

23185

**SUPREME COURT OF PRINCE EDWARD ISLAND  
(GENERAL SECTION)**

BETWEEN:

**L. ANNETTE STEWART**

Plaintiff

AND:

**PURDUE FREDERICK INC., PURDUE PHARMA INC., PURDUE PHARMA L.P.,  
PURDUE PHARMA, PURDUE PHARMA COMPANY, THE PURDUE FREDERICK  
COMPANY, INC., PURDUE PHARMACEUTICALS L.P., AND  
P.F. LABORATORIES INC.  
(collectively, "PURDUE")**

Defendants



**STATEMENT OF CLAIM**  
(Proposed Common Law Class Proceeding)

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 a Prince Edward Island 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 Prince Edward Island.

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 PAY THE PLAINTIFF'S CLAIM, and \$100.00 for costs, within the time for serving and filing your statement of defence, you may move to have this proceeding dismissed by the Court. If you believe the amount claimed for costs is excessive, you may pay the Plaintiff's claim and \$100.00 for costs and have the costs assessed by the Court.

(SGD.) MARJORIE MacDONALD  
Deputy Registrar

DATE: MAY 1<sup>ST</sup>, 2009

Issued by

Registrar

Address of Court: 42 Water St.  
P.O. Box 2000  
Charlottetown, PEI  
C1A 7N8

TO: Purdue Pharmaceuticals L.P.  
4701 Purdue Drive  
Wilson, North Carolina

AND TO: P.F. Laboratories  
700 Union Boulevard  
Totowa, New Jersey

AND TO: Purdue Pharma L.P.  
Purdue Pharma Company  
Purdue Frederick Company Inc.  
One Stamford Forum  
201 Tresser Boulevard  
Stamford, Connecticut

AND TO: Purdue Pharma Inc.  
40 King Street, West  
Suite 4400  
Toronto, ON M5H 3Y2

AND TO: Purdue Frederick Inc.  
123 Sunrise Avenue  
Toronto, ON M4A 2V9

AND TO: Purdue Pharma  
575 Granite Court  
Pickering, ON L1W 3W8

## CLIAM

### **I. RELIEF SOUGHT**

1. The Plaintiff claims on her own behalf and on behalf of all of the members of the Class (as defined below):
  - (a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;
  - (b) general damages, including aggravated damages for personal injuries;
  - (c) special damages for medical expenses and other expenses related to the use of OxyContin;
  - (d) aggravated, punitive and exemplary damages;
  - (e) further or alternatively the Plaintiff claim, on her own behalf and on behalf of the Class Members:
    - (i) a declaration that the benefits which accrued to the Defendants as a result of their wrongful acts unjustly enriched the Defendants;
    - (ii) an accounting of the benefits which accrued to the Defendants as a result of their wrongful acts;
    - (iii) a declaration that the Defendants hold in trust for the Class the benefits which accrued to the Defendants as a result of their wrongful acts;
    - (iv) disgorgement of the benefits which accrued to the Defendants as a result of their wrongful acts;
  - (f) damages for the funding of a "Medical Monitoring Program", supervised by the Court, for the purpose of retaining appropriate health and other experts to review and monitor the health of the Plaintiff and Class Members, and to make recommendations about their treatment;
  - (g) subrogated claims on behalf of the Provincial provider of medical services;

- (h) where applicable a declaration that the Representation constitutes an unfair trade practice and/or an unfair practice, an unconscionable act and/or an unconscionable consumer representation and corresponding orders for remedies available pursuant to s. 4 of the Prince Edward Island *Business Practices Act*, R.S.P.E.I. 1988, Cap. B-7;
- (i) interest pursuant to ss. 57 and 58 of the Judicature Act, R.S.P.E.I. 1988, Cap. J-2.1;
- (j) her costs of this action; and,
- (k) such further and other relief as this Honourable Court deems just.

## II. DEFINITIONS

2. In this Statement of Claim, the following capitalized terms have the meanings set out below:

- (a) "Class" or "Class Member" means, a Family Class Member or an Injury Class Member and/or such other Class Members as will be further defined in the Application for Certification.
- (b) "Class Period" means the period from 1996 to the present.
- (c) "Family Class Member" means any person who has a derivative claim on account of a family relationship with a person described in the Injury Class.
- (d) "FDA" means the United States Food and Drug Administration.
- (e) "Injury Class Member" means any person who claims personal injury and/or damage as a result of being prescribed OxyContin.
- (f) "Oxycodone" means a drug classified as a narcotic in the schedule to the Narcotic Control Regulations. In Canada Oxycodone exists in regular oral, controlled-release oral and combination preparations sold under various trade-names: OxyContin, Supeudol, Endocet,

Oxycocet, Percocet, Percocet-Demi, Endodan, Oxycodan, Percodan, and Percodan-Demi.

- (g) "OxyContin" is the trade name for oxycodone hydrochloride controlled-release tablets an opioid analgesic. OxyContin is made to slowly release Oxycodone over a 12 hour period, and requires a dose every 12 hours to control pain. OxyContin is used to treat moderate to severe pain requiring the continuous use of an opioid analgesic preparation for several days or more.
- (h) "Representation" means the representation made expressly and impliedly that OxyContin was less addictive, less subject to abuse and less likely to cause withdrawal symptoms than other pain medications.

### **III. OVERVIEW**

3. OxyContin is an opioid analgesic drug that was approved in 1995 by the FDA for the management of moderate to severe pain and in 1996 by Health Canada as a prescription opioid. The design of OxyContin is based on a timed-release formula that releases the narcotic on an incremental basis over a twelve hour period.
4. During the Class Period, the Defendants falsely and misleadingly marketed OxyContin as less addictive, less subject to abuse and less likely to cause withdrawal than other pain medications.
5. On May 10, 2007, in the State of Virginia, United States of America, the Purdue Frederick Company, Inc. and three of its executives pleaded guilty to the misbranding of OxyContin and agreed to pay a total of \$634,575,475.00 US in criminal and civil fines, penalties, forfeitures and compensation.
6. The Plaintiff and Class Members have all been prescribed OxyContin and became dependant on it or addicted to it.
7. In this action, the Plaintiff seeks, on her own behalf and on behalf of the Class:

- (a) compensation for the personal injuries and other costs they incurred as a result of having taken OxyContin and/or;
- (b) disgorgement of the benefits that accrued to the Defendants as a result of their wrongful acts; and
- (c) damages in the form of total funds required to establish a medical monitoring process for the benefit of the Plaintiff and Class Members.

#### **IV. REPRESENTATIVE PLAINTIFF AND CLASS**

- 8. The Plaintiff, L. Annette Stewart resides in Charlottetown, Prince Edward Island.
- 9. The Plaintiff seeks to certify this action as a class proceeding, and pleads the Supreme Court of Canada's decision in *Western Canadian Shopping Centers Inc. v. Dutton*, [2001] 2 S.C.R. 534, and Rule 12 of Prince Edward Island's *Civil Procedure Rules*, as providing the basis for such certification. The Plaintiff, as the Representative Plaintiff, does not have any interest adverse to any of the members of the proposed Class. The Plaintiff states that there is an identifiable class that would be fairly and adequately represented by the Plaintiff; that the Plaintiff's claim raise common issues; and that a class proceeding would be the preferable procedure for the resolution of such common issues.
- 10. The Plaintiff proposes to bring a class proceeding on behalf of herself and a Class of other individuals resident in Prince Edward Island who have suffered personal injuries and other damages as a result of having been prescribed OxyContin. The proposed Class, which will include Injury Class Members and Family Class Members, will be further defined in the Application for Certification.
- 11. The Plaintiff and Class Members have been continuously harmed by their use of the medication OxyContin as hereinafter described. The Plaintiff is an Injury Class Member or a Family Class Member.

## V. DEFENDANTS

### Purdue

12. The Defendant, Purdue Frederick Inc., is a corporation which is incorporated pursuant to the laws of Canada with its registered office located at 123 Sunrise Avenue, Toronto, Ontario.
13. The Defendant, Purdue Pharma Inc., is a corporation which is incorporated pursuant to the laws of Canada with its registered office located at 40 King Street West, Suite 4400, Toronto, Ontario.
14. The Defendant, Purdue Pharma, is a corporation which is incorporated pursuant to the laws of Ontario with its head office located in Pickering, Ontario.
15. The Defendant, Purdue Pharma L.P., is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut, USA.
16. The Defendant, Purdue Pharma Company, is a general partnership organized and existing under the laws of the State of Delaware with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut, USA.
17. The Defendant, The Purdue Frederick Company, Inc., is a corporation organized and existing under the laws of the State of New York with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut, USA.
18. The Defendant, Purdue Pharmaceuticals L.P., is a limited partnership organized and existing under the laws of the State of Delaware with its principal place of business located at 4701 Purdue Drive, Wilson, North Carolina, USA.

19. The Defendant, P.F. Laboratories Inc., is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at 700 Union Boulevard, Totowa, New Jersey, USA.
20. The Purdue Defendants, collectively known as "Purdue", at all material times are/were engaged in, involved in and/or responsible for the designing, testing, researching, formulation, development, manufacturing, production, labelling, advertising, promoting, distribution and/or selling of OxyContin in the US, Canada and elsewhere.
21. The business of each of the Purdue Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the designing, testing, researching, formulation, development, manufacturing, production, labeling, advertising, promoting, distribution and/or selling of OxyContin in the US, Canada and elsewhere.
22. At all material times, the Defendants, all or any one of them, were carrying on business as, inter alia, the designers, testers, researchers, formulators, developers, manufacturers, producers, marketers, labelers, advertisers, promoters, distributors and/or sellers of OxyContin in US, Canada and elsewhere.

## **VI. OXYCONTIN**

23. OxyContin is the trade name for oxycodone hydrochloride controlled-release tablets, an opioid analgesic drug. In 1995, the FDA approved OxyContin for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. In 1996 OxyContin was approved by Health Canada as a prescription opioid.
24. Oxycodone is a drug that is highly addictive and is rated by the United States Government as a Schedule II narcotic, which indicates it is a prescription medication that has serious potential for abuse. A Schedule II designation means that the drug, while accepted for medical use, also has severe

restrictions and abuse of the drug has a high potential to lead to severe psychological or physical dependence.

25. OxyContin is patented and its design is based on a timed-release formula that releases the narcotic on an incremental basis over a 12 hour period. It is this formula that differentiates OxyContin from short-acting medications that must be taken more frequently. Because of the timed-release formulation, OxyContin contains much more oxycodone than short-acting opioids.
26. Shortly after it was introduced in 1995, OxyContin became Purdue's top seller and also proved to be their most profitable product. In 2001, sales of OxyContin were approximately \$1.4 billion.
27. As OxyContin quickly became a highly prescribed drug for the relief of pain, concerns began to arise with respect to its safety.
28. The FDA sent correspondence to Purdue, which was received on May 11, 2000, warning Purdue to cease the use of an advertisement for OxyContin that recommended using OxyContin for the treatment of arthritis patients without first trying milder drugs.
29. The United States Drug Enforcement Agency also recognized problems associated with OxyContin, and reports linking OxyContin to various deaths and addiction problems began surfacing in the media.
30. On July 25, 2001, the FDA ordered Purdue to place a warning on all OxyContin labels. In FDA terminology, this is known as a "black box warning". This is the strongest warning possible for a drug that has been approved by the FDA. The warning was to indicate that OxyContin has a serious potential for misuse, abuse, and addiction and the warning was also to limit the type of patients for whom OxyContin use would be appropriate.
31. Throughout the period from when the drug first appeared on the market and continuing up to the present the use of OxyContin has contributed to serious addiction, health problems and deaths. The Plaintiff and the Class Members

have suffered loss of income, cost of care, loss of valuable services, special damages and other damages.

32. The true scope of the misrepresentations by the Defendant Purdue were not known or could have not been known by the Plaintiff or by the Class Members until after May 2007 when the Defendant Purdue and three of its current and former executives entered guilty pleas.

## VII. THE GUILTY PLEAS

33. On or about May 10, 2007 the United States Attorney's Office for the Western District of Virginia and The Purdue Frederick Company, Inc. (Purdue) along with its President, Michael Friedman, Chief Legal Officer, Howard R. Udell, and Chief Medical Officer, Paul D. Goldenheim, entered a plea agreement by which Purdue and its executives pleaded guilty to charges of misbranding Purdue's addictive and highly abusable drug OxyContin.

34. The plea agreement referred to above contained an Agreed Statement of Facts.

35. The Purdue Frederick Company, Inc. and the three executives admitted that they fraudulently marketed OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support these claims and without the FDA approval of these claims.

36. The Purdue Frederick Company, Inc. and the executives agreed to pay a total of \$634,515,475.00. The payments include:

**\$276.1 million** forfeited to the United States

**\$160 million** to federal and state government agencies to resolve liability for false claims made to Medicaid and other government healthcare programs

**\$130 million** set aside to resolve private civil claims (monies remaining after 36 months will be paid to the United States)

**\$5.3 million** to the Virginia Attorney General's Medicaid Fraud Control Unit to fund future health care fraud investigations

**\$20 million** to fund the Virginia Prescription Monitoring Program for the foreseeable future

In addition, The Purdue Frederick Company, Inc. will pay the maximum statutory criminal fine of \$500,000.

Purdue's top executives will pay the following amounts to the Virginia Attorney General's Medicaid Fraud Control Unit:

**\$19 million** paid by Michael Friedman

**\$8 million** paid by Howard R. Udell

**\$7.5 million** paid by Dr. Paul D. Goldenheim

Each executive will also pay a \$5,000 criminal fine.

37. A press release issued by the United States Attorney's Office on May 10, 2007 stated the following:

According to the Statement of Facts contained in the plea agreement, the following facts were admitted to be true:

Beginning in January 1996 and continuing through June 30, 2001, Purdue's market research found that "[t]he biggest negative of [OxyContin] was the abuse potential." Despite this finding, Purdue's supervisors and employees falsely and misleadingly marketed OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal than other pain medications. Purdue misbranded OxyContin in three specific ways:

(i) Purdue sales representatives falsely told some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids. This message was presented to some health care providers through the use of graphs that exaggerated the differences between blood plasma levels achieved by OxyContin compared to the levels of other pain relief medications.

A. Purdue supervisors and employees participated in the misbranding in the following ways. Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to falsely teach Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids.

B. Purdue supervisors and employees permitted new Purdue sales representatives to use similar exaggerated graphical depictions during role-play training at Purdue's headquarters in Stamford, Connecticut.

(ii) Purdue supervisors and employees drafted an article about a study of the use of OxyContin in osteoarthritis patients that was published in a medical journal on March 27, 2000. On June 26, 2000, each sales representative was provided a copy of the article together with a "marketing tip" that stated that the article was available for use in achieving sales success. Sales representatives distributed copies of the article to health care providers to falsely or misleadingly represent that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms. The article also indicated that patients on such doses would not develop tolerance. The marketing tip that accompanied the article stated that one of the twelve key points was, "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR [controlled release] oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d [milligrams per day] can be discontinued without tapering the dose if the patient condition so warrants." These marketing claims were made even though Purdue representatives were well aware of the following information:

A. The year before the article was published and distributed to sales representatives, Purdue received an analysis of the osteoarthritis study and a second study from a United Kingdom company affiliated with Purdue that listed eight patients in the osteoarthritis study "who had symptoms recorded that may possibly have been related to opioid withdrawal," and stated that "[a]s expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

B. In May of 2000, Purdue received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms. Executives also learned that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms ha[d] come up quite a bit . . . in Medical Services lately (at least 3 calls in the last 2 days)."

C. In February 2001, Purdue received a review of the accuracy of the withdrawal data in the osteoarthritis study that listed eleven study patients who reported adverse experience due to possible withdrawal symptoms during the study's respite periods and stated "[u]pon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms;" Even after receiving this information, on March 28, 2001, supervisors and employees decided not to write up the findings because of a concern that it might "add to the current negative press."

D. Supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything “to make physicians think that oxycodone was stronger to or equal to morphine” or to “take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians['] mind[s].”

(iii) Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that “[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug,” meant that OxyContin did not cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to “weed out” addicts and drug seekers.

The statement was later amended to read, “[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug.” Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Purdue supervisors and employees took part in the misbranding in the following ways:

A. Supervisors instructed Purdue sales representatives to use the reduced abuse liability statement and the amended statement to market and promote OxyContin.

B. Supervisors told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chances for addiction than immediate-release opioids.

C. Supervisors trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue’s own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet merely by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

D. By March 2000, Purdue had received reports of OxyContin abuse and diversion occurring in different communities but allowed sales staff to continue promoting and marketing OxyContin in this manner.

38. The Plaintiff and Class Members plead that as a result of the admissions in the plea agreement and Agreed Statement of Facts, and because of the

relationship between and among the Defendants as pleaded, the Defendants are estopped in this action from denying any of the facts admitted therein.

#### **VIII. NATURE OF THE ACTION**

39. The Plaintiff and Class Members allege that the Defendants conspired to market and promote OxyContin in Canada:

- (a) as being less addictive than the Defendants knew it to be; and
- (b) for a wider range of patients and pain treatment than approved by Health Canada.

40. The Plaintiff and Class Members allege that the Defendants engaged in tortious conduct in the manufacturing, marketing, promotion, distributing and selling of OxyContin in complete disregard for the health and safety of the Plaintiff and Class Members.

41. The Plaintiff and Class Members further allege that the Defendants engaged in highly coercive sales tactics and used means of seduction that influenced the sales of OxyContin. These tactics included paying costs and fees for doctors to attend various pain management meetings and to recruit other physicians to prescribe OxyContin.

42. The Plaintiff and Class Members also allege that pharmacists were advised that if they did not renew prescriptions for OxyContin, even if abuse of the drug was suspected, the non renewal may cause harm to their patients.

43. The Plaintiff and Class Members further allege that the Defendants were wholly and grossly negligent.

44. The Plaintiff and Class Members further allege that the Defendants failed to warn the Plaintiff and Class Members of the serious complications and problems that would ensue with the use of OxyContin and that the Defendants misrepresented the drug as safe and appropriate treatment for all levels of pain, including short-term pain.

45. The Plaintiff and Class Members further allege that the Defendants expressly and impliedly breached warranties.
46. The Plaintiff and Class Members further allege that they and thousands of other Canadians have sustained physical, mental, and economic harm through dependence on and/or addiction to OxyContin as a result of the wholly and grossly negligent actions of the Defendants and in the misrepresentation by the Defendants in the manufacture and in the overly aggressive marketing approach that was taken to the sale of OxyContin.
47. The Plaintiff and Class Members further allege that the Defendants failed and/or chose not to inform both users of OxyContin and the doctors who prescribed the medication of the very serious risk of abuse and addiction associated with OxyContin.
48. Specifically the Plaintiff and Class Members further allege that the widespread abuse of OxyContin occurred due to the formulation of OxyContin. OxyContin is a controlled release medication and is designed to release Oxycodone into the system gradually over a 12 hour period. If the tablet is crushed or dissolved, the immediate 12 hour dose may be administered at one time as OxyContin does not contain what is known as an "antagonistic drug". An antagonistic drug is added to medications to prevent such an immediate dose.
49. If an individual crushes or dissolves the tablet and administers OxyContin in this form, they obtain a sudden and intense high which is similar to the effects of heroin.
50. The Plaintiff and Class Members also assert that the Defendant Purdue did not produce the tablets in smaller dosages to avoid the possibility of addiction by patients who have never taken an opioid.
51. OxyContin has caused damage to the physical and mental health of the Plaintiff and Class Members.

52. The continued use of OxyContin by the Plaintiff and Class Members creates ongoing risks to the health of the Plaintiff and Class Members.
53. During the applicable times within the Class Period when each of the respective Defendants were involved with the manufacture, promotion and distribution of OxyContin they knew or ought to have known of the potential for addiction to and other problems with the drug.
54. None of the Defendants took any steps to prevent harm to the Plaintiff and the Class Members or to protect the health and safety of the Plaintiff and Class Members.
55. Until in or about May 2007, the Plaintiff and Class Members were unaware of the existence, nature, extent and ramifications of using OxyContin.
56. The Plaintiff and Class Members have been prescribed and continue to be prescribed the drug.

#### **IX. HARM TO THE PLAINTIFF**

57. The Plaintiff, L. Annette Stewart was first prescribed OxyContin in 2001 to address back pain as a result of having fractured a vertebra.
58. The Plaintiff took four or more tablets per day.
59. While taking OxyContin the Plaintiff suffered addiction, nausea, drowsiness, constipation, lightheadedness and mood swings.
60. Even though the Plaintiff was addicted to OxyContin, her consumption of it did not make her pain free and she was hospitalized for an overdose.
61. The Plaintiff became severely addicted to OxyContin and engaged in extreme and uncharacteristic behaviour to access the OxyContin.
62. The Plaintiff states that these personal injuries were caused or materially contributed to by her use of OxyContin

63. In addition, the Plaintiff has suffered and continues to suffer from anxiety about her own and their family's health because of the effect that OxyContin has had on her life. The Plaintiff states that all of the Defendants bear the responsibility to, *inter alia*, create a medical monitoring fund/mechanism as described below that would give them and Class Members access to experts who could address their health concerns.

## **X. CAUSES OF ACTION**

### **(a) Conspiracy**

64. During the period from on or about December 28, 1994 to the date hereof, at Pickering, Ontario and in the States of Delaware, New Jersey, New York, Virginia and elsewhere, the Defendants, by their directors, officers, servants and agents, wrongfully, unlawfully, maliciously and lacking bona fides, conspired and agreed together, the one with the other and with persons unknown, as hereinafter set out.
65. The Plaintiff pleads that the Defendants' conspiracy involved both lawful and unlawful means with the predominant purpose of causing the Plaintiff and the other Injury Class Members to acquire and ingest OxyContin when they knew or should have known that such use would cause harm to the Injury Class Members and the Family Class Members.
66. The Defendants conspired with each other and others to unlawfully market, distribute, advertise and sell OxyContin, intending that their conduct be directed towards the Injury Class Members, when they knew or should have known that in the circumstances, injury and damage to the Injury Class Members and the Family Class Members was likely to result.
67. As a result of the conspiracy, the Plaintiff and the other Injury Class Members have suffered damage and loss, including addiction, withdrawal symptoms and other side effects as a result of the use of OxyContin.
68. As a further result of the conspiracy, Family Class Members have suffered damages and loss, and continue to suffer damages and loss, including actual

expenses reasonably incurred for the benefit of the Injury Class Member, a reasonable allowance for loss of income or the value of services provided to the Injury Class Member and an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Injury Class Member.

69. Some, but not all, of the Defendants' concerns, motivations and intentions in engaging in the conspiracy were to:
- (a) increase the sales of OxyContin and their profits;
  - (b) increase or hold their market share;
  - (c) avoid adverse publicity;
  - (d) place their profits above the safety of Injury Class Members and others;
  - (e) maintain brand trust and corporate image;
  - (f) avoid alerting the Injury Class Members, Health Canada, the FDA, health practitioners, the public and their competitors to the dangers and addictive properties and effect of OxyContin; and
  - (g) cause the Injury Class Members to ingest and continue to ingest OxyContin and thereby suffer harm.
70. In furtherance of the conspiracy, the following are some, but not all, of the acts carried out by the Defendants or one or some of them:
- (a) they submitted false, inaccurate and misleading information to Health Canada for the purpose of obtaining approval to market OxyContin in Canada;

- (b) they concealed and disguised information about the addictive properties and effect of OxyContin from Health Canada, from health practitioners and from Injury Class Members;
- (c) they misled Injury Class Members, health practitioners and others about the efficacy, safety and effect of OxyContin;
- (d) they refused to issue correcting information or to stop selling OxyContin even after its harmful effects and addictive properties became manifest;
- (e) they promoted and marketed OxyContin for use by a wider range of patients and pain treatment than Health Canada had approved;
- (f) they decided not to warn Class Members and others in Canada of the dangers of taking OxyContin even after the FDA required such warnings in the US;
- (g) they developed and used marketing and promotional strategies that covered up the truth about OxyContin's addictive properties and effect; and
- (h) they engaged in the conduct described and admitted in the plea agreement and Agreed Statement of Facts described more fully in paragraphs 34 to 38.

**(b) Negligence**

- 71. Each of the Defendants owed a duty of care to the Plaintiff and Class Members and breached the requisite standard of conduct expected of them in the circumstances.
- 72. The Defendants negligently breached their duty of care.

73. The Plaintiff and Class Members state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following that the Defendants jointly and severally:

- (a) chose not to ensure that OxyContin was not dangerous to recipients during the course of its use and that the drug was fit for its intended or reasonably foreseeable use;
- (b) chose to inadequately test OxyContin in a manner that concealed the magnitude of the risks associated with its use, including but not limited to the risk of serious addiction, abuse and other problems;
- (c) misinformed Health Canada by providing it with incomplete and inaccurate information;
- (d) conducted inadequate or no follow-up studies on the efficacy and safety of OxyContin;
- (e) concealed and mislead the Plaintiff, Class Members and their physicians with inadequate and incomplete warning of the risks associated with ingesting OxyContin, including but not limited to the risk of serious addiction, abuse and other problems;
- (f) provided the Plaintiff, Class Members and their physicians with inadequate or incomplete or no information and warnings respecting the correct usage of OxyContin;
- (g) provided inadequate or incomplete or no updated and current information to the Plaintiff, Class Members and their physicians respecting the risks and efficacy of OxyContin as it came available from time to time;
- (h) chose not to provide warnings of the potential hazards of ingesting OxyContin on package labels and by other means;

- (i) chose not to provide warnings of the risks associated with OxyContin, including the risk of serious addiction, abuse and other problems on the customer information pamphlets in Canada;
- (j) chose not to warn the Plaintiff, Class Members and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of potentially serious addiction, abuse and other problems from the use of OxyContin;
- (k) after noticing problems with OxyContin chose not to issue adequate warnings, recall the drug in a timely manner, publicize the problem and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff, Class Members and their physicians of the drug's inherent dangers, including but not limited to the danger of serious addiction, abuse and other problems;
- (l) engaged in a system of improper and inadequate direction to their sales representatives and prescribing physicians respecting the correct usage of OxyContin and the risks associated with the drug;
- (m) represented that OxyContin 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;
- (n) misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of OxyContin and its associated risks, including but not limited to the risk of serious addiction, abuse and other problems;
- (o) 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;
- (p) continued to manufacture, market and promote the selling and/or distribution of OxyContin when they knew or ought to have known that

this drug caused or could cause serious addiction, abuse and other problems;

- (q) actively encouraged aggressive dispensation of OxyContin;
- (r) breached other duties of care to the Plaintiff and the Class Members, details of which breaches are known only to the Defendants.

**(c) Negligent and Fraudulent Misrepresentation**

74. As pleaded in subparagraph 1(h), "Representation" means the representation made expressly and impliedly that OxyContin was less addictive, less subject to abuse and less likely to cause withdrawal symptoms than other pain medications and was free from known defects and include the acts admitted in the guilty pleas more particularly described in paragraphs 34 to 38.

75. Beginning in January 1996, the Defendants made the Representation to the Plaintiff and Class Members and others. The Defendants made the Representation directly to each Class Member by the use of the name of OxyContin and by the product itself and, in particular, through the labelling on the package. They also made the Representation in their print and electronic advertising, in their brochures and in their point-of-purchase displays. They made the Representation repeatedly and in all manner of ways, including the following:

- (a) by their conduct in seeking approval from Health Canada and in offering OxyContin for sale and/or use by the Class Members; and
- (b) by their express words, stating that OxyContin:
  - (i) would result in less euphoria and less potential for abuse than short-acting opioids;
  - (ii) patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms and patients on such doses would not develop tolerance;

- (iii) delayed absorption as provided by OxyContin tablets is believed to reduce the abuse liability of a drug;
- (iv) OxyContin potentially creates less chances for addiction than immediate-release opioids; and
- (v) it was more difficult to extract oxycodone from an OxyContin tablet for the purpose of intravenous abuse.

76. The Plaintiff and Class Members relied on the Representation.

77. The reliance upon the Representation by the Plaintiff and Class Members is established by his or her purchase and/or use of OxyContin. Had the Plaintiff and Class Members known that the Representation was false and misleading, he or she would not have purchased and/or used OxyContin.

78. The Defendants made the Representation negligently or fraudulently, knowing it was false and misleading or, recklessly caring not whether it was true or false, intending that the Plaintiff and Class Members rely upon the Representation, intending that the Plaintiff and Class Members would purchase OxyContin from pharmacies and/or acquire OxyContin and the Plaintiff and Class Members did rely upon this Representation to his or her detriment by using OxyContin and, in doing so, increased the Defendants' revenues from their distribution network.

**(d) Strict Liability**

79. The Defendants are strictly liable for some or all of the damages suffered by the Plaintiff and other Class Members in that:

- (a) the Defendants manufactured OxyContin;
- (b) OxyContin is an opioid prescription drug that is considered to be inherently dangerous;
- (c) the Plaintiff and other Class Members had no opportunity to inspect or test OxyContin to ensure its safety; and

- (d) OxyContin was used by the Plaintiff, L. Annette Stewart, and the Class Members.

**(e) Breach of Warranty**

- 80. The Defendants warranted to the Plaintiff and the Class Members that OxyContin was of merchantable quality and fit for use. The Defendants breached the warranty to the Plaintiff and the Class Members by designing, testing, researching, formulating, developing, manufacturing, producing, labelling, advertising, promoting, distributing and/or selling OxyContin which was inherently dangerous to users and which the Defendants knew or ought to have known would lead to dependency and addiction.

**(f) Waiver of Tort**

- 81. As a result of the Defendants' conduct described herein, the Plaintiff and Class Members reserve the right to elect at the trial of the common issues to waive the torts and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, or the net income received by the Defendants or a percent of the proceeds from the sale of OxyContin as a result of the Defendants' conduct.
- 82. The Plaintiff and Class Members claim that such an election is appropriate for the following reasons, among others:
  - (a) revenue was acquired in a manner in which the Defendants cannot in good conscience retain it;
  - (b) the integrity of the pharmaceutical regulations and marketplace would be undermined if the court did not require an accounting;
  - (c) absent the Defendants' tortious conduct OxyContin could not have been marketed nor would the Defendants have received any revenue from its sale in Canada; and
  - (d) the Defendants engaged in wrongful conduct by putting into the marketplace a pharmaceutical product which causes or has the

potential to cause serious risk of injury, drug dependency and addiction.

**(g) Breach of Section 52 of the *Competition Act***

83. The Defendants made the Representation to the public as particularized in paragraphs 118 to 122. In so doing, the Defendants breached s. 52 of the *Competition Act*, R.S., 1985, c. C-34, s. 1; R.S., 1985, c. 19 (2nd Supp.), s. 19 because the Representation:

- (a) was made for the purpose of promoting the business interests of the Defendants;
- (b) was made to the public;
- (c) was false and misleading in a material respect; and
- (d) stated a level of safety of ingesting OxyContin which was not accurate.

84. The Plaintiff and Class Members relied upon the Representation by using OxyContin and suffered damages and loss.

85. Alternatively, the Plaintiff and Class Members rely upon section 52 (1.1) of the *Competition Act* and plead that it is unnecessary for any Plaintiff or Class Member to show actual reliance on the misleading statements of the Defendants for the purposes of establishing a breach of the *Competition Act*.

86. Pursuant to s. 36 of the *Competition Act*, the Defendants are liable to pay the damages which resulted from the breach of s. 52.

**XI. DAMAGES**

87. The Plaintiff's and Class Members' injuries and damages were caused by the Defendants, their servants and agents.

88. The Defendants have caused injury to the Plaintiff and to the Class Members including:

- (a) reduced standard of living as a result of illness;
- (b) cost of treatment to combat the adverse health effects caused by their use of OxyContin; and
- (c) enhanced risk of future problems attributable to the use of OxyContin.

89. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiff and Class Members have been placed in a position where they have sustained or will sustain serious personal injuries and damages including but not limited to addiction, abuse and other problems.

90. As a result of the conduct of the Defendants, the Plaintiff and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

91. Some of the expenses related to the medical treatment that the Plaintiff and Class Members have undergone, and will continue to undergo have been borne by the provincial health insurer the Prince Edward Island Hospital and Medical Services Insurance Plans. As a result of the negligence of the Defendants, the provincial health insurer has suffered and will continue to suffer damages.

**(A) Manifest Harm and Injuries:**

92. In addition, the past and ongoing use of OxyContin has resulted in the Plaintiff's and Class Members' physical and mental health injuries pleaded above, and have further led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, and out of pocket expenses.

93. The Plaintiff and Class Members assert a claim for each of the types of damages listed above.

**(B) Medical Monitoring: Responding to Material Risk of Illness**

94. Further, the past and ongoing use of OxyContin have also caused or materially contributed to increased risks of addiction, abuse and other health risks to the Plaintiff and other Class Members. As a result of the use, the Plaintiff and Class Members have already and will continue to experience addiction, illness, anxiety, loss of amenities and enjoyment of life.
95. There are medically accepted tests and diagnostic tools which, if used properly and on a timely basis, will detect at an early stage the addiction and abuse which may result from the use of OxyContin by the Plaintiff and Class Members. However, not all of these tests are generally available or being administered to the Plaintiff and Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm and risk of death therefrom.
96. The Plaintiff and Class Members seek to recover damages in the form of the total funds required to establish a 'medical monitoring' process to be made available to the Plaintiff and Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Plaintiff and Class Members.
97. The damages referred to above may have been incurred directly by the Plaintiff and Class Members, or may constitute subrogated claims owed to provincial health insurer, or to private health, disability, or group benefit insurers.
98. The Plaintiff further alleges that the establishment of a medical monitoring process is a necessary and appropriate step for all of the Defendants to take in the course of fulfilling their obligation to minimize the damages suffered by Plaintiff and Class Members.

**XII. AGGRAVATED, PUNITIVE AND EXEMPLARY DAMAGES**

99. The Defendants manufactured, marketed, promoted and sold OxyContin with full knowledge of the fact that they were adversely impacting the physical and

psychological health of the Plaintiff and the Class Members. Knowledge of the risks associated with the use of OxyContin was not released to the Plaintiff and Class Members. Despite having specific information that the Plaintiff and Class Members were at risk of addiction to and abuse of OxyContin due to the formulation of the medication, the Defendants continued or permitted the continuation of the manufacturing, marketing, promoting and selling of OxyContin without any or reasonable controls.

100. These activities were carried out with reckless, callous and wanton disregard for the health, safety and pecuniary interests of the Plaintiff and other Class Members. The Defendants knowingly compromised the interests of the Plaintiff and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that OxyContin posed to the Plaintiff and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.
101. 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 Plaintiff and Class Members.
102. Consequently, the Plaintiff and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.
103. The Plaintiff and Class Members plead that, by virtue of the acts described herein, Purdue are liable to them in damages. Each of the Defendants is vicariously liable for the acts and omissions of the others for the following reasons:
  - (a) each was the agent of the other;
  - (b) each Defendants' business was operated so that it was inextricably interwoven with the business of the other;

- (c) each Defendant entered into a common advertising and business plan with the other to distribute and sell OxyContin;
- (d) each Defendant owed a duty to the other and to the Plaintiff and Class Members by virtue of the common business plan to distribute and sell OxyContin; and
- (e) each Defendant intended that the businesses be run as one global business organization.

### **XIII. GENERAL PROVISIONS**

104. The Plaintiff states that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiff and other Class Members.
105. The Plaintiff pleads the doctrine of *respondeat superior* and state that the Defendants are vicariously liable to the Plaintiff and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.
106. The Plaintiff pleads and relies on the Prince Edward Island *Business Practices Act*, R.S.P.E.I. 1988, Cap. B-7, the Prince Edward Island *Consumer Protection Act*, R.S.P.E.I. 1988, Cap. C-19, as am., the Prince Edward Island *Contributory Negligence Act*, R.S.P.E.I. 1988, Cap. C-21 and the Prince Edward Island *Sale of Goods Act*, R.S.P.E.I. 1988, Cap. S-1, as am.
107. Further, the Plaintiff states that the Representation made by the Defendants constitutes both an unfair practice and an unconscionable consumer representation within the meaning of s. 2(a) and s. 2(b) respectively of the Prince Edward Island *Business Practices Act*, R.S.P.E.I. 1988, cap. B-7.

The Plaintiff proposes that this action be tried at the City of Charlottetown, in the Province of Prince Edward Island.

**DATED** at Charlottetown, this 1<sup>st</sup> day of May, 2009.

**(SG'D.) PAUL J.D. MULLIN, Q.C.**

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