CV-11-430114CP
Court File No.

**ONTARIO**
**SUPERIOR COURT OF JUSTICE**

BETWEEN:

Sean Ramsaran and Chris Asimakopoulos

Plaintiffs

-and-

Merck Canada Inc., Merck Frosst Canada & Co.
Merck & Co., Inc., Merck Sharpe & Dohme Corp.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

**STATEMENT OF CLAIM**

**TO THE DEFENDANTS:**

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

**IF YOU WISH TO DEFEND THIS PROCEEDING,** you or an Ontario lawyer acting for you must prepare a Statement of Defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the 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 WILL 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 of Issue: July 6, 2011

Issued by: B Sadegun
Local Registrar

Address of court office:
393 University Avenue
Toronto, Ontario
M5G 1E6

TO: Merck Canada Inc.
16711 Trans-Canada Highway West
Kirkland, QC H9H 3L1

AND TO: Merck Frosst Canada & Co.
1959 Upper Water Street, Suite 900
Halifax, NS B3J 3N2

AND TO : Merck & Co, Inc.
One Merck Drive, P.O. Box 100
Whitehouse Station, NJ 08889-100

AND TO : Merck & Co, Inc.
One Merck Drive, P.O. Box 100
Whitehouse Station, NJ 08889-100

## CLAIM

1. The Plaintiffs claim:

   (a) an order certifying this action as a class proceeding;

   (b) general damages of $1 million or such other amount as may be proved by the Plaintiffs and class members;

   (c) special damages;

   (d) punitive damages;

   (e) pre-judgment and post-judgment interest;

   (f) costs, including the costs of notice and of administering the plan of distribution of the recovery in this action, plus applicable taxes; and

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

**Parties and Overview**

2. This action concerns the prescription drugs Propecia and Proscar which are prescribed as a cosmetic treatment for male pattern hair loss also known as androgenic alopecia. Androgenic alopecia is a naturally occurring process in men – it is not an illness or disease.

3. The active ingredient in Propecia and Proscar is finasteride. The use of finasteride has been linked to a number of serious side effects. These side effects include the development of depression and various forms of sexual dysfunction including but not limited to, erectile dysfunction, reduced ejaculate volume, low sex drive, reduced sexual sensation and infertility. In some patients, the sexual dysfunction is temporary but in others the condition persists.

4. The Plaintiff, Sean Ramsaran, resides in Aurora, Ontario. He was prescribed Propecia by his physician for cosmetic purposes to treat male pattern hair loss. He consumed Propecia for approximately 14 months. As a result of his use of Propecia, Mr. Ramsaran suffered mental and physical injury, including sexual dysfunction and depression. These injuries have persisted even after Mr. Rasmsaran stopped taking the drug.

5. The Plaintiff, Chris Asimakopoulos, resides in Toronto, Ontario. He was prescribed Propecia by his physician for cosmetic purposes to treat male pattern hair loss. He consumed Propecia for approximately 7 years. As a result of his use of Propecia, Mr. Asimakopoulos suffered mental and physical injury, including sexual dysfunction and depression. These injuries have persisted even after Mr. Asimakopoulos stopped taking the drug.

6. The Plaintiffs bring this action on their own behalf and on behalf of a proposed class of similarly situated persons. This proposed class is to be further defined in the Plaintiffs' Notice of Motion for Class Certification, but for present purposes is defined as:

> "All persons who were prescribed Propecia and/or Proscar in Ontario, and elsewhere in Canada, excluding British Columbia, for hairloss and experienced side effects which continued after ceasing to take these drugs (the "Class")."

7. And also:

> "All persons who by reason of his or her relationship to a member of the Class are entitled to make claims under any of the Dependants Statutes in Canada as a result of the injury of such member of the Class (the "Family Class").
>
> "Dependants Statutes" means the *Family Law Act* (Ontario), *Fatal Accidents Act* (Alberta), *Tort-Feasors Act* (Alberta), *Fatal Accidents Act* (Saskatchewan) *Fatal Accidents Act* (Manitoba), *Code civil* (Quebec), *Loi sur la protection du consommateur* (Quebec), *Fatal Accidents Act* (New Brunswick), *Fatal Accidents Act* (P.E.I.), *Fatal Injuries Act* (Nova Scotia), *Fatal Accidents Act* (Newfoundland), *Fatal Accidents Act* (Nunavut), *Fatal Accidents Act* (Northwest Territories), and *Fatal Accidents Act* (Yukon).

8. The Defendant, Merck Canada Inc. is a corporation incorporated pursuant to the laws of Canada, with its registered head office in Kirkland, Quebec.

9. The Defendant, Merck Frosst Canada & Co., is a corporation incorporated pursuant to the laws of Nova Scotia with its headquarters in Halifax, Nova Scotia.

10. At all material times, Merck Canada Inc. and Merck Frosst Canada & Co. were affiliates of the Defendant Merck & Co., Inc.

11. The Defendant, Merck & Co., Inc. is a corporation incorporated pursuant to the law of the United States of America, with its corporate headquarters at Whitehouse Station, New Jersey,

USA. The Defendant Merck Sharpe & Dohme Corp. is a subsidiary of Merck & Co., Inc. and is also incorporated under the laws of the United States of America and has its corporate headquarters at Whitehouse Station, New Jersey, US. Merck Sharpe & Dohme Corp. owns the registered trademarks for Propecia and Proscar in Canada.

12. The Defendants functioned as a joint enterprise for the promotion and sale of Propecia and Proscar within Canada for their mutual benefit and profit. The Defendants may have divided among themselves certain responsibilities for the manufacture and marketing of Propecia and Proscar but each had an independent responsibility to ensure the safety of Propecia and Proscar and the adequacy of the warnings. Within this joint enterprise, the Defendants individually and jointly researched, tested, developed, marketed, manufactured, imported, promoted, licensed, labeled, monitored adverse reactions to, and placed into the stream of commerce Propecia and Proscar for sale in Canada and in particular Ontario.

13. Propecia is the brand name of the 1 milligram tablet of the drug finasteride which is prescribed to treat male pattern hair loss. Proscar is the brand name of the 5 milligram tablet of the drug finasteride. Proscar in its full 5 milligram strength is indicated for the treatment of benign prostatic hyperplasia and prevention of urologic events. In many cases, physicians prescribe Proscar for the treatment of male pattern hair loss instead of Propecia, and advise patients to split the pills into quarters for use. Splitting Proscar into quarters is a more economical option for the patient as one tablet of Proscar can be divided to make four tablets, making the Proscar prescription less expensive for the patient. Proscar and Propecia were approved for sale in Canada by Health Canada in 1992 and 1998, respectively.

14. The Defendants know that a large portion of their sales of Proscar in Canada are for hair loss, and that both Propecia, and Proscar cut into quarters, are used interchangeably by Canadian doctors and their patients for hair loss.

15. Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a hormone, called dihydrotestosterone (DHT). DHT contributes to shortening the growth phase of the hair and to thinning of the hair. According to the Defendants, finasteride is a type II 5-Alpha reductase inhibitor that prevents the conversion of androgen

testosterone to DHT in the scalp leading to a reduction of hair loss. DHT is a significant hormone that is critical for the proper mental, physical, sexual and fertility functioning of men. The Defendants failed to conduct long-term studies on male health to determine the effect of blocking DHT and instead have opted to place their product on the market putting the health of Canadians who use it at risk.

16. Such studies as the Defendants did conduct on the safety of the drugs were inadequate. They were too short in duration. They were under-powered in terms of the number of individuals included. They were insufficiently focused in terms of the side effects examined and followed up on. And they relied upon inappropriate patient groups, not sufficiently comparable to the actual consumers for whom these drugs were to be marketed.

17. The Defendants promote the use of Propecia for treatment of male pattern hair loss as a safe treatment with little risk. In their product labeling, the side effects of sexual dysfunction such as decreased libido, erectile dysfunction, ejaculation disorder and decreased ejaculate volume experienced while on the medication are said to resolve. The October 6, 2010 product monograph for Propecia states "Resolution of these adverse reactions occurred in men who discontinued therapy with PROPECIA and in most who continued therapy." This statement is not true. There have been numerous reports in Canada and elsewhere of persistent sexual dysfunction experienced by men who have discontinued use.

18. Regulators in the United States and in Europe have required the Defendants to amend the warning labels for Propecia sold in those jurisdictions to include a warning of persistent side effects, including sexual dysfunction which continues after patients stop taking the drug.

19. In Sweden, the warning label was changed in or about June 2008.

20. In Italy, the warning label was changed in or about March 2010.

21. In the United Kingdom, the warning label was changed in or about April 2010.

22. In the United States, the warning label was changed in or about June 2011.

23. In Canada, the warning label has yet to be corrected. The Defendants continue to assure class members, and their doctors, that any sexual dysfunction experienced when taking Propecia will resolve, either by continuing to take the drug, or by stopping it. This is incorrect, and given the experience of the Defendants in these others countries, the Defendants know, or ought to know that their Canadian warning label is inaccurate, and that it has been inaccurate for years.

24. The Defendants owe the Plaintiffs and class members a duty to provide clear, complete, accurate and timely warnings of all side effects of the drugs. The Defendants have breached that duty.

25. The Defendants did amend their warning label for Propecia in Canada on October 6, 2010, to include depression as a side effect. There was no listing for depression as a side effect on the Propecia warning label in Canada prior to that date. The Defendants knew or ought to have known of the risk of this side effect well before October 6, 2010. The Defendants again failed in their duty to provide the Plaintiffs and class members with a clear, complete, accurate and timely warning of all side effects of the drugs.

26. As the manufacturer of a pharmaceutical drug, the Defendants must keep up to date with scientific developments regarding their drugs through continued research, by investigating adverse reaction reports, by tracking scientific literature, medical conferences, the experience of doctors and patients, and by other available methods. This is a continuing and pro-active duty, not a passive one. The Defendants must actively follow up on, and investigate information suggesting that their product may be unsafe.

27. The Defendants have received substantial numbers of reports of adverse effects due to finasteride for years, from patients in Canada, and from around the world. The Defendants failed to adequately investigate such reports.

28. For years, prominent physicians in the United States and Europe have expressed concerns about the safety of finasteride at medical conferences and in the medical literature. The Defendants have failed to adequately follow upon and investigate such concerns.

29. For years, patients in Canada and other countries taking finasteride have expressed concerns about the safety of this drug on the internet, and elsewhere, and have formed support groups for patients harmed by finasteride. The Defendants have failed to adequately investigate these concerns expressed by their own customers.

30. The Defendants' duty to warn is informed by the nature of the drug, including an assessment of its risks versus its benefits. Even if the probability of injury is very small, this duty to warn is heightened where the potential injury is serious and the potential benefit is limited. In this case, the Defendants' drugs are prescribed for a cosmetic purpose (to treat hair loss) but carry serious side effects (persistent sexual dysfunction and depression). This information needs to be properly communicated to consumers and their physicians so that an informed decision can be made on whether the risk of developing a serious side effect is reasonable for a cosmetic treatment.

31. There is ample information available to show that men have experienced sexual dysfunction as a persistent side effect after discontinuing use, and yet the Defendants have not updated their warning. The Defendants have ignored all of this information and continue to promote their products as safe. The Defendants are refusing to do this because adding the warning would affect the sales of this profitable medication. The Defendants are placing the profits of their company above the health of Canadian consumers.

**Negligence and Failure to Warn**

32. As the manufacturers, marketers, developers, distributors, labelers and/or importers of Propecia and Proscar, the Defendants were in such a close and proximate relationship to the Plaintiffs, and other class members, as to owe them a duty of care. They caused the drug to be introduced into the stream of commerce in Canada, and they knew that any dangers or adverse effects related to the drug would cause foreseeable injury to the Plaintiffs and class members.

33. The Defendants owed a duty to the Plaintiffs and class members to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, distributing, importing, and selling Propecia and Proscar.

34. The Defendants jointly and severally owed a duty of care to the Plaintiffs and class members to ensure that Propecia and Proscar was safe for its intended use. Particulars of the Defendants' negligence include:

(a) failing to test Propecia and Proscar properly, thoroughly and adequately before releasing the drugs on to the market;

(b) failing to adequately disclose the serious side effects of Propecia and Proscar;

(c) failing to conduct an adequate and timely analysis of adverse event reports;

(d) failing to follow up on and investigate concerns about the drugs' safety expressed by doctors and patients;

(e) failing to instruct their employees to accurately and candidly disclose consumer complaints and serious side effects of Proscar and Propecia to Health Canada in a timely manner, or at all;

(f) employing inadequately trained personnel;

(g) failing to provide adequate warnings of the potential long term effects of ingesting Propecia and Proscar on the package inserts and labels;

(h) marketing Propecia and Proscar in such a way as to give the Plaintiffs and class members no reason to suspect that Propecia and Proscar had potentially harmful and serious adverse effects;

(i) failing to design and implement an appropriate post marketing surveillance system to monitor and quickly identify adverse risks; and

(j) placing Propecia and Proscar on the market when they knew or ought to have known that these drugs that the potential risks of these drugs outweighed their potential benefits.

**Mr. Ramsaran's Particulars**

35. The Plaintiff, Mr. Ramsaran, was prescribed Propecia by his doctor for hair loss on or about November 14, 2009. Mr. Ramsaran took Propecia regularly and as directed.

36. While on Propecia, Mr. Ramsaran experienced side effects which worsened over time. He suffered erectile dysfunction. His libido substantially decreased and he found it difficult to derive any interest or satisfaction from sexual activity. He became depressed.

37. Mr. Ramsaran stopped taking Propecia on or about January 15, 2011. To date, the side effects he experienced on the drug have still not resolved. He continues to have difficulty getting or maintaining an erection, or experiencing any interest or pleasure from sexual activity. He remains depressed.

38. Mr. Ramsaran has sought medical treatment for these side effects. Such treatment, to date, has not been successful.

39. Propecia has caused Mr. Ramsaran serious physical and psychological injury. It has diminished his quality of life, and harmed his personal relationships. The stress of his situation has interfered with his ability to complete his education and to pursue a career.

40. If Mr. Ramsaran had been warned of a risk of persistent side effects before taking Propecia, he never would have taken the drug. If he had been properly warned of these risks while on the drug, he would have stopped.

**Mr. Asimakopoulos' Particulars**

41. The Plaintiff, Mr. Asimakopoulos, was prescribed Propecia by his doctor for hair loss in 1999. He took the drug regularly and as directed.

42. While on Propecia, Mr. Asimakopoulos experienced side effects which worsened over time. He suffered erectile dysfunction. His libido substantially decreased and he found it difficult to derive any interest or satisfaction from sexual activity. He became depressed.

43. Mr. Asimakopoulos stopped taking Propecia in 2006. To date, the side effects he experienced on the drug have still not resolved. He continues to have difficulty getting or maintaining an erection, or experiencing any interest or pleasure from sexual activity. He remains depressed.

44. Mr. Asimakopoulos has sought medical treatment for these side effects. Such treatment, to date, has not been successful.

45. Propecia has caused Mr. Asimakopoulos serious physical and psychological injury. It has diminished his quality of life, and harmed his personal relationships.

46. It was not until 2011, when Mr. Asimakopoulos was referred to an endocrinologist and specialist in men's sexual health, Dr. Jerald Bain, at Mount Sinai Hospital, that Mr. Asimakopoulos had sufficient information to fully understand that his persistent side effects are the result of his past intake of Propecia.

47. The injuries that Mr. Asimakopoulos has suffered are of a personal and intimate nature. It was not until 2011 that Mr. Asimakopoulos was mentally and emotionally ready to pursue litigation for such injuries.

48. If Mr. Asimakopoulos had been warned of a risk of persistent side effects before taking Propecia, he never would have taken the drug. If he had been properly warned of these risks while on the drug, he would have stopped. Such a warning issued by the Defendant at any time after Mr. Asimakopoulos stopped taking the drug would still have helped him, both to understand his situation and to obtain medical assistance.

**Causation and Damages**

49. As a result of the Defendants' negligence, the Plaintiffs and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage suffered by the Plaintiffs and class members which were caused or materially contributed to by the aforementioned acts of the Defendants include:

(a) personal injury;

(b) special damages for medical expenses and out of pocket expenses;

(c) loss of both past and prospective income; and

(d) cost of future care.

50. The conduct of the Defendants warrants a claim for punitive damages. They have conducted themselves in a high-handed, wanton and reckless manner, and without regard to public safety. Particularly egregious is the Defendants' lack of warnings regarding sexual dysfunction in light of all the available information indicating that men are experiencing persistent sexual dysfunction after discontinuing use. The Defendants have ignored the labeling changes in other countries and have continued to market the product in Canada as safe and effective when they knew or should have known of the risks associated with its use.

51. This case raises issues of general deterrence. A punitive damage award in this case is necessary to express society's condemnation of conduct such as the Defendants', to advance public safety and to achieve the goal of both specific and general deterrence.

**Family Class**

52. As a result of the Defendants' negligence, members of the Family Class have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants. Particulars of the loss and damage include loss of guidance, care and companionship, loss of income and loss of value of services as a result of the injury to the primary claimant, and expenses incurred as a result of the injury to the primary claimant.

**Service Outside of Ontario**

53. The originating process may be served without court order outside Ontario because the claim is:

(a) in respect of a tort committed in Ontario (Rule 17.02(g));

(b) in respect of damages sustained in Ontario arising from a tort (Rule 17.02(h);

(c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (Rule 17.02(o)); and

(d) against a person carrying on business in Ontario (Rule 17.02(p)).

**Place of Trial**

54. The Plaintiffs proposes that this action be tried at the City of Toronto in the Province of Ontario.

July , 2011

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Plaintiffs Defendants

Court File No. CV-11-430114CP

**ONTARIO**
**SUPERIOR COURT OF JUSTICE**

PROCEEDINGS COMMENCED AT
TORONTO

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**STATEMENT OF CLAIM**

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