Court File No. 04-CV-281149CP

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

PORTIA WAHEED

Plaintiff

-and-

PFIZER CANADA INC. and PFIZER INC.

Defendants

Proceedings 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 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 (60) 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 (10) 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.....Dec 21/04.....

Issued by.....
Local Registrar

Address of court office
10th Floor,
393 University Avenue
Toronto, Ontario

TO: **PFIZER CANADA INC.**
17300 Trans Canada Highway
Kirkland, Quebec
H9J 2M5

AND TO: **PFIZER INC.**
235 East 42nd Street
New York, NY
U.S.A.
10017

1. The plaintiff claims:

   a. damages in the amount of $1,000,000,000.

   b. punitive damages in the amount of $500,000,000;

   c. an order certifying the herein action as a class proceeding pursuant the *Class Proceedings Act*, 1992;

   d. pre-judgment interest pursuant to section 130 or, in the alternative, section 128 of the *Courts of Justice Act*, R.S.O. 1990, c. C-43;

   e. post judgment interest pursuant to section 130 or, in the alternative, section 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C-43;

   f. costs on a substantial indemnity basis;

   g. such further and other relief as this Honourable Court deems just.

2. The plaintiff resides in the City of Mississauga, in the Province of Ontario.

3. The defendant Pfizer Canada Inc. ("Pfizer Canada") is a corporation incorporated pursuant to the laws of the Dominion of Canada with its registered head office located in the City of Kirkland in the Province of Quebec. The defendant Pfizer Inc. ("Pfizer U.S.") is corporation incorporated pursuant to the laws of the State of Delaware in the United States of America with its registered head office located in the City of New York in the State of New York.

4. Pfizer develops, manufactures, markets and distributes pharmaceuticals throughout the world. At all material times, Pfizer U.S. and/or Pfizer Canada manufactured and distributed Celebrex throughout Canada.

5. Celebrex, also generically known as Celecoxib, is a medication prescribed to patients to aid, inter alia, in the treatment of arthritis, familial adenomatous polyposis, moderate or severe pain secondary to dental and orthopaedic procedures, and pain during menstruation.

6. The pain relief effect of Celebrex is thought to be dependent on its ability to inhibit COX-2 enzymes which, in turn, inhibit those compounds that lead to inflammation and pain from being released into the bloodstream.

7. Celebrex comes in four strength doses: 100 mg, 200 mg., 400 mg., and 800 mg. Depending upon the ailment for which Celebrex is prescribed, the usual dosage is either 100, 200, 400 or 800 mg. once or more per day.

8. Celebrex accounts for multi-billion dollar annual sales of Pfizer Canada and Pfizer U.S.

9. The consumption of Celebrex has been strongly associated with serious adverse cardiovascular events, sometimes resulting in death, including, but not limted to:

   a. heart attack;
   b. stroke;
   c. angina;
   d. atrial fibrilation;
   e. bradycardia;

f. tachycardia;

g. hematoma;

h. irregular heart beat;

i. pulmonary embolism;

j. blood clot;

k. deep venous thrombosis;

l. palpatation;

m. premature ventricular contractions;

n. venous insufficiency;

o. cerebrovascular accident;

p. congestive heart failure;

q. transient ischemic attack; and

r. hypertension,

(hereinafter referred to as "adverse cardiovascular events').

10. Other serious side effects include headache, abdominal pain, dyspepsia, diarrhea, nausea, flatulence, insomnia, fainting, heart failure, kidney failure, aggravation of hypertention, chest pain, gastroinstestinal complications (ulcers, bleeding), drowsiness, weakness, liver complications, as well as allergic reaction (difficulty breathing, skin rashes/blemishes and itching).

11. In or about December 1998, the United States Food and Drug Adminstration ("FDA") approved Celebrex for use in the United States for the treatment of arthritis.

12. In our about April 1999 Health Canada approved the sale of Celebrex as a anti-arthritic medication. In or about April 2002 Health Canada issued conditional approval for an 800

mg. dosage of Celebrex for the treatment of a condition known as Familial Adenomatous Polyposis. At the same time, a 400 mg. dosage was approved for the treatment of, inter alia, rheumatoid arthritis and the management of acute pain.

13. In December 2004, Health Canada issued a bulletin revoking approval of Celebrex for the treatment of Familial Adenomatous Polyposis and advised that patients who are on long-term 400 mg. daily doses of Celebrex should discuss alternative therapeutic options with their physicians.

14. Pfizer Canada and Pfizer U.S. manufactured, marketed, and supplied Celebrex, a drug that was defective in design or formulation in that the foreseeable risks exceeded the benefits associated with the design or formulation.

15. Alternatively, the Celebrex manufactured and/or supplied by the defendants was defective in design or formulation, in that, when it left the hands of the manufacturer and/ or supplier, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and more dangerous than other similarly suited medication without concomitant accurate information and warning accompanying the product for physicians and the medical community to rely upon in their treatment and administration to patients like the plaintiff.

16. The Celebrex manufactured and/or supplied by the defendants was defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of same.

17. The Celebrex manufactured and/or supplied by the defendants was defective due to

inadequate post-marketing warning or instruction because, after the defendants knew or should have known of the risk of injury from Celebrex, the defendants failed to provide adequate warnings to the medical community and specifically to physicians who prescribed the medication to their patients, the ultimate users or consumers of the product and, despite this information and knowledge, failed to report these problems to the medical community and continued to promote the product as safe and effective.

18. As the direct and legal result of the defective condition of Celebrex as manufactured and/or supplied by the defendants, and of the negligence, carelessness, other wrongdoing and actions of the defendants herein:

a. the plaintiff suffered serious and grievous personal injuries and harm;

b. the plaintiff suffered economic loss, including loss of earnings and loss of earning capacity; and,

c. the plaintiff has and will continue to expend fair and reasonable expenses for necessary health care, attention and services and did incur incidental and related expenses.

19. The plaintiff pleads and relies on the provisions of the *Sale of Goods Act*, R.S.O. 1990, c. S-1.

20. The plaintiff submits that the defendants were negligent in the design, testing, advertising, marketing, promoting, labeling, warnings given and sale of Celebrex in that they:

a. failed to accompany the drug, Celebrex, with proper warnings regarding all possible adverse side effects associated with its use;

b. failed to conduct adequate pre-clinical and clinical testing and post-marketing

surveillance to determine the safety of the drug, Celebrex;

c. failed to provide adequate training and instructions to medical care providers for appropriate use of the drug, Celebrex;

d. failed to warn the plaintiff prior to actually encouraging the sale of Celebrex, either directly or indirectly through third parties or related entities, about the following:

(i) the need for comprehensive, regular monitoring to ensure early discovery of the potential side effects caused by this drug;

(ii) the possibility of severe complications, including adverse cardiovascular events and, in certain cases, death as a result of use of the drug and/or having to undergo medical treatment in order to correct or control side effects;

(iii) side effects may become protracted, debilitating, difficult, and painful, necessitating several visits to the doctor and/or hospitalization;

(iv) the need for regular medical monitoring.

e. failed to warn that the risks associated with Celebrex would exceed the risks of other comparable forms of treatment;

f. negligently marketed Celebrex despite the fact that the risk of the drug was so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, excercising due care, would have done so;

g. recklessly, falsely, and deceptively represented, or knowingly, omitted, suppressed or concealed, material facts regarding the safety and efficacy of Celebrex;

h. remained silent, despite their knowledge of the growing public acceptance of their information and misrepresentations regarding the safety and efficacy of Celebrex,

and did so because the prospect of profits outweighed health and safety issues, all to the significant detriment of the plaintiff;

i. failed to comply with their post-manufacturing duty to warn which arose when they knew, or with reasonable care should have known, that their drug was being prescribed without warning of the true risks of side effects;

j. were otherwise careless, negligent, grossly negligent, reckless and acted with willful and wanton disregard for the rights of the plaintiff; and

k. failed to warn the plaintiff and the medical community in a timely fashion that the consumption of Celebrex could cause adverse cardio vascular events.

21. The defendants knew, or should have known, that consumers such as the plaintiff would foreseeably suffer injuries as a result of the defendants failure to exercise ordinary care, as described above.

22. The defendants' actions constitute knowing omission, suppression, and/or concealment of material facts, made with the intent that others, including the plaintiff, relied upon such omissions, suppressions, and/or concealment in connection with the marketing of Celebrex.

23. The defendants' negligence was the proximate cause of the increased risk of harm suffered by the plaintiff.

24. The conduct of the defendants as aforesaid constitutes unlawful conduct, negligence, and false promises or misrepresentations.

25. The defendants manufactured, marketed and distributed Celebrex, and made

misrepresentations, as previously set forth herein, to the plaintiff, her physicians and the general public, including but limited to the misrepresentation that Celebrex was safe, fit and effective for human consumption. At all material times, the defendants conducted a sales and marketing campaign to promote the sale of Celebrex and knowlingly deceived the plaintiff, the medical community and the general public as to the health and risks and consequences of the use of Celebrex. More particularly, the defendants continuously sought to have certain label warnings removed and advertised the positive effects of Celebrex, without specifically naming the drug, in order to avoid laws requiring side effects to be stated on advertisements.

26. The defendants made the foregoing misrepresentations without any reasonable grounds for believing them to be true. These misrepresentations were made directly by the defendants, by sales representatives and other authorized agents of the defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of Celebrex.

27. The foregoing representations by the defendants were in fact false, in that Celebrex was not safe, fit and effective for human consumption. The use of Celebrex is hazardous to health. Celebrex has a serious propensity to cause serious injuries or death to users, including but not limited to the injuries suffered by the plaintiff.

28. In reliance on the misrepresentations by the defendants and/or their failure to warn, the plaintiffs' physicians were induced to prescribe Celebrex and the plaintiff was induced to buy Celebrex. If the plaintiff and the plaintiffs' physicians had known of the true facts and the facts concealed by the defendants, the plaintiff would not have used Celebrex.

The reliance of the plaintiff and the plaintiffs' physicians upon the defendants' misrepresentations and inaccurate information was justified because such misrepresentations and concealment were made and conducted by individuals and entities who were in a position to know the true facts.

29. At the time the defendants marketed, sold, distributed the drug, Celebrex, for use by the plaintiff, the defendants knew of the use for which Celebrex was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

30. The plaintiff and the plaintiffs' physicians reasonably relied upon the skill and judgment of the defendants as to whether Celebrex was of merchantable quality and safe and fit for its intended use.

31. The defendants breached the implied warranty of merchantability because Celebrex was not of merchantable quality, and was not safe or fit for its intended use because the product was and is reasonably dangerous and unfit for the ordinary purpose for which it was intended.

32. As a direct and proximate result of the defendants' breach of the implied warranty of merchantability, the plaintiff suffered an increased risk of harm, and is entitled to the damages claimed.

33. The defendants expressly warranted that Celebrex was safe and well tolerated by patients studied.

34. The plaintiff purchased Celebrex for the purpose of ingesting it and obtaining health

benefits therefrom.

35. The plaintiffs and the plaintiff's physicians reasonably relied upon the skill and judgment of the defendants as to whether Celebrex was of merchantable quality and safe and fit for its intended use.

36. Celebrex did not conform to the defendants' express representations because Celebrex is not safe and has high levels of serious side effects, including life-threatening side effects.

37. As a direct and proximate result of the defendants' conduct as aforesaid, the plaintiff was caused to suffer injuries, harm and economic and other pecuniary losses.

38. The defendants acted fraudulently, recklessly, intentionally and maliciously and or with callous disregard for the rights and safety of the plaintiff, as aforesaid, entitling the plaintiff to punitive damages in an amount appropriate to punish the defendants.

39. The plaintiff paid for and consumed Celebrex.

40. The defendants accepted payment by plaintiff for the purchase of Celebrex.

41. The plaintiff did not receive a safe and effective drug for which she paid.

42. It would be inequitable for the defendants to keep this money if the plaintiffs did not, in fact, receive a safe and efficacious drug.

43. The plaintiff seeks certification of the following Class:

a. All persons, their estates, administrators or other legal representatives, throughout Canada or, in the alternative, throughout Ontario, who were prescribed, purchased, used, and/or ingested the drug Celebrex and who claim personal injury as a result ("the Class"); and

b. All persons who have a derivative claim on account of a family relationship with a person in (a) ("the Family Class").

44. The claims herein include claims in respect of a tort committed in Ontario and throughout Canada and in respect of damage sustained in Ontario and throughout Canada arising from a tort.

45. The plaintiff pleads and relies on the provisions of Rule 17.02 (g) and (h) of the Rules of Civil Procedure relative to service of the Statement of Claim outside Ontario.

46. The plaintiff, therefore, submits that judgment be granted for the relief sought herein.

The plaintiff proposes that this action be tried at the City of Toronto.

Date: December 21, 2004

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Proceedings commenced at Toronto

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STATEMENT OF CLAIM

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