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ONTARIO

SUPERIOR COURT OF JUSTICE

BETWEEN:

GERARD SCHICK

Plaintiff

- and -

**BOEHRINGER INGELHEIM (CANADA) LTD.,
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
and PFIZER INC.**

Defendants

Proceeding under the Class Proceedings Act, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS

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 court, 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 court. 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.

ISSUE DATE: *May 5, 2005* Issued by


Local Registrar

Address of court office:

10th Floor
393 University Avenue
Toronto, Ontario
M5G 1E6

TO: BOEHRINGER INGELHEIM (CANADA) LTD.
5180 South Service Road
Burlington, Ontario
L7L 5H4

AND TO: BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.
900 Ridgebury Road
Ridgefield, CT
06877, USA

AND TO: PFIZER INC.
235 East 42nd Street
New York, NY
10017, USA

CLAIM

1. THE PLAINTIFF, GERARD SCHICK, claims on behalf of himself and others similarly situated in Canada:

- (a) general damages in the amount of \$3,000,000 for each;
- (b) special damages for, *inter alia*, gambling losses in an amount to be determined;
- (c) punitive, aggravated, and exemplary damages in the amount of \$50,000,000;
- (d) prejudgment interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;
- (e) costs on a substantial indemnity basis, including GST; and,
- (f) such further and other relief as this Honourable Court may deem just.

2. The Plaintiff, Gerard Schick, is an individual residing in Midland, Ontario.

3. The Defendant, Boehringer Ingelheim (Canada) Ltd., is a federal corporation with its headquarters in Burlington, Ontario. Boehringer Ingelheim (Canada) Ltd. is currently involved in and/or responsible for the research, development, manufacturing, sales, distribution and marketing of pramipexole dihydrochloride (trade name "MIRAPEX") in Canada. At all material times, Mirapex was manufactured, marketed, sold and/or distributed in Canada directly or indirectly through an agent, affiliate or subsidiary of Boehringer Ingelheim (Canada) Ltd.

4. The Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., is an American corporation with its headquarters in Ridgefield, Connecticut.

Boehringer Ingelheim Pharmaceuticals, Inc. is currently involved in and/or responsible for the research, development, manufacturing, sales, distributing and marketing of Mirapex in the United States and/or in Canada. At all material times, Boehringer Ingelheim Pharmaceuticals, Inc. was an affiliate of the Defendant, Boehringer Ingelheim (Canada) Ltd.

5. The Defendant, Pfizer Inc, is an American company with its headquarters in New York, New York. Pfizer Inc. is currently involved in and/or responsible for the research, development, manufacturing, sales, distribution and/or marketing of Mirapex in the United States and/or in Canada. In 2002, Pfizer Inc. acquired Pharmacia Corporation which had formerly been known as Pharmacia & Upjohn Company. Pfizer Inc. is responsible for all liabilities which result from any acts or omissions of Pharmacia Corporation and/or Pharmacia & Upjohn Company. Prior to being acquired by Pfizer Inc., Pharmacia Corporation and/or Pharmacia & Upjohn Company was/were responsible for the research, development, manufacturing, sales, distribution and/or marketing of Mirapex in the United States and/or in Canada.

6. The business of each of Boehringer Ingelheim (Canada) Ltd. and Boehringer Ingelheim Pharmaceuticals, Inc., is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the manufacturing, marketing, selling and distributing of Mirapex in Canada.

7. At all material times, the Defendants, all or any one of them, were carrying on business as, *inter alia*, the manufacturers and distributors of Mirapex in Canada.

8. In bringing this action on behalf of a class of people in Canada who were prescribed Mirapex (hereinafter referred to as “the Plaintiffs”), to be further defined in the motion for certification, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings Act, 1992*, S.O. 1992, c.6.

THE DRUG

9. Mirapex is the trade name for pramipexole dihydrochloride. Mirapex is a medication promoted for and commonly prescribed as an aid in the treatment of the symptoms of Parkinson’s disease or Restless Leg Syndrome. Mirapex is a Schedule F drug under the *Food and Drugs Act Regulations* in accordance with the *Food and Drugs Act*, R.S.C. 1985, c. F-27.

10. Mirapex has been widely advertised and marketed by the Defendants as a safe and effective Parkinson’s disease/Restless Leg Syndrome medication. The Defendants sell the drug under this and other trade names in more than 70 countries around the world, including Canada.

11. People with Parkinson’s disease do not produce enough dopamine in their brains. When not enough dopamine is available, people can experience the tremors, rigidity, and other symptoms associates with Parkinson’s disease. Mirapex belongs to a class of drugs knows as dopamine agonists. Mirapex works by mimicking the action of dopamine in the brain. Mirapex is designed to stimulate dopamine receptors thereby replicating its behaviour without discriminating between the nerve endings it attaches to, including those related to “pleasure centers”.

12. Mirapex was first approved for marketing and sale in Canada on or about October 13, 1999. The Defendants immediately and heavily promoted Mirapex as a desirable option for the treatment of Parkinson's disease, saying it was more effective and safer than other drugs available to treat Parkinson's disease.

THE MARKETING OF MIRAPEX

13. The Defendants' strategy has been to aggressively market and sell Mirapex by understating risks associated with the use of the product and intentionally misleading users about the potential adverse consequences which the Defendants knew or ought to have known would result from use of the product.

14. The Defendants widely and successfully marketed Mirapex in Canada and the United States to induce widespread use of the product. The marketing campaign consisted of direct-to-consumer advertisements, promotional literature placed in the offices of doctors and other healthcare providers, and other promotional materials provided to potential Mirapex users.

15. This marketing campaign, including a significant advertising program developed by or for the Defendants, sought to create the image, impression and belief in consumers and physicians that the use of Mirapex was safer and had fewer side effects and adverse reactions than other methods for treating Parkinson's disease and/or Restless Leg Syndrome, even though the

Defendants knew these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

16. The Defendants purposefully downplayed and understated the health hazards and risks associated with the use of Mirapex. The Defendants, through promotional literature and the aforementioned marketing campaign, deceived potential users of Mirapex by relaying only positive information, and manipulating statistics to suggest widespread acceptability, while at the same time downplaying actual and potential adverse and serious health effects. The Defendants concealed material relevant information from potential Mirapex users and thereby minimized the concern by users and prescribers, regarding the safety of Mirapex.

17. In particular, in the marketing materials produced by the Defendants, the Defendants misrepresented the severity, frequency and nature of adverse health effects caused by Mirapex and falsely represented that adequate testing had been conducted concerning Mirapex. As a result of the Defendants' advertising and marketing efforts, and representations concerning Mirapex, it was widely prescribed throughout Canada.

18. Neither the consumer information, nor the prescribing information provided to physicians and pharmacists in Canada, warned and/or adequately warned of the serious adverse impacts associated with ingesting Mirapex, including the risk of compulsive/obsessive behaviour, including compulsive/obsessive gambling.

19. The product warnings in effect during the period when Plaintiffs took Mirapex were wholly inadequate to alert prescribing physicians and consumers about the dangers of Mirapex, including the compulsive behaviour, obsessive behaviour, and mental instability risks associated with Mirapex which were then known to the Defendants or ought reasonably to have been known by them.

ADVERSE CONSEQUENCES

20. Mirapex has long been associated with compulsive/obsessive behaviour, including compulsive/obsessive gambling, and has been identified as a cause for these behaviours in users.

21. The Defendants knew or ought to have known at least as early as 1993 that there was a significant risk of serious adverse impacts from ingesting Mirapex, as several members of their clinical trials developed these symptoms.

22. Numerous studies examining the link between compulsive behaviour and dopamine agonists, including Mirapex, have been conducted since 1998, outlining such catastrophic effects. The Defendants were or ought to have been aware of same.

23. In August 2003, Dr. Mark Stacy published a report in the Journal "Neurology" entitled "Pathological gambling associated with dopamine agonist therapy in Parkinson's disease", showing a correlation between the use of Mirapex and such compulsive/obsessive behaviour. Dr. Stacy described how certain individuals who take Mirapex develop gambling compulsions leading to

loss of income, loss of savings, loss of family contact, divorce, alienation of friends and family, loss of good name, loss of employment, bankruptcy, loss of good credit, and even death. In or about August of 2003 the media reported on the information in Dr. Stacy's report. This was the first opportunity for patients prescribed Mirapex to hear about the causal link between Mirapex and compulsive/obsessive behaviour, including compulsive/obsessive gambling.

24. At all times herein mentioned, the Defendants knew or ought to have known that Mirapex can cause serious behavioural changes with permanent and devastating consequences and yet they failed to adequately disseminate this information to, or adequately warn, governmental agencies, physicians, pharmacists, drug consumers and/or the general public. Instead they have continued to advise physicians and the general public that Mirapex is safe, thereby continuing their tortious activities against consumers.

25. Had consumers known about the number and type of adverse reactions associated with Mirapex, including those described above, they would not have taken Mirapex and/or would have taken appropriate and necessary precautions when doing so.

26. The Defendants actively encouraged and/or affirmatively failed to take effective steps to discourage aggressive dispensation of Mirapex and the unsafe use of same by consumers.

27. Despite the prior knowledge of the Defendants, it was not until December of 2004, that the Defendant, Boehringer Ingelheim (Canada) Ltd., filed a request with Health Canada to update the drug information available on

Mirapex to list addictive gambling as a potential side effect. The Plaintiffs plead and rely on this request by the Defendant as an admission by the Defendants of the causal link between addictive gambling and the use of Mirapex and of their knowledge of said risk.

THE EVENTS

28. The Plaintiff, Gerard Schick, is currently 56 years old. He has been married for 34 years. He has two daughters and three grandchildren. Gerard Schick began working when he was 16 years old. He was employed primarily as a pressman supervisor and ultimately as a plant manager. He and his wife owned their own home.

29. On or about June of 1996, Gerard Schick was diagnosed with Parkinson's disease. In 1997 he ceased working on account of his illness. Initially, in early 1997, Gerard Schick was prescribed the drug Sinemet for treatment of the symptoms of his Parkinson's disease. Thereafter, and prior to August of 1999, he was prescribed various other additional medications for the treatment of his Parkinson's disease, including Novo-Selegiline, Levodopa and Tasmar.

30. In August of 1999, Mr. Schick was first prescribed Mirapex for treatment of the symptoms of his Parkinson's disease. He was prescribed Mirapex on the Defendants' representations that Mirapex was a safe and effective drug for the treatment of Parkinson's disease.

31. Until August of 1999, Gerard Schick gambled infrequently and only with nominal sums of money. Soon after beginning to take Mirapex, Gerard Schick developed a compulsive, obsessive gambling addiction. He gambled indiscriminately and relentlessly. He visited casinos and racetracks on a frequent basis. He played the slot machines compulsively. He spent large sums of money on lottery tickets.

32. In order to finance his gambling, he borrowed on all of his credit cards to their limits. He withdrew all available cash from his bank accounts. He cashed his pension and disability cheques and spent the proceeds on gambling. He did not pay his household accounts. He mortgaged the home in which he and his wife lived. He borrowed large sums of money from friends and members of his family. He borrowed money from former co-workers and from virtual strangers.

33. Gerard Schick concealed his compulsive gambling and the borrowing he did to finance the gambling from his wife, family and friends. He and his wife were forced to file for bankruptcy and sell their home.

34. As a result of his compulsive gambling, Gerard Schick lost in excess of \$100,000. He became alienated from his wife, children and friends. He suffered depression, anxiety, guilt, remorse, embarrassment, humiliation and a significant loss of reputation in the community.

35. In December of 2004, Gerard Schick first learned of the causal connection between his use of Mirapex and his compulsive, obsessive gambling.

36. In January, 2005, Gerard Schick stopped taking Mirapex. He is now taking other Parkinson's disease medications. He is no longer suffering from a compulsive gambling addiction and is no longer gambling and suffering gambling losses.

37. At no time prior to December of 2004, did Gerard Schick receive any warning about the risk of compulsive behaviour and in particular an addiction to gambling that could result from the use of Mirapex.

38. Had Gerard Schick been aware of the serious health complications he might experience from taking Mirapex, including, but not limited, to compulsive and/or obsessive behaviour such as compulsive gambling, he would not have taken Mirapex and/or would have taken appropriate and necessary precautions when doing so.

CAUSES OF ACTION

39. The Defendants at all material times owed a duty of care to the Plaintiffs to:

- (a) Ensure that Mirapex was fit for its intended or reasonably foreseeable use;
- (b) Conduct appropriate testing and research to determine whether and to what extent ingestion of Mirapex posed serious health risks, including the increased risk of compulsive and/or obsessive behaviour, including but not limited to, compulsive gambling;
- (c) Properly warn the Plaintiffs and their physicians that ingestion of Mirapex carries increased risk of developing serious health related complications such as an increased risk of compulsive and/or obsessive behaviour, including but not limited to, compulsive gambling; and,

- (d) To protect users from unreasonably dangerous side effects.

40. The Plaintiffs state that the Defendants negligently breached their duty of care, are strictly liable, are liable for breach of express and/or implied warranty including breach of warranty under various provincial Sale of Goods Act such as the *Sale of Goods Act*, R.S.O. 1990, c. S.1, and are liable for negligent and/or fraudulent misrepresentation, as a result of which the Plaintiffs suffered damages as set out herein. In particular and in addition to the allegations set out herein, the Plaintiffs claim against the Defendants for their:

- (a) Failure to ensure that taking Mirapex was not dangerous for consumers during the course of its use and that the drug was fit for its intended or reasonably foreseeable use;
- (b) Failure to adequately test Mirapex in a manner that would fully disclose the magnitude of the risks associated with its use, including but not limited to the increased risk of developing serious adverse health related complications such as, but not limited to, compulsive and/or obsessive behaviour such as compulsive gambling;
- (c) Failure to give Health Canada complete and accurate information;
- (d) Failure to conduct adequate follow-up studies on the efficacy and safety of Mirapex;
- (e) Failure to provide the Plaintiffs and their physicians with adequate warning of the risks associated with ingestion of Mirapex, including but not limited to the increased risk of developing serious health related complications such as, but not limited to, compulsive and/or obsessive behaviour such as compulsive gambling;
- (f) Failure to provide the Plaintiffs and their physicians with adequate information and warning respecting the proper usage of Mirapex;

- (g) Failure to provide adequate updated and current information to the Plaintiffs and their physicians respecting the risks and efficacy of Mirapex as it became available from time to time;
- (h) Failure to provide adequate warnings on package labels of the potential hazards of ingesting Mirapex;
- (i) Failure to provide adequate warnings on the customer information pamphlets in Canada of the risks associated with Mirapex, including the increased risk of developing serious adverse health related complications including, but not limited, to compulsive and/or obsessive behaviour such as compulsive gambling;
- (j) Failure to warn the Plaintiffs and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of potentially health related complications from the use of Mirapex such as compulsive and/or obsessive behaviour including compulsive gambling;
- (k) Failure to investigate, research and warn consumers, physicians, pharmacists and others of the propensity of Mirapex to stimulate compulsive behaviour when they knew or ought to have known from their previous experience with dopamine receptors and dopamine agonists that these drugs may cause compulsive behaviour;
- (l) Failure to warn that the risks associated with Mirapex would exceed the risks of other comparable forms of treatment for Parkinson's disease and/or Restless Leg Syndrome;
- (m) Failure to comply with their post-manufacturing duty to warn which arose when they knew, or with reasonable care should have known, that Mirapex was being prescribed without warning of the true risks of side effects, and were otherwise careless, negligent, grossly negligent, reckless and acted with wilful and wanton disregard for the rights of the Plaintiffs;
- (n) Failure to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the proper usage of Mirapex and the risks associated with the drug;
- (o) Representations that Mirapex was safe and fit for its intended purpose and of merchantable quality when they

knew or ought to have known that such representations were false;

- (p) Misrepresentations of the state of research, opinion and medical literature pertaining to the purported benefits of Mirapex and its associated risk, including but not limited to compulsive and/or obsessive behaviour such as compulsive gambling;
- (q) Warranting, expressly or impliedly, by and throughout statements made by Defendants or their authorized agents or sales representatives, orally and in publications, submissions to regulators and governmental authorities, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned product was safe, effective and well-tolerated by patients in studies, knowing that the Plaintiffs and Plaintiffs' physicians reasonably relied on the skill, judgment, representations and foregoing express and/or implied warranties of the Defendants, which were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended;
- (r) Failure to follow up with patients and their physicians regarding side effects and possible side effects of Mirapex;
- (s) Failure to monitor scholarly reviews, academic and clinical research studies and trials and the literature with respect to dangers associated with dopamine agonists, such as Mirapex, and failing to properly advise patients and their physicians of the information contained therein;
- (t) Failure to continue testing and researching Mirapex;
- (u) Active encouragement and/or affirmative failure to take effective steps to discourage aggressive dispensation of Mirapex; and,
- (v) Breach of other duties of care to the Plaintiffs and the class of Plaintiffs, the details of which breaches are known only to the Defendants.

41. The risks associated with the ingestion of Mirapex, including the risk of compulsive and/or obsessive behaviour such as compulsive gambling,

were in the exclusive knowledge and control of the Defendants. The extent of the risks were not known and could not have been known to the Plaintiffs. The Plaintiffs' injuries would not have occurred but for the breaches described in paragraph 40 and/or the negligence and/or conduct of the Defendants in failing to ensure that Mirapex was safe for use or, in the alternative, for failure to provide an adequate warning of the risks associated with Mirapex to the Plaintiffs and to the Plaintiffs' physicians.

42. The Plaintiffs further plead that any and all limitation statutes applicable to these causes of action alleged herein are tolled by reason that Plaintiffs did not discover, nor could they have reasonably discovered, a factual basis or cause for their injuries until, at the earliest, the media reports that followed the publication of the report by Dr. Stacy mentioned above, in or after August of 2003. Moreover the Defendants' actions in concealing the true extent and nature of the harms associated with Mirapex operate to toll statutes of limitation under principles of equitable tolling.

DAMAGES

43. The Plaintiffs injuries and damages were caused by the Defendants' misconduct above and the negligence of the Defendants, their servant and agents, described above and, in particular, in paragraph 40 herein.

44. As a result of the Defendants' said misconduct, the Plaintiffs have suffered and continued to suffer serious personal injuries and pain and suffering including loss of reputation.

45. As a result of the said misconduct of the Defendants, the Plaintiffs suffered and continue to suffer expenses and special damages, including extensive gambling losses, of a nature and amount to be particularized prior to trial.

46. The Plaintiffs have sustained and will continue to sustain injuries on a continuing basis by virtue of the ingestion of Mirapex, which has continued to cause injuries from the date of ingestion to the present.

47. The damages sustained by the Plaintiffs include but are not limited to special and general damages for pain and suffering, physical and emotional losses, as well as loss of earnings and earning capacity, monetary damages and medical and other bills and expenses.

48. As a result of the said misconduct of the Defendants, the Plaintiffs suffered out of pocket expenses and losses relating to their compulsive and/or obsessive behaviour, such as compulsive gambling, the nature and amount of which will be particularized prior to trial.

49. Some of the expenses related to the medical treatment that the plaintiffs have undergone, and will continued to undergo, have been borne by the various provincial health insurers including the Ontario Health Insurance Plan ("OHIP"). As a result of the negligence of the Defendants, the various provincial health insurers have suffered and will continue to suffer damages.

50. The Plaintiffs claim punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

51. The Plaintiffs plead and rely on section 17(g), (h), (o) and (p) of the *Rules of Civil Procedure*, allowing for service ex juris on the foreign Defendants. Specifically, this originating process may be served without Court order outside Ontario in that 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 or breach of contract wherever committed (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

52. The Plaintiffs propose that this action be tried at the City of Toronto in the province of Ontario.

DATE OF ISSUE: The 5th day of May, 2005.

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Cv
Court File No. 05cv. 788 851

ONTARIO

SUPERIOR COURT OF JUSTICE

Proceeding Commenced at Toronto

STATEMENT OF CLAIM

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(92/913 DRM/srj)