaintiff and Class Members further allege that the Defendants falsely and fraudulently represented to the medical and healthcare community, to the class

members, the FDA, Health Canada, and the public in general, that Yasmin and Yaz had been tested and were found to be safe and effective for their indicated use.

- 53) The Plaintiff and Class Members further allege that these false representations were made by the Defendants with the intent of defrauding and deceiving the Representative Plaintiff, Class Members, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense, purchase and use Yasmin and Yaz despite the associated risks.
- 54) The Plaintiff and Class Members further allege that the Defendants knew and were aware or should have been aware that Yasmin and Yaz had not been sufficiently tested, were defective in their design and testing, and/or lacked adequate and/or sufficient warnings.
- 55) The Plaintiff and Class Members further allege that the Defendants knew or should have known that Yasmin and Yaz had a potential to, could, and would cause severe and grievous injury and death to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or mitigated warnings.
- 56) The Plaintiff and Class Members further allege that the Defendants fraudulently concealed and intentionally omitted the following material information:
 - a) That Yasmin and Yaz are not as safe as other available contraceptives;
 - b) That the risks of adverse events with Yasmin and Yaz were higher than those of other available contraceptives;
 - c) That the Plaintiff and Class Members were put at risk of experiencing serious and dangerous side effects including, but not limited to, stress, pulmonary embolisms, blood clots, heart attacks, strokes, gallbladder complications, hyperkalemia as well as other severe and personal injuries, physical pain, and mental anguish;
 - d) That the Plaintiff and Class Members needed to be monitored more regularly than normal while using Yasmin or Yaz; and/or
 - e) That Yasmin and Yaz were designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

- 57) The Plaintiff further alleges on behalf of Class Members that the continued use of Yasmin or Yaz by Class Members creates ongoing risks to the health of the Class Members.
- 58) During the applicable times within the Class Period while the Defendants were involved with researching, developing, designing, testing, manufacturing, distributing, packaging, promoting, and/or marketing Yasmin and/or Yaz, they knew or ought to have known of the potential safety risks associated with the drug.
- 59) None of the Defendants took any steps to prevent harm to the Plaintiff and the Class Members or to protect the health and safety of the Plaintiff and Class Members.
- 60) Class Members have been prescribed and continue to be prescribed Yasmin and/or Yaz.

VI. HARM TO THE PLAINTIFF

- 61) Ms. Pauley was initially prescribed Yasmin by her health care provider in September 2008.
- 62) Ms. Pauley justifiably relied on and/or was induced by the misrepresentations and/or active concealment of the Defendants to purchase and consume Yasmin to the detriment of her health and safety.
- 63) As a result of ingesting Yasmin from September 2008 through to June 2009, Ms. Pauley has suffered serious and potentially life threatening side effects including but not limited to shortness of breath, chest pains, chest tightening, and fainting spells. In addition, Ms. Pauley has experienced severe physical pain, mental anguish, loss of enjoyment of life, and the fear of developing other health risks associated with Yasmin including but not limited to blood clots, heart attacks, strokes, gall bladder complications, and hyperkalemia.
- 64) Ms. Pauley states that the personal injuries were caused or materially contributed to by her use of Yasmin.
- 65) Ms. Pauley did not discover, nor did she have any reason to discover, that her injury was the result of a defective drug and/or the wrongful conduct of the Defendants, as set forth herein, until at least July 2009.
- 66) The Plaintiff and Class Members have suffered and continue to suffer from anxiety about their own and their family's health because of the effect that Yasmin or Yaz has had on

their lives. The Plaintiff states that all of the Defendants bear the responsibility to, *inter alia*, create a medical monitoring fund/mechanism as described below that would give Class Members access to experts who could address their health concerns.

VII. CAUSES OF ACTION

(a) Conspiracy

- 67) During the class period, the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking bona fides, conspired and agreed together, the one with the other and with persons unknown, as hereinafter set out.
- 68) The Plaintiff pleads that the Defendants' conspiracy involved both lawful and unlawful means with the predominant purpose of causing the Plaintiff and the other Injury Class Members to acquire and ingest Yasmin or Yaz when they knew or should have known that such use would cause harm to the Injury Class Members and the Family Class Members.
- 69) The Defendants conspired with each other and others to unlawfully market, distribute, advertise and sell Yasmin and Yaz, intending that their conduct be directed towards the Injury Class Members, when they knew or should have known that in the circumstances, injury and damage to the Injury Class Members and the Family Class Members was likely to result. They derived substantial compensation and revenues from the conspiracy.
- 70) As a result of the conspiracy, the Plaintiff and the other Injury Class Members have suffered damage and loss, including other side effects as a result of the use of Yasmin or Yaz.
- 71) As a further result of the conspiracy, Family Class Members have suffered damages and loss, and continue to suffer damages and loss, including actual expenses reasonably incurred for the benefit of the Injury Class Member, a reasonable allowance for loss of income or the value of services provided to the Injury Class Member and an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Injury Class Member.
- 72) Some, but not all, of the Defendants' concerns, motivations and intentions in engaging in the conspiracy were to:
- (a) increase the sales of Yasmin and Yaz and their profits;

- (b) increase or hold their market share;
- (c) avoid adverse publicity;
- (d) place their profits above the safety of Injury Class Members and others;
- (e) maintain brand trust and corporate image;
- (f) avoid alerting the Injury Class Members, Health Canada, the FDA, health practitioners, the public and their competitors to the dangerous properties and effects of Yasmin and Yaz; and
- (g) cause the Injury Class Members to ingest and continue to ingest Yasmin and Yaz and thereby suffer harm.

73) In furtherance of the conspiracy, the following are some, but not all, of the acts carried out by the Defendants or one or some of them:

- (a) they submitted false, inaccurate and/or misleading information to Health Canada for the purpose of obtaining approval to market Yasmin and Yaz in Canada;
- (b) they concealed and disguised information about the dangerous properties and effects of Yasmin and Yaz from Health Canada, from health practitioners, and from Injury Class Members;
- (c) they misled Injury Class Members, health practitioners, and others about the safety and effect of Yasmin and Yaz;
- (d) they refused to issue correcting information or to stop selling Yasmin and Yaz even after its harmful effects became manifest;
- (e) they decided not to warn Class Members and others in Canada of the dangers of taking Yasmin and Yaz; and
- (f) they developed and used marketing and promotional strategies that covered up the truth about Yasmin and Yaz's dangerous properties and effects.

(b) Negligence

74) Each of the Defendants owed a duty of care to the Plaintiff and Class Members and breached the requisite standard of conduct expected of them in the circumstances.

- 75) The Defendants negligently breached their duty of care in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that they, directly and indirectly, advertised, marketed and promoted Yasmin and Yaz for the prevention of pregnancy, even though Yasmin and Yaz, in fact, were a danger to the public. Furthermore, the Defendants failed to adequately warn of the increased risk of serious injury, which the Defendants knew or should have known about.
- 76) The Plaintiff and Class Members state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following, that the Defendants jointly and severally:
- (a) chose not to ensure that Yasmin and Yaz were not dangerous to recipients during the course of its use and that the drug was fit for its intended or reasonably foreseeable use;
 - (b) chose to inadequately test Yasmin and Yaz in a manner that concealed the magnitude of the risks associated with its use, including but not limited to the risk of blood clots, heart attacks, strokes, gall bladder complications, and hyperkalemia;
 - (c) chose to misinform Health Canada by providing it with incomplete and/or inaccurate information;
 - (d) chose to conduct inadequate or no follow-up studies on the efficacy and safety of Yasmin and Yaz;
 - (e) chose to conceal and mislead the Plaintiff, Class Members and their physicians with inadequate and/or incomplete warning of the risks associated with ingesting Yasmin and Yaz;
 - (f) chose to provide the Plaintiff, Class Members and their physicians with inadequate or incomplete or no information and warnings respecting the correct usage of Yasmin and Yaz;
 - (g) chose to provide inadequate or incomplete or no updated and current information to the Plaintiff, Class Members and their physicians respecting the risks of Yasmin or Yaz as it came available from time to time;
 - (h) chose not to provide warnings of the potential hazards of ingesting Yasmin and Yaz on package labels and by other means;

- (i) chose not to provide warnings of the risks associated with Yasmin and Yaz on the customer information pamphlets in Canada;
- (j) chose not to warn the Plaintiff, Class Members, and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of serious problems from the use of Yasmin and Yaz;
- (k) after noticing problems with Yasmin and Yaz, chose not to issue adequate warnings, recall the drug in a timely manner, publicize the problem and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff, Class Members and their physicians of the drug's inherent dangers;
- (l) chose to engage in a system of improper and inadequate direction to their sales representatives and prescribing physicians respecting the correct usage of Yasmin and Yaz and the risks associated with the drugs;
- (m) chose to represent that Yasmin and Yaz were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
- (n) chose to misrepresent the state of research, opinion, and medical literature pertaining to the purported benefits of Yasmin and Yaz and their associated risks;
- (p) chose to continue to manufacture, market, and promote the selling and/or distribution of Yasmin and Yaz when they knew or ought to have known that this drug caused or could cause serious problems;
- (q) chose to actively encourage aggressive dispensation of Yasmin and Yaz;
- (r) chose to breach other duties of care to the Plaintiff and the Class Members, details of which breaches are known only to the Defendants.

(c) Strict Liability

- 77) The Defendants are strictly liable for some or all of the damages suffered by the Plaintiff and other Class Members in that:
- (a) the Defendants manufactured and marketed Yasmin and Yaz;
 - (b) Yasmin and Yaz are prescription drugs that are considered to be inherently

dangerous;

(c) the Plaintiff and other Class Members had no opportunity to inspect or test Yasmin and Yaz to ensure their safety; and

(d) Yasmin and Yaz were used by the Plaintiff and other Class Members.

(d) Breach of Warranty

78) The Defendants warranted to the Plaintiff and the Class Members that Yasmin and Yaz were of merchantable quality and fit for use and safe for human consumption. The Defendants breached the warranty to the Plaintiff and the Class Members by researching, developing, designing, testing, manufacturing, distributing, packaging, promoting, marketing and/or selling Yasmin and Yaz which was inherently dangerous to users and which the Defendants knew or ought to have known would lead to serious injuries.

(e) Waiver of Tort

79) As a result of the Defendants' conduct described herein, the Plaintiff and Class Members reserve the right to elect at the trial of the common issues to waive the torts and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, or the net income received by the Defendants or a percent of the proceeds from the sale of Yasmin and Yaz as a result of the Defendants' conduct.

80) The Plaintiff and Class Members claim that such an election is appropriate for the following reasons, among others:

(a) revenue was acquired in a manner in which the Defendants cannot in good conscience retain it;

(b) the integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;

(c) absent the Defendants' tortious conduct, Yasmin and Yaz could not have been marketed nor would the Defendants have received any revenue from its sale in Canada; and

(d) the Defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the potential to cause serious risk of injury.

(f) Breach of Section 52 of the *Competition Act*, R.S. 1985, c. C-34

81) The Defendants knowingly or recklessly made material false representations to the Plaintiff and Class Members for the purposes of promotion, the supply, and use of Yasmin and Yaz.

(g) Breach of Sections 3 & 9 of the *Food and Drugs Act*, R.S. 1985, c. F-27

82) The Defendants engaged in unlawful trade practices, labeling, selling and advertising Yasmin and Yaz in a manner that is false, misleading, and deceptive which creates an erroneous impression regarding the drug's safety.

(h) Unjust enrichment

83) The Defendants voluntarily accepted and retained profits and benefits, derived from the Plaintiff and Class Members, with full knowledge and awareness that, as a result of their conscious and intentional wrongdoings, Plaintiff and Class Members did not receive a product of the quality, nature or fitness that had been represented by the Defendants or that Plaintiff and Class Members, as a reasonable consumer, expected.

84) By virtue of the conscious wrongdoings alleged, the Defendants have been unjustly enriched at the expense of the Plaintiff and Class Members.

VIII. DAMAGES

85) The Plaintiff's and Class Members' injuries and damages were caused by the Defendants, their servants, and agents.

86) The Defendants have caused injury to the Plaintiff and to the Class Members including:

- (a) a reduced standard of living as a result of injury;
- (b) the cost of treatment to combat the adverse health effects caused by their use of Yasmin or Yaz; and
- (c) an enhanced risk of future problems attributable to the use of Yasmin or Yaz.

87) As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiff and Class Members have been placed in a position where they have sustained or will sustain serious personal injuries and damages.

88) As a result of the conduct of the Defendants, the Plaintiff, and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

89) Some of the expenses related to the medical treatment that the Plaintiff and Class Members have undergone, and will continue to undergo have been borne by provincial health insurer including the Nova Scotia Medical Services Insurance Plan. As a result of the negligence of the Defendants, the provincial health insurer has suffered and will continue to suffer damages.

(A) Manifest Harm and Injuries:

90) In addition, the past and ongoing use of Yasmin or Yaz has resulted in the Plaintiff and Class Members' physical and mental health injuries pleaded above, and has further led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, and out of pocket expenses.

91) The Plaintiff and Class Members assert a claim for each of the types of damages listed above.

(B) Medical Monitoring: Responding to Material Risk of Illness

92) Further, the past and ongoing use of Yasmin or Yaz has also caused or materially contributed to increased health risks to the Plaintiff and other Class Members. As a result of the use, the Plaintiff and Class Members have already and will continue to experience illness, anxiety, loss of amenities and enjoyment of life.

93) There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will detect at an early stage the serious problems which may result from the use of Yasmin or Yaz by the Class Members. However, not all of these tests are generally available or being administered to the Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm and risk of death therefrom.

94) The Class Members seek to recover damages in the form of the total funds required to establish a 'medical monitoring' process to be made available to the Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Class Members.

- 95) The damages referred to above may have been incurred directly by the Plaintiff and Class Members, or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.
- 96) The Plaintiff further allege that the establishment of a medical monitoring process is a necessary and appropriate step for all of the Defendants to take in the course of fulfilling their obligation to minimize the damages suffered by Class Members.

IX. AGGRAVATED, PUNITIVE AND EXEMPLARY DAMAGES

- 97) The Defendants designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labelled, and sold Yasmin and Yaz with full knowledge of the fact that they were adversely impacting the physical and psychological health of the Plaintiff and the Class Members. Knowledge of the risks associated with the use of Yasmin or Yaz was not released to the Plaintiff and Class Members. Despite having specific information that the Plaintiff and Class Members were at risk of serious problems associated with the use of Yasmin or Yaz, the Defendants continued or permitted the continuation of the designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and selling of Yasmin and Yaz without any or reasonable controls.
- 98) These activities were carried out with reckless, callous, and wanton disregard for the health, safety and pecuniary interests of the Plaintiff and other Class Members. The Defendants knowingly compromised the interests of the Plaintiff and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that Yasmin and Yaz posed to the Plaintiff and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.
- 99) The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety or welfare of the Plaintiff and Class Members.
- 100) Consequently, the Plaintiff and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.

The Plaintiff and Class Members plead that, by virtue of the acts described herein, the Defendants are liable to them in damages. Each of the Defendants is vicariously liable for the acts and omissions of the others for the following reasons:

- (a) each was the agent of the other;
- (b) each Defendants' business was operated so that it was inextricably interwoven with the business of the other;
- (c) each Defendant entered into a common advertising and business plan with the other to distribute and sell Yasmin and Yaz;
- (d) each Defendant owed a duty to the other and to the Plaintiff and Class Member by virtue of the common business plan to distribute and sell Yasmin and Yaz; and
- (e) each Defendant intended that the businesses be run as one global business organization.

X. GENERAL PROVISIONS

- 101) The Plaintiff states that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiff and other Class Members.
- 102) The Plaintiff pleads the doctrine of *respondeat superior* and states that the Defendants are vicariously liable to the Plaintiff and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.
- 103) The Plaintiff pleads and relies on the *Canada Food and Drugs Act*, R.S. 1985, c. F-27, the *Canada Competition Act*, R.S., 1985, c. C-34, s. 1; R.S., 1985, c. 19 (2nd Supp.), s. 19.

XI. RELIEF SOUGHT

- 104) The Plaintiff repeats the foregoing paragraphs and states that the Defendants are jointly and severally liable for the following:
 - (a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;
 - (b) general damages, including aggravated damages for personal injuries;

- (c) special damages for medical expenses and other expenses related to the use of Yasmin or Yaz;
- (d) aggravated, punitive and exemplary damages;
- (e) further or alternatively the Plaintiff claims, on her own behalf and on behalf of the Class Members:
 - (i) a declaration that the benefits which accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;
 - (ii) an accounting of the benefits which accrued to the Defendants as a result of their wrongful acts;
 - (iii) a declaration that the Defendants hold in trust for the Class the benefits which accrued to the Defendants as a result of their wrongful acts;
 - (iv) disgorgement of the benefits which accrued to the Defendants as a result of their wrongful acts;
- (f) damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Class Members, and to make recommendations about their treatment;
- (g) subrogated claims on behalf of the Provincial providers of medical services;
- (h) interest pursuant to the *Judicature Act*,
- (i) costs; and
- (j) such further and other relief as this Honourable Court deems just.

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Halifax, Nova Scotia this day of , 2010.



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