

NO.
VANCOUVER REGISTRY

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

MEAH BARTRAM, an INFANT,
by her Mother and Litigation Guardian, FAITH GIBSON,
and the said FAITH GIBSON

PLAINTIFFS

AND:

GlaxoSmithKline Inc. and GlaxoSmithKline UK Limited

DEFENDANTS

Brought pursuant to the *Class Proceedings Act*, R.S.B.C. 1996, c. 50

STATEMENT OF CLAIM

THE PARTIES

1. The Plaintiff, Meah Bartram is an Infant and was born on September 14, 2005.
2. The Plaintiff, Faith Gibson is the mother of the Plaintiff, Meah Bartram. Faith Gibson is a full-time mother, residing at 5475 Bakerview Drive, in the City of Surrey, in the Province of British Columbia.
3. The Plaintiff, Meah Bartram, is an Infant, is under a legal disability and brings this action by way of her Litigation Guardian, Faith Gibson.
4. The Defendant, **GLAXOSMITHKLINE INC.** is incorporated under the *Canada Business Corporations Act*, and is extra provincially registered in British Columbia with an address for service in British Columbia at 2600 Three Bentall Centre, PO Box 49314, 595 Burrard Street, Vancouver, British Columbia, Canada.

5. The Defendant, **GLAXOSMITHKLINE UK LIMITED** is incorporated in the United Kingdom, with a registered office at 980 Great West Road, Brentford, Middlesex, England.

BACKGROUND INFORMATION

6. The Defendant, **GLAXOSMITHKLINE INC.** and the Defendant, **GLAXOSMITHKLINE UK LIMITED** (both hereinafter collectively referred to as GSK) are research-based pharmaceutical companies. GSK researches, develops, designs, manufacturers and markets pharmaceutical products.
7. Both Defendants are part of the GlaxoSmithKline group of companies which are headquartered in the United Kingdom, and have operations in 40 countries including Canada.
8. One of the pharmaceutical products developed, designed, manufactured and marketed in Canada by GSK is Paxil (generically known as Paroxetine Hydrochloride), an orally-administered psychotropic drug.
9. Paxil is in a class of drugs known as "Selective Serotonin Re-Uptake Inhibitors" (SSRI's) and is widely prescribed by physicians to treat depression, anxiety disorder, obsessive compulsive disorder (OCD), post traumatic stress disorder (PTSD), panic disorder (PD) and generalized anxiety disorder (GAD).
10. Paxil has been used by thousands of pregnant women in Canada.
11. Paxil was prescribed for the Plaintiff, Faith Gibson in December, 2002, before she became pregnant and she continued taking Paxil during and after her pregnancy.
12. The Plaintiff, Faith Gibson continued taking Paxil during her pregnancy and gave birth to the Plaintiff, Meah Bartram on September 14, 2005.

THE RISKS

13. The Defendants were at all material times aware that Paxil had a teratogenetic potential.
14. Paxil has been associated with an increased risk of serious adverse cardiovascular complications for newborns when taken by women during the first trimester of pregnancy.
15. Paxil increases the risk of damage to the heart and lungs of newborn infants. Babies are unable to breath properly due to constricted blood vessels which cut off oxygen to the blood and cause damage to other organs such as brain and kidneys.
16. The Defendants knew or ought to have known at least as early as June, 2003, that there was a significant risk of serious adverse cardiovascular complication for newborns from pregnant mothers ingesting Paxil. The Defendants failed to apprise the Plaintiff, Faith Gibson or her physicians of that risk.

MEDICAL COMPLICATIONS

17. The Plaintiff, Meah Bartram, suffered serious complications during her birth. In particular Meah Bartram suffered cardiovascular defects, and was born with a moderate sized perimembranous Ventricular Septal Defect.
18. The Plaintiff, Meah Bartram, has not fully recovered from her injuries and it is not expected that she will make a full recovery. The Plaintiff, Meah Bartram continues to suffer serious medical complications, and the full extent of her injuries and those consequences are not yet known.
19. The medical complications experienced by Meah Bartram were caused, or contributed to, by the use of Paxil by the Plaintiff, Faith Gibson while she was pregnant.

THE PROPOSED CLASS

20. The Plaintiff, Faith Gibson brings this action on behalf of herself, her child, and others similarly affected, as members of the proposed class, defined as follows:

"any person in Canada, born with cardiovascular defects, to women who ingested Paxil while pregnant, and the mothers of those persons".

CAUSE OF ACTION

21. As a result of the teratogenic effect of Paxil, it was inherently dangerous when taken by pregnant women.
22. The Defendants at all material times owed a duty of care to the Plaintiffs to:
- a. ensure that Paxil was fit for its intended or reasonably foreseeable use;
 - b. conduct appropriate testing to determine whether and to what extent ingestion of Paxil posed serious health risks to pregnant women, including the risk of serious adverse complications for newborn children of mothers who ingest Paxil during pregnancy; and
 - c. warn the Plaintiff, Faith Gibson and her physicians that the ingestion of Paxil carries the risk of serious adverse complications for newborn children of mothers who ingest Paxil during pregnancy.
23. The Defendants negligently breached their duty of care, particulars of which are set out in the following paragraph.
24. The Plaintiffs state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following:
- a. the Defendants failed to ensure that Paxil was not dangerous to children born to women who ingested Paxil while pregnant and that the drug was fit for its intended or reasonably foreseeable use;
 - b. the Defendants failed to adequately test Paxil in a manner that would fully disclose the magnitude of the risks associated with its use, including but not limited to the risk of serious adverse cardiovascular complications for those children born to mothers who ingested Paxil while pregnant;

- c. the Defendants failed to give Health Canada complete and accurate information about Paxil and the risk it posed to those children born to mothers who ingested Paxil while pregnant;
- d. the Defendants failed to conduct any, or any adequate, follow-up studies on the efficacy and safety of Paxil for pregnant women and children of women who ingested Paxil while pregnant;
- e. the Defendants failed to provide the Plaintiff, Faith Gibson, and her physicians with any adequate warning of the risks associated with ingesting Paxil during pregnancy, including but not limited to the risk of serious adverse cardiovascular complications for those children born to mothers who ingested Paxil while pregnant;
- f. the Defendants failed to provide any, or any adequate, updated and current information to the Plaintiff, Faith Gibson and her physicians respecting the risk and efficacy of Paxil for pregnant women or those children born to mothers who ingested Paxil while pregnant, as it came available from time to time;
- g. the Defendants failed to provide warnings on package labels of the potential hazards of ingesting Paxil for pregnant women and those children born to mothers who ingested Paxil while pregnant;
- h. the Defendants failed to provide warnings on the customer information pamphlets of the risks associated with Paxil including the risk of serious adverse complications to those children born to mothers who ingested Paxil while pregnant;
- i. the Defendants failed to warn the Plaintiff, Faith Gibson, and her physicians about the need for comprehensive regular medical monitoring to ensure early discovery of potentially fatal adverse complications from the use of Paxil;
- j. the Defendants, after becoming aware of problems with Paxil before June, 2003, failed to: issue adequate warnings, issue a timely recall of the drug, publicize the problem and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff, Faith Gibson, and her physicians of the drug's inherent dangers, including but not limited to the danger of serious adverse cardiovascular complications to those children born to mothers who ingested Paxil while pregnant;
- k. the Defendants failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of Paxil and the risks associated with the drug;
- l. the Defendants represented that Paxil was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;
- m. the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of Paxil and its associated risks, including the risk of serious adverse complications to those children born to mothers who ingested Paxil while pregnant;

- n. the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known to the Defendants;
 - o. the Defendants failed to timely cease distribution of Paxil for use by pregnant women, when they knew or ought to have known that this drug caused or could cause serious adverse complications to those children born to mothers who ingested Paxil while pregnant;
 - p. the Defendants actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Paxil for use by pregnant women; and
 - q. the Defendants breached other duties of care to the Plaintiffs and the class of Plaintiffs, details of which breaches are known only to the Defendants.
25. The risks associated with the ingestion of Paxil, including the risk of serious adverse cardiovascular complications to those children born to mothers who ingested Paxil while pregnant, were in the exclusive knowledge and control of the Defendants. The extent of the risks was not known and could not have been known to the Plaintiff, Faith Gibson. The Plaintiff, Faith Gibson would not have taken Paxil during her pregnancy had she been adequately warned.

BUSINESS PRACTICES AND CONSUMER PROTECTION ACT

26. In its sales brochures, advertisements and other forms of representations to the public the Defendants made statements concerning the safe use of Paxil by pregnant women, that had the capability, tendency or effect of deceiving or misleading consumers.
27. These representations as to the safety of Paxil were untrue, deceptive, and misleading and as a result constituted deceptive and unconscionable acts and the Plaintiffs plead and rely upon the provisions of the British Columbia *Business Practices and Consumer Protection Act* [S.B.C.2004] Chapter 2.

SALE OF GOODS

28. Women who are pregnant may be especially vulnerable to depression given the emotional ups and downs that can be caused by shifting hormones. As a result women of childbearing years are a target market for the Defendants. The Defendants preyed upon this vulnerability in marketing their product.

29. The Defendants intended that pregnant women such as the Plaintiff, Faith Gibson would use their product and would rely on the Defendants' skill and judgement in marketing the product to them. The Plaintiffs say there was an express, or in the alternative an implied condition that Paxil would be reasonably fit for use by pregnant women.
30. The Plaintiffs say that Paxil was not reasonably fit for use by pregnant women and plead and rely upon the *Sale of Goods Act* [RSBC 1996] Chapter 410.

DAMAGES

31. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiffs and other proposed class members have incurred, and will continue to incur, medical expenses, home care expenses, loss of income, loss of opportunity, pain and suffering, and an inability to enjoy their lives.
32. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiff, Meah Bartram will require extraordinary care and assistance throughout her lifetime, and the Plaintiff, Faith Gibson will be required to forgo income in order to properly care for her child, Meah Bartram.
33. It was foreseeable that as a result of the conduct of the Defendants as hereinbefore set out that, the Plaintiff, Faith Gibson, would experience severe emotional trauma arising from the birth defect caused to her child, Meah Bartram by the Defendants.

AGGRAVATED AND PUNITIVE DAMAGES


34. The conduct of the Defendants as hereinbefore set out showed reckless disregard for the well being of the public, the Plaintiffs and members of the potential class. 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 Plaintiffs and all other members of the proposed class and the Plaintiffs on their own behalf and on behalf of all proposed class members hereby claim aggravated and punitive damages.

WHEREFORE the Plaintiffs each claim on their own behalf and on behalf of members of the proposed class as follows:

- a. General damages;
- b. Aggravated damages;
- c. Punitive damages;
- d. Special damages;
- e. Damages for loss of income and opportunity to earn income;
- f. Damages for costs of care past and future;
- g. Interest pursuant to the *Court Order Interest Act*;
- h. Costs; and
- i. Such further and other relief as to this Court may deem due and just.

Place of Trial: Law Courts, 800 Smithe Street, Vancouver, B.C.

DATED at the City of Vancouver, Province of British Columbia, this 27th day of February, 2008.



David M. Rosenberg
Solicitor for the Plaintiffs,
Meah Bartram, an Infant by her Mother and
Litigation Guardian, Faith Gibson, and the
said Faith Gibson

THIS WRIT OF SUMMONS and STATEMENT OF CLAIM are filed and delivered by David M. Rosenberg of the law firm of Rosenberg & Rosenberg, Solicitors for the Plaintiff, whose place of business and address for delivery is 671D Market Hill Road, in False Creek, Vancouver, B.C. V5Z 4B5 Telephone: 604-879-4505 Fax: 604-879-4934