

**ONTARIO
SUPERIOR COURT OF JUSTICE**

In the matter of a Claim under the
Class Proceedings Act, 1992, S.O. 1992, c. 6

B E T W E E N:

BONNIE NORTH

Plaintiff

and

GLAXOSMITHKLINE PLC
and GLAXOSMITHKLINE INC.

Defendant

STATEMENT OF CLAIM

TO THE DEFENDANT(S)

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff.
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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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: May 2, 2002

Issued by _____
Local registrar

Address of court office:
45 Main Street East
Hamilton, Ontario
L8N 2B7

TO: GlaxoSmithKline PLC
7333 Mississauga Road North
Mississauga, Ontario
L5N 6L4

AND GlaxoSmithKline Inc.
TO: 7333 Mississauga Road North
Mississauga, Ontario
L5N 6L4

CLAIM

1. The Plaintiff claims on her own behalf and on behalf of all Class Members:
 - a. General damages for negligence as set-out below;
 - b. Special damages where applicable;
 - c. Punitive, aggravated and exemplary damages;
 - d. Pre and post-Judgment interest pursuant to the provisions of the *Courts of Justice Act*, R.S.O. 1990, c. C-43 as amended;
 - e. Costs on a substantial indemnity basis; and
 - f. Such further and other relief as this Honourable Court may deem just and appropriate in the circumstances.

THE PARTIES

2. The Plaintiff is an individual residing in the City of Barrie, in the Province of Ontario.
3. The Defendant, GlaxoSmithKline PLC ("GSK") is a United Kingdom public limited company whose shares trade on the London and New York Stock Exchanges.
4. GSK is headquartered in the United Kingdom and has operations based in the United States of America. GSK has approximately 100,000 employees world-wide and has annual sales revenues in excess of CDN \$45 billion. GSK has operations in 40 countries and its products are sold world-wide.
5. GSK is registered to carry-on business in the Province of Ontario as an extra-provincial corporation and does so with its head office in Ontario at Mississauga, Ontario.

6. GlaxoSmithKline Inc. is a corporation incorporated pursuant to the laws of Canada and is a wholly-owned subsidiary of GSK through which GSK operates in Canada. Its head office is in Mississauga, Ontario.

BACKGROUND INFORMATION

7. GSK was formed in January, 2001 as a result of a merger between GlaxoWellcome and SmithKline Beecham.
8. GSK is a research-based pharmaceutical company. It researches, develops, designs, manufactures and markets pharmaceutical products.
9. One of the pharmaceutical products developed, designed, manufactured and marketed by GSK is Paxil (generically known as Paroxetine Hydrochloride), an orally-administered psychotropic drug.

10. 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).
11. The Plaintiff was prescribed Paxil in or about November, 1998 by her treating psychiatrist.
12. In or about July, 2001, the Plaintiff attempted to discontinue use of Paxil with the approval of her treating psychiatrist and family physician.
13. The Plaintiff states that her Paxil dosage was gradually reduced over time upon the advice of her family physician.
14. The Plaintiff states that she experienced the following symptoms immediately upon the Paxil dosage being reduced:
 - a. Diarrhea;
 - b. Irritability;
 - c. Insomnia;
 - d. Dizziness;
 - e. Feelings of lightheadedness;

- f. Loss of balance and vertigo;
- g. Intestinal gas, cramps and extreme nausea; and
- h. Back pain, etc.

15. The Plaintiff states that as the Paxil dosage continued to be reduced, the symptoms experienced by her became extreme and included the following:

- a. Severe back pain;
- b. Bloating, cramps and severe diarrhea;
- c. Severe headaches;
- d. Dizziness and blurred vision;
- e. Loss of balance, vertigo and severe dizzy spells;
- f. Hysteria;
- g. Shaking;
- h. Memory loss; and
- i. Lack of concentration, etc.

THE CLASS

16. The Plaintiff brings this action on behalf of herself and others similarly affected, as members of the proposed Class, defined as follows:

Any person in Canada, outside the Provinces of British Columbia or Quebec, who have taken Paxil and who have suffered, are suffering, or will suffer from dependency/withdrawal reactions following termination or reduction of their Paxil dosage.

NATURE OF THE CASE AND CLASS ACTION ALLEGATIONS

17. This is a proposed class proceeding on behalf of all individuals in Canada outside the Provinces of British Columbia and Quebec, who were prescribed and took the drug Paxil and who experienced dependency/withdrawal reactions.

18. The Plaintiff and Class Members state that thousands of Paxil users suffered dependency/withdrawal reactions. The pain and suffering experienced by each of these individuals is a direct result of the failure by GSK to warn users of the addictive nature of Paxil, its inducement of physical and psychological dependency, and its infliction of dependency/withdrawal reactions when the dosage is terminated or reduced.

19. The Plaintiff and Class Members state that Paxil has caused some people who take it to experience serious and unexpected dependency/withdrawal reactions. These reactions are unexpected to the patient and prescribing physicians because GSK has failed to properly warn of these possible effects.

20. The Plaintiff and Class Members were not informed before ingesting Paxil that it was addictive, that it induced dependency and that it caused withdrawal reaction when dosage was terminated or reduced.

21. The members of the proposed Class number in the thousands. The Class is so numerous that joinder in a single action is impractical. The Plaintiff and Class Members state, however, that each Class Member should be readily identifiable from information and records available to GSK.

22. The Plaintiff and Class Members state that individual members of the proposed Class do not have a significant interest in individually prosecuting separate actions, and that individual litigation would also present the potential for varying, inconsistent or contrary judgments and would magnify the delay and expense to all parties resulting from multiple trials of the same factual issues. The cost to pursue individual actions would effectively deny Class Members access to justice.

23. The Plaintiff and Class Members state that there are a number of common legal and factual questions which may be determined without reference to the individual circumstances of Class Members. These include, but are not limited to, the following:
 - a. Whether GSK properly and adequately warned the Plaintiff and Class Members that Paxil can cause dependency/withdrawal reactions;

- b. Whether GSK properly and adequately warned physicians in Canada (outside British Columbia and Quebec), that Paxil can cause dependency/withdrawal reactions;
 - c. Whether GSK over-promoted Paxil to such an extent that any warnings it may have given regarding dependency/withdrawal reactions were nullified;
 - d. Whether GSK wrongly asserted in its advertising material and campaign that Paxil was not addictive and not habit-forming;
 - e. Whether the drug Paxil is addictive and does cause dependency/withdrawal reactions.
24. The Plaintiff and Class Members state that the claim of the Plaintiff is typical of the Class.
25. The Plaintiff and Class Members were uninformed as to the hazards involved in taking Paxil and in subsequently terminating or reducing the dosage of Paxil.

26. The Plaintiff and Class Members state that she and Class Members experienced one or more of the following dependency/withdrawal reactions upon termination or reduction of their Paxil dosages:

- a. Jolting electric “zaps”;
- b. Dizziness;
- c. Lightheadedness;
- d. Vertigo;
- e. Loss of coordination;
- f. Gait disturbances;
- g. Sweating;
- h. Extreme nausea;
- i. Vomiting;
- j. High fever;
- k. Chills;
- l. Anorexia;
- m. Diarrhea;
- n. Agitation;
- o. Tremulousness;
- p. Irritability;
- q. Aggressions;
- r. Insomnia;
- s. Nightmares;

- t. Tremor;
- u. Confusion;
- v. Memory and concentration difficulties;
- w. Lethargy;
- x. Malaise;
- y. Weakness;
- z. Fatigue;
- aa. Paraesthesias;
- bb. Ataxia, and/or myalgia.

27. The Plaintiff and Class Members state that on termination or reduction of Paxil dosage they became very ill without realizing the cause of their distress. Typically, individuals visited their treating physicians who, unaware of the symptoms of withdrawal syndrome due to the failure of GSK to properly warn in that regard, began other investigations to attempt to diagnose the problem. This often included unnecessary testing and investigation and sometimes included relapse which resulted in the prescription of an increase of Paxil dosage thus compounding the dependency problem.

28. The Plaintiff and Class Members state that treating physicians were unable to recognize that the termination of reduction of Paxil dosage was the cause of the difficulty because of inadequate warnings from GSK in that regard.
29. The Plaintiff and Class Members state that the pain, suffering and resulting disabilities experienced by the Plaintiff and Class Members were prolonged, often lasting many weeks, even months.
30. The Plaintiff and Class Members state that some Class Members, after a lengthy regime of gradually tapering down the Paxil dosage, were successful in completely weaning themselves from the drug, but only after suffering dependency/withdrawal reactions including the symptoms described above.
31. The Plaintiff and Class Members state that other Class Members remain on Paxil presently because of dependency and an inability to terminate or reduce dosage.

32. The Plaintiff and Class Members state that the only differences among Class Members is the extent of damages suffered, which damages can be readily determined through individual assessment and ought not bar certification of this action as a class proceeding.
33. The Plaintiff states that neither she nor her counsel have interests which are contrary to or conflicting with those of Class Members in respect of the common issues.

CONDUCT OF GSK

34. The Plaintiff and Class Members state that GSK promoted the use of Paxil as a non-addictive, non-habit forming drug to physicians and the general public when it knew or ought to have known that individuals taking Paxil would become addicted to its use and that the termination or reduction of dosage would cause severe dependency/withdrawal reactions as described above.

35. The Plaintiff and Class Members state that they relied on class-wide misrepresentations of GSK and were induced to purchase and ingest Paxil.
36. The Plaintiff and Class Members state that had the true facts been disclosed, ie., that Paxil is addictive and habit-forming and that termination or reduction of dosage causes dependency/withdrawal reactions, the Plaintiff and Class Members would not have used Paxil.
37. The Plaintiff and Class Members state that GSK failed to provide physicians and the public with sufficient, proper and adequate notice of the addictive, habit-forming nature of Paxil and the dependency/withdrawal reactions possible upon termination or reduction of dosage, and that GSK was negligent in that regard.
38. The Plaintiff and Class Members state that GSK deceived the Plaintiff and Class Members by class-wide representations in written labeling, written marketing materials and television advertising suggesting that Paxil is not addictive, that it does not cause physical or physiological dependency, and that it does not cause dependency/withdrawal reactions if dosage is terminated or reduced.

39. The Plaintiff and Class Members state that GSK conveyed to physicians and healthcare providers in Canada that dependency/withdrawal reactions caused by termination or reduction of Paxil dosage were only “mild and transient” when in fact GSK knew or ought to have known that the withdrawal reactions were in fact severe and long-lasting.

40. The Plaintiff and Class Members state that GSK has deceived the medical community and the public into believing that Paxil does not have addictive, habit-forming qualities and does not cause dependency/withdrawal reactions which GSK knows or ought to have known that in fact it does.

41. The Plaintiff and Class Members state that GSK impliedly warranted that Paxil was a drug of merchantable quality and safe and fit for its intended and foreseeable purpose. GSK breached this implied warranty because Paxil was not, and is not, of merchantable quality or safe for its intended use in that it is addictive and habit-forming and causes dependency/withdrawal reactions upon termination or reduction of dosage.

42. The Plaintiff and Class Members plead and rely upon the *Sale of Goods Act*, R.S.O. 1990, c. S-1 and equivalent or similar legislation in provinces and territories outside Ontario.
43. The Plaintiff and Class Members state that the misrepresentations by GSK as to the addictive nature of Paxil constitute unlawful and deceptive trade practices and that GSK is in violation of Section 52 (1) of the *Competition Act*, R.S.C. 1985, c. C-34.

DAMAGES

44. The Plaintiff and Class Members state that they have suffered damages as a result of the use of Paxil and specifically as a result of the failure by GSK to properly and adequately warn that use of Paxil can cause dependency/withdrawal reactions.
45. The Plaintiff and Class Members state that GSK is liable and responsible for such loss and damage.

46. The Plaintiff and Class Members claim entitlement to general damages, special damages where applicable, and punitive, aggravated and exemplary damages.

LEGISLATION

47. The Plaintiff and Class Members plead and rely upon the provisions of the *Class Proceedings Act, 1992*, S.O. 1992, c. C-6, the *Business Practices Act*, R.S.O. 1990, c. B-18, the *Sale of Goods Act*, R.S.O. 1990, c. S-1 and equivalent/similar legislation in provinces and territories outside Ontario, and the provisions of the *Food and Drugs Act*, R.S.C. 1985 c. F-27 and the *Competition Act*, R.S.C. 1985, c. C-34.

48. The Plaintiff proposes this action be tried in the City of Toronto.

May 2, 2002

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Court File No.

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PROCEEDING COMMENCED AT HAMILTON

STATEMENT OF CLAIM

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