

Form 4.02A
2007

Court Administration
AUG 26 2015
Halifax, N.S.

Hfx. No. 285995

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

GEORGE BELLEFONTAINE and STEPHEN MACGILLIVRAY

Plaintiffs

- 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.**

Defendants

Proceeding under the *Class Proceedings Act*, S.N.S 2007, c. 28

**Second Fresh as Amended Notice of Action
Amended on the 26th day of August, 2015.**

TO: PURDUE FREDERICK INC.
123 Sunrise Avenue
Toronto, ON

AND TO: PURDUE PHARMA INC.
40 King Street West,
Suite 4400
Toronto, Ontario

AND TO: PURDUE PHARMA L.P.
One Stamford Forum, 201
Tresser Boulevard
Stamford, Connecticut, USA

AND TO: PURDUE PHARMA
575 Granite Crt
Pickering, Ontario

AND TO: PURDUE PHARMA COMPANY
One Stamford Forum, 201
Tresser Boulevard
Stamford, Connecticut, USA

AND TO: THE PURDUE FREDERICK COMPANY, INC.
One Stamford Forum, 201
Tresser Boulevard
Stamford, Connecticut, USA

AND TO: PURDUE PHARMACEUTICALS L.P.
4701 Purdue Drive
Wilson, North Carolina, USA

AND TO: P.F. LABORATORIES, INC.,
700 Union Boulevard
Totowa, New Jersey, USA

Action has been started against you

The plaintiffs take action against you.

The plaintiffs started the action by filing this notice with the court on the date certified by the prothonotary.

The plaintiffs claim the relief described in the attached second fresh as amended statement of claim. The claim is based on the grounds stated in the statement of claim.

Deadline for defending the action

To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

- 15 days if delivery is made in Nova Scotia
- 30 days if delivery is made elsewhere in Canada
- 45 days if delivery is made anywhere else.

Judgment against you if you do not defend

The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

You may demand notice of steps in the action

If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

If you file a demand for notice, the plaintiffs must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

Rule 57 - Action for Damages Under \$100,000

Civil Procedure Rule 57 limits pretrial and trial procedures in a defended action so it will be more economical. The Rule applies if the plaintiff states the action is within the Rule.

Otherwise, the Rule does not apply, except as a possible basis for costs against the plaintiffs.

This action is not within Rule 57.

Filing and delivering documents

Any documents you file with the court must be filed at the office of the Prothonotary, The Law Courts, 1815 Upper Water Street, Halifax, Nova Scotia (telephone #902-424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

Contact information

The plaintiffs designate the following addresses:

Wagners Law Firm
1869 Upper Water Street
Suite PH301, Historic Properties
Halifax, Nova Scotia B3J 1 S9
Email: classaction@wagners.co

Documents delivered to this addresses are considered received by the plaintiffs on delivery.

Further contact information is available from the prothonotary.

Proposed place of trial

The plaintiffs propose that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Signature

Signed this 26th day of August, 2015.

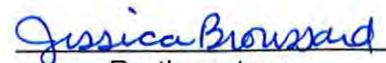


RAYMOND F. WAGNER, Q.C.

Wagners Law Firm
Counsel for the Plaintiffs

Prothonotary's certificate

I certify that this notice of action, including the attached second fresh as amended statement of claim, was filed with the court on August 26, 2015



JESSICA BROUSSARD
Deputy Prothonotary

I. DEFINITIONS

1. 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 in Canada 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.

II. OVERVIEW

2. 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.
3. 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. The result was that many users of OxyContin suffered from overdose, addiction and/or withdrawal effects which were severe, profound, and of long duration. Notwithstanding these effects of addiction and/or withdrawal, the Defendants failed to adequately warn Class Members of such risks.
4. 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.
5. The Plaintiffs and Class Members have all been prescribed OxyContin and became dependant on it or addicted to it.
6. In this action, the Plaintiffs seek, on their 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 Plaintiffs and Class Members.

III. REPRESENTATIVE PLAINTIFFS AND CLASS

- 7. The Plaintiff, George Bellefontaine resides in the Halifax Regional Municipality, Nova Scotia.
- 8. The Plaintiff, Stephen MacGillivray resides in Glace Bay, Nova Scotia.
- 9. The Plaintiffs seek to certify this action as a class proceeding, and plead the *Class Proceedings Act*, S.N.S. 2007, c. 28, as providing the basis for such certification. The Plaintiffs, as the Representative Plaintiffs, do not have any interest adverse to any of the members of the proposed Class. The Plaintiffs state that there is an identifiable class that would be fairly and adequately represented by the Plaintiffs; that the Plaintiffs' claims raise common issues; and that a class proceeding would be the preferable procedure for the resolution of such common issues.
- 10. The Plaintiffs propose to bring a class proceeding on behalf of themselves and other residents of Canada who claim to 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 Plaintiffs and Class Members have been continuously harmed by their use of the medication OxyContin as hereinafter described. Each of the Plaintiffs is an Injury Class Member or a Family Class Member.

IV. 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. It owns the OxyContin® trademark in Canada, and has owned the Canadian patent for OxyContin® since approximately 2005. Purdue Pharma Inc. is the general partner of Purdue Pharma.
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. It owns the OxyContin® trademark for the United States. It owned the Canadian patent for OxyContin® until 2005 and during that period Purdue Pharma L.P. licensed the manufacture, distribution, marketing, promotion and sale of OxyContin® in Canada. Purdue Pharma L.P.'s partners are closely held private American corporations which, directly or indirectly, own all issued shares of the co-Defendants. In concert with its subsidiary and sister companies, Purdue Pharma L.P. manufactures, markets, and distributes OxyContin® in the United States. It manufactures, markets, and distributes OxyContin® in Canada. It controls numerous wholly owned subsidiaries, including the co-Defendants, who were engaged and are still engaged in the development, manufacture, distribution, marketing, and sale of OxyContin® in Canada.
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. The Purdue Frederick Company

carried on research and development of OxyContin. The Purdue Frederick Company was dissolved on May 7, 2004, and reinstated on September 23, 2004 as The Purdue Frederick Company, Inc. Upon reinstatement, liability for the wrongs committed by The Purdue Frederick Company was assumed by The Purdue Frederick Company, Inc.

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. It manufactured OxyContin that was distributed in Canada.
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.
23. In particular, the Defendants provided executive services to each other, copied each other with correspondence in relation to OxyContin's regulatory

approval, marketing and sale, and met and conferred frequently to discuss and advance the promotion and sale of OxyContin within the Canadian market. In particular:

(a) Purdue Pharma L.P. and P.F. Laboratories, Inc., in entering into a plea agreement in the United States regarding the marketing and misbranding of OxyContin, included the Canadian Purdue entities, insulating them from claims against their property with respect to further U.S. liabilities, evidencing the control of the US entities over the Canadian entities; and

(b) The plea agreement also contained provisions, (particularized below at paragraphs 38-43), whereby it is evident that the U.S. Purdue entities exercised control over the Canadian entities with respect to the manner in which the Canadian Purdue entities placed OxyContin into the stream of commerce, as well as exercised control over research, sales, marketing and promotion of OxyContin in Canada.

24. The Defendants failed to warn or otherwise adequately communicate the addictive properties, abuse potential and severe withdrawal effects of OxyContin to regulatory authorities, health practitioners and Class Members. The Defendants were aware, at all material times, of the consequent harm being done to Class Members by OxyContin. The Defendants participated in, acquiesced in and approved the decision to continue promoting, marketing, distributing and selling OxyContin in Canada nonetheless.

25. The Defendants are therefore liable for the acts and omissions of each other.

V. OXYCONTIN

26. 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.

27. 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.
28. 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.
29. 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.
30. As OxyContin quickly became a highly prescribed drug for the relief of pain, concerns began to arise with respect to its safety.
31. 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.
32. 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.
33. 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.

34. 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. Usage of OxyContin in accordance with its prescription resulted in dependency on the drug, requiring more frequent and higher doses and leading, in the majority of cases, to addiction in patients.
35. Discontinuance of OxyContin also causes severe withdrawal symptoms which are extremely painful and often require further medical intervention. Moreover, many patients require painful medical detoxification, including a weaning off OxyContin program, or prescriptions of clonidine or methadone.
36. The concerns about OxyContin addiction and severe withdrawal symptoms were well known to the Defendants for many years. In 2003, the Newfoundland and Labrador government established the OxyContin Task Force in response to a number of deaths resulting from OxyContin use in that province.
37. The true scope of the misrepresentations by the Defendant Purdue were not known or could have not been known by the Plaintiffs or by the Class Members until after May 2007 when the Defendant Purdue and three of its current and former executives entered guilty pleas.

VI. THE GUILTY PLEAS

38. 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.
39. The plea agreement referred to above contained an Agreed Statement of Facts.
40. 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.

41. The Plaintiffs 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.

VII. NATURE OF THE ACTION

42. The Plaintiffs and Class Members allege that the Defendants unlawfully marketed and promoted 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.

43. The Plaintiffs 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 Plaintiffs and Class Members.

44. The Plaintiffs 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.

45. The Plaintiffs 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.

46. The Plaintiffs and Class Members further allege that the Defendants were wholly and grossly negligent.

47. The Plaintiffs and Class Members further allege that the Defendants failed to warn the Plaintiffs 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.
48. The Plaintiffs and Class Members further allege that the Defendants expressly and impliedly breached warranties.
49. The Plaintiffs 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.
50. The Plaintiffs 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.
51. Specifically the Plaintiffs 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.
52. 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.

53. The Plaintiffs 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.
54. OxyContin has caused damage to the physical and mental health of the Plaintiffs and Class Members.
55. The continued use of OxyContin by the Plaintiffs and Class Members creates ongoing risks to the health of the Plaintiffs and Class Members.
56. 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.
57. None of the Defendants took any steps to prevent harm to the Plaintiffs and the Class Members or to protect the health and safety of the Plaintiffs and Class Members.
58. Until in or about May 2007, the Plaintiffs and Class Members were unaware of the existence, nature, extent and ramifications of using OxyContin.
59. The Plaintiffs and Class Members have been prescribed and continue to be prescribed the drug.

VIII. HARM TO THE PLAINTIFFS

(a) George Bellefontaine

60. The Plaintiff, George Bellefontaine, was first prescribed OxyContin for chronic pain as a result of a motor vehicle accident on April 30, 2003 in which he suffered cracked ribs and wrist, ankle, back, neck and shoulder problems. He continued to take OxyContin for approximately three years.
61. Initially he was prescribed 20 milligram tablets twice a day. His doctor increased his dosage to 80 milligrams twice a day.

62. This Plaintiff found that he needed more and more OxyContin tablets and he sometimes took as many as four or five 80 milligram tablets per day. Sometimes this Plaintiff's need for OxyContin was so great that he purchased it from street level drug dealers.
63. While taking OxyContin this Plaintiff had severe mood swings and suicidal thoughts.
64. When this Plaintiff decided to discontinue the use of OxyContin he experienced severe withdrawal symptoms including dizziness, shaking and convulsions. Although this Plaintiff has not used OxyContin in the last six months he continues to experience some withdrawal symptoms at the present time.
65. This Plaintiff states that these personal injuries were caused or materially contributed to by his use of OxyContin.

(b) Stephen MacGillivray

66. The Plaintiff, Stephen MacGillivray, was first prescribed OxyContin in 1997 for a shattered clavicle as a result of an injury sustained at his place of employment. He continued to take OxyContin for approximately six years.
67. Initially he was prescribed 20 milligram tablets twice a day.
68. This Plaintiff suffered serious and severe addiction as a result of his use of OxyContin.
69. As a result of his addiction to OxyContin this Plaintiff has lost his family as well as his job.
70. This Plaintiff is presently on Methadone Maintenance and expects that he will be required to receive Methadone treatment for many years to come.
71. This Plaintiff states that these personal injuries were caused or materially contributed to by his use of OxyContin.

72. In addition, all of the Plaintiffs have suffered and continue to suffer from anxiety about their own and their family's health because of the effect that OxyContin has had on their lives. All of the Plaintiffs state 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.

IX. CAUSES OF ACTION

(a) Negligence

73. The Defendants knew or ought to have known that OxyContin had addictive properties and could cause damage to persons who ingested it, including severe withdrawal symptom.
74. At all material times, the Defendants owed a duty of care to the Plaintiffs and Class Members. The Defendants breached the standard of care owed to the Plaintiffs and Class Members.

(b) Negligent design, development and testing:

75. The Defendants owed the Plaintiffs and Class Members a duty of care as follows:
- (a) to ensure that OxyContin was thoroughly and appropriately tested so as to determine if there were any potentially adverse side effects in consuming the drug;
 - (b) to ensure that OxyContin was fit for its intended or reasonably foreseeable use;
 - (c) to design, develop and test OxyContin using methods and processes that conform to industry standards and regulations; and
 - (d) to conduct appropriate follow-up studies on the efficacy and safety of OxyContin.
76. The Defendants were negligent in the design, development and testing of OxyContin. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

- (a) failed to thoroughly and appropriately test OxyContin to determine the magnitude of the risks associated with its use, including but not limited to the risk of serious addiction;
- (b) failed to conduct adequately powered studies and testing to determine the addictive effects of OxyContin;
- (c) designed and developed OxyContin in a manner that caused an increase in the risk of serious addiction when they knew, or should have known, that this significantly increases the risk of adverse outcomes in its users;
- (d) failed to adequately test the effects of OxyContin's absorption rate on a user's risk of addiction;
- (e) conducted inadequate or no follow-up studies on the efficacy and safety of OxyContin;
- (f) failed to conform to industry standards, practices and regulations in the design, development and testing of OxyContin;
- (g) failed to conform with applicable disclosure and reporting obligation;
- (h) failed to monitor the post-market effects of OxyContin;
- (i) failed to conduct appropriate follow-up studies when the risks of OxyContin became known to them;
- (j) disregarded reports of symptoms of adverse events among patients who participated in clinical trials of OxyContin;
- (k) failed to instruct their employees to properly monitor and record complaints of adverse health effects, including the development of serious addiction, associated with OxyContin;

- (l) hired incompetent personnel and failed to adequately supervise the personnel conducting the design, development and testing of OxyContin; and,
- (m) failed to take reasonable steps to ensure that OxyContin was fit for its intended or reasonably foreseeable use.

77. There existed alternative designs which were safer and economically feasible to manufacture.

78. The negligence of the Defendants in the design, development and testing of OxyContin created a substantial likelihood of harm for users of OxyContin. The Plaintiffs and Class Members have suffered harm and damages as a result of the Defendants' negligence.

(c) Negligent Manufacturing

79. The Defendants owed the Plaintiffs and Class Members a duty of care as follows:

- (a) to conform to industry standards, practices and regulations in the manufacturing of OxyContin;
- (b) to conduct adequate and routine inspections of the plants manufacturing OxyContin; and,
- (c) to have adequate and appropriate quality control methods in place at the plants manufacturing OxyContin.

80. The Defendants were negligent in the manufacturing of OxyContin. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

- (a) failed to meet industry standards, practices and regulations in the manufacturing of OxyContin;
- (b) failed to adequately and routinely inspect the plants manufacturing OxyContin;

- (c) manufactured OxyContin without having in place adequate quality control protocols, or in disregard of those protocols;
- (d) hired incompetent personnel and failed to adequately supervise the personnel manufacturing OxyContin;
- (e) manufactured the high-dose SR formulation without a safety mechanism to prevent its immediate release by grinding, chewing or, other means, and,
- (f) continued to manufacture OxyContin when they knew or ought to have known that this drug caused or could cause serious addiction and associated health problems.

The Plaintiffs and Class Members have suffered harm and damages as a result of the Defendants' negligence in the manufacturing of OxyContin.

(d) Negligent distribution, marketing and sale

81. The Defendants owed the Plaintiffs and Class Members a duty of care as follows:

- (a) to warn the Plaintiffs and Class Members that ingestion of OxyContin carried a significant risk of developing an addiction to the drug;
- (b) to take reasonably necessary and appropriate steps to ensure that prescribing physicians were apprised and fully and regularly informed of all the health risks associated with ingesting OxyContin; and
- (c) to inform Health Canada and other regulating agencies fully, properly, and in a timely manner of the addictive properties, health risks and complaints associated with the ingestion of OxyContin.

82. The Defendants were negligent in the distribution, marketing and sale of OxyContin. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

- (a) failed to provide Class Members and their physicians with any or any adequate warnings of inherent risks associated with OxyContin;
- (b) failed to provide Class Members and their physicians with any or any adequate information and warnings respecting the correct usage of OxyContin;
- (c) failed to provide any or any adequate updated and current information to Class Members and their physicians respecting the risks and efficacy of OxyContin as such information became available;
- (d) failed to provide prompt warnings of potential hazards of OxyContin in the product monograph and in the product labelling;
- (e) failed to warn Class Members and their physicians about the need for comprehensive regular medical monitoring to ensure early discovery of potential addiction;
- (f) after receiving actual or constructive notice of problems with OxyContin, failed to issue adequate warnings, to withdraw or to recall the drug, to publicize the problem and otherwise to act properly and in a timely manner to alert the public, Class Members and their physicians, of the drug's inherent dangers;
- (g) failed to establish any adequate procedures to educate their sales representatives and prescribing physicians respecting the correct usage of OxyContin and the risks associated with the drug;
- (h) falsely stated and/or implied that OxyContin was safe and fit for its intended purpose when they knew or ought to have known that these representations were false;

- (i) misstated the state of research, opinion and medical literature pertaining to the purported benefits of OxyContin and its associated risks, as compared to other available Opioid analgesics;
- (j) failed to cease the manufacture and/or distribution of OxyContin when they knew or ought to have known that this drug caused or could cause significant injury;
- (k) marketed OxyContin at dosage levels that they knew or ought to have known to be unsafe;
- (l) disregarded reports of symptoms of addiction among patients who consumed OxyContin;
- (m) failed to instruct their employees to properly evaluate, record and advise on complaints of the addictive effects of OxyContin;
- (n) failed to accurately and promptly disclose to HC information relating to addiction risks associated with OxyContin and to modify OxyContin's product monograph and product labelling accordingly in a timely manner or at all even though this information was available in the United States, to regulators, consumers and physicians;
- (o) failed to monitor and to initiate a timely review, evaluation and investigation of reports of addiction associated with the use of OxyContin in Canada;
- (p) marketed OxyContin as a safer, less addictive Opioid analgesic, when they knew or ought to have known of the high risks of addiction;
- (q) failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and the regulations thereunder;

- (r) hired incompetent personnel and appointed incompetent officers and directors;
- (s) failed to instruct their servants, agents, officers and directors to act ethically and responsibly;
- (t) failed to properly supervise their employees, their subsidiaries and their affiliated corporations;
- (u) encouraged their employees to increase sales volumes while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the serious risks of addiction associated with OxyContin;
- (v) failed to withdraw or recall OxyContin in a timely manner because of the cost and the negative publicity and their overriding concern for lost profits;
- (w) falsely understated the addictive risks of OxyContin, while at the same time falsely overstating the safety and efficacy of the drug; and
- (x) used the SR formulation to justify a larger dose of the Opioid Oxycodone than an IR formulation would contain (and in some cases release immediately).

83. The Plaintiffs and Class Members have suffered harm and damages as a result of the Defendants' negligence in the distribution, marketing and sale of OxyContin.

84. The Plaintiffs plead that the Defendants' negligence caused the Class Members to acquire and ingest OxyContin when they knew or should have known that such use would cause harm to the Class Members and the Family Class Members.

85. The Defendants developed, designed, marketed, distributed, advertised and sold OxyContin, when they know or should have known that in the

circumstances, injury and damage to the Class Members and the Family Class Members was likely to result.

86. As a result of the acts and omissions of the Defendants, the Class Members have suffered damages and losses, and continue to suffer damages and losses, including addiction, severe withdrawal symptoms and other side effects of OxyContin.
87. As a further result of the acts and omissions of the Defendants, the Family Class have suffered damages and losses, and continue to suffer damages and losses, including actual expenses reasonably incurred for the benefit of the Class Members, a reasonable allowance for loss of income or the value of services provided to the Class Members and an amount to compensate for the loss of guidance, care and companionship they might reasonably have expected to receive from the Class Members.
88. Some, but not all, of the Defendants' concerns, motivations and intentions in engaging in the negligent conduct 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 Class Members and others;
 - (e) maintain brand trust and corporate image;
 - (f) avoid alerting Class Members, HC, the FDA, health practitioners, the public and their competitors to the dangers and addictive properties and effect of OxyContin; and
 - (g) cause Class Members to ingest and continue to ingest OxyContin and thereby suffer harm.
89. The Plaintiffs plead and rely on the Canada *Food and Drugs Act*, R.S. 1985, c. F-27, the Canada *Competition Act*, R.S., 1985, c. C-34, s. 1; R.S., 1985, c.

19 (2nd Supp.), s. 19, , the Nova Scotia *Sale of Goods Act*, R.S., c. 408, s. 1, the Nova Scotia *Consumer Protection Act*, R.S., c. 92, s. 1 and the Nova Scotia *Fatal Injuries Act*, R. S. N. S. 1989, c. 163 as amended.

(e) Waiver of Tort

90. In the alternative to the claims in negligence, the Plaintiffs plead that they are entitled to claim “waiver of tort” and thereby to claim an accounting or other such restitutionary remedy for disgorgement of the revenues generated by the Defendants as a result of the sale of OxyContin, due to the failure of the Defendants to properly bring the risks associated with OxyContin to the attention of the Plaintiffs.

91. The Plaintiffs claim that such an election is appropriate for the following reasons:

(a) Revenue was acquired in a manner in which the Defendants cannot in good conscience retain;

(b) The integrity of the marketplace would be undermined if an accounting was not required;

(c) Absent the Defendants’ tortuous conduct OxyContin could not have been marketed nor would the Defendants have received any revenue in Canada; and

(d) The Defendants engaged in wrongful conduct by putting into the marketplace a product which causes or had the potential to cause serious risks of injury.

(f) Breach of Sections 36 and 52 of the *Competition Act*

92. As a result of their conduct in actively marketing OxyContin as less addictive, less subject to abuse, and less likely to cause severe withdrawal symptoms than other pain medications, the Defendants are liable under sections 36 and 52 of the *Competition Act* R.S.C. 1985, c. C-34 (“*Competition Act*”) for knowingly or recklessly making a representation to the public that is false or misleading in a material respect. The Defendants at all times knew, or were

reckless as to their knowledge that OxyContin was and is a highly addictive drug.

93. The Plaintiffs plead and rely upon the facts and allegations referred to above.

94. By virtue of making representations to the public as to the effectiveness of OxyContin, the Defendants breached section 52 of the *Competition Act*, in that the representations:

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

95. The Plaintiffs plead that the non-disclosure of the serious effects of ingesting OxyContin constituted material and misleading representations for the purposes of section 52 of the *Competition Act*.

96. The Plaintiffs plead that they and other Class Members relied upon the Defendants' representations. Alternatively, the Plaintiffs rely upon section 52(1.1) of the *Competition Act* and plead that it is unnecessary for any Class Member to show actual reliance on the misleading statements of the Defendants for the purposes of establishing a breach of the *Competition Act*.

X. DAMAGES

97. The Plaintiffs' and Class Members' injuries and damages were caused by the Defendants, their servants and agents.

98. The Defendants have caused injury to the Plaintiffs 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.

99. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiffs 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.

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

101. Some of the expenses related to the medical treatment that the Plaintiffs and Class Members have undergone, and will continue to undergo have been borne by provincial health insurers. As a result of the negligence of the Defendants, the provincial health insurers have suffered and will continue to suffer damages.

(A) Manifest Harm and Injuries:

102. In addition, the past and ongoing use of OxyContin has resulted in the Plaintiffs' 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.

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

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

104. 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 Plaintiffs and other Class Members. As a result of the use, the Plaintiffs and Class Members have already and will continue to experience addiction, illness, anxiety, loss of amenities and enjoyment of life.

105. 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 Plaintiffs and Class Members. However, not all of these tests are generally available or being administered to the Plaintiffs and Class Members despite their elevated risk. The early detection of these conditions will significantly reduce the harm and risk of death therefrom.
106. The Plaintiffs 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 Plaintiffs and Class Members. Such damages include the costs of medical screening and treatment incurred by or on behalf of the Plaintiffs and Class Members.
107. The damages referred to above may have been incurred directly by the Plaintiffs and Class Members, or may constitute subrogated claims owed to provincial health insurers, or to private health, disability, or group benefit insurers.
108. The Plaintiffs further allege 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 Plaintiffs and Class Members.

XI. AGGRAVATED, PUNITIVE AND EXEMPLARY DAMAGES

109. 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 Plaintiffs and the Class Members. Knowledge of the risks associated with the use of OxyContin was not released to the Plaintiffs and Class Members. Despite having specific information that the Plaintiffs 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.

110. These activities were carried out with reckless, callous and wanton disregard for the health, safety and pecuniary interests of the Plaintiffs and other Class Members. The Defendants knowingly compromised the interests of the Plaintiffs 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 Plaintiffs and Class Members, the Defendants failed to advise them in a timely fashion, or fully, or at all.
111. 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 Plaintiffs and Class Members.
112. Consequently, the Plaintiffs and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.
113. The Plaintiffs 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 each Plaintiff and Class Member 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.

XII. GENERAL PROVISIONS

- 114. The Plaintiffs state that the Defendants are responsible, jointly and severally, for the injuries and damages suffered by the Plaintiffs and other Class Members.
- 115. The Plaintiffs plead the doctrine of *respondeat superior* and state that the Defendants are vicariously liable to the Plaintiffs and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.

XIII. STATUTES

- 116. The Plaintiffs plead and rely, *inter alia*, upon the following legislation:

Newfoundland

- *Consumer Protection Act*, R.S.N.L. 1990 c. C-31
- *Fatal Accidents Act*, R.S.N.L. 1990, c. F-6
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990, c. H-7
- *Medical Care Insurance Act*, 1999 S.N. 1999, c. 5.1
- *Sale of Goods Act*, R.S.N.L. 1990, c.S-6
- *Trade Practices Act*, R.S.N.L. 1990 T-7
- Current to Gazette Vol. 81:46 (November 17, 2006)

Nova Scotia

- *Consumer Protection Act*, R.S., c.92
- *Tortfeasors Act*, R.S.N.S., c. 471
- *Fatal Injuries Act*, R.S.N.S. 1989, c. 163, amended 2000, c. 29, ss 9-12

- *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197
- *Sale of Goods Act*, R.S., c.408
- Current to Gazette Vol. 30:21 (November 10, 2006)

Prince Edward Island

- *Business Practices Act*, R.S.P.E.I. 1988, cap. B-7
- *Consumer Protection Act*, R.S.P.E.I. 1988, c. C-19
- *Contributory Negligence Act*, R.S.P.E.I. 1988, cap. C-21
- *Fatal Accidents Act*, R.S.P.E.I. 1988, c. F-5, as amended
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c H-8
- *Sale of Goods Act*, R.S.P.E.I. 1988, c. S-1, as amended
- Current to Gazette Vol. 132:47 (November 25, 2006)

New Brunswick

- *Consumer Product Warranty and Liability Act*, Chap. C-18.1
- *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9
- *Sale of Goods Act*, RS.N.B. 1973, c.S-1
- *Tortfeasors Act*, R.S.N.B. 1978, c. T-8 as am.
- Current to Gazette Vol. 164:1901 (November 29, 2009)

Quebec

- *Civil Code of Quebec* Book 5
- *Consumer Protection Act*, R.S.Q. chapter P-40.1

Ontario

- *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;
- *Consumer Protection Act*, 2002 S.O. 2002, c.30, Sched. A;
- *Courts of Justice Act*, R.S.O. 1990, c.43;
- *Family Law Act*, R.S.O. 1990, c. F.3;
- *Health Insurance Act*, R.S.O. 1990, c. 11.6;

- *Negligence Act*, R.S.O. 1990, c. N.1;
- *Sale of Goods Act*, R.S.O. 1990, c. S.1;
- *Trustee Act*, R.S.O. 1990, c. T.23

Manitoba

- *Fatal Accidents Act*, C.C.S.M. c. F50, as amended
- *Manitoba Public Insurance Corporation Act*, C.C.S.M. c. P215
- *Sale of Goods Act*, C.C.S.M. c. S10
- *The Consumer Protection Act*, C.C.S.M. c. C200
- *The Health Services Insurance Act*, R.S.M. 1987, c. H35
- *Trustee Act*, C.C.S.M. c.T160
- Current to Gazette Vol. 135:44 (November 4, 2006)

Saskatchewan

- *Department of Health Act*, R.S.S. 1978, c. D-17
- *Fatal Accidents Act*, R.S.S. 1978, c. F-11 as amended
- *The Consumer Protection Act*, 1996, c. C-30.1
- *The Sale of Goods Act*, R.S.S. 1978, c. S-1
- Current to Gazette Vol. 102:44 (November 3, 2006)

Alberta

- *Alberta Health Care Insurance Act*, R.S.A., 2000, C.A-20
- *Domestic Relations Act*, R.S.A. 2000, c. D10.5, was repealed by R.S.A. 2003, c. F-4.5 [*Family Law Act*]
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8
- *Hospital's Act*, R.S.A. 2000, c. H-12
- *Sale of Goods Act*, S-2 R.S.A 2000
- *Tort Feasors Act*, R.S.A. 2000, c. T-5

British Columbia

- *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2

- *Hospital's Insurance Act*, R.S.B.C. 1996, c. 204 [en. 1994, c. 37, s. 4; am. 1996, c. 24, s. 1(3)]
- *Sale of Goods Act*, R.S.B.C. 1996, c.410
- Current to Gazette Vol. 49:19 (October 20, 2006)

Nunavut

- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- Current to Gazette Vol. 8:10 (October 31, 2006)

Northwest Territories

- *Consumer Protection Act*, R.S.N.W.T. 1988, c. C-17
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3
- *Sale of Goods Act*, R.S.N.W.T. 1988, c. S-2
- *Trustee Act* RSNWT 1988, C.S-2
- Current to Gazette Vol. XXVII:10 (October 31, 2006)

Yukon

- *Consumers Protection Act*, R.S.Y. 2002, c. 40
- *Hospital Insurance Services Act*, R.S.Y. 2002, c. 112
- *Sale of Goods Act*, R.S.Y. 2002, c. 198
- Current to Gazette Vol. 25:10 (October 15, 2006)

Canada

- *Food and Drugs Act*, (R.S., 1985, c. F-27)
- *Competition Act*, R.S., 1985, c. C-34, s. 1; R.S., 1985, c. 19 (2nd Supp.), s. 19

XIV. RELIEF SOUGHT

117. The Plaintiffs repeat the foregoing paragraphs and state that the Defendants are jointly and severally liable for the following:

- (a) an Order certifying this proceeding as a class proceeding and appointing the Plaintiffs as Representative Plaintiffs 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 Plaintiffs claim, on their 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 Plaintiffs and other Class Members, and to make recommendations about their treatment;
- (g) subrogated claims on behalf of Provincial providers 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 the Statutes referred to at paragraph 116 herein;

- (i) interest pursuant to the *Judicature Act*;
- (j) costs; and
- (k) such further and other relief as this Honourable Court deems just.

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Halifax, Nova Scotia this 26th day of September, 2007.

AMENDED at Halifax, Nova Scotia this 5th day of December, 2007.

SECOND AMENDED at Halifax, Nova Scotia this 26th day of August, 2015.

SECOND FRESH AMENDED at Halifax, Nova Scotia this 26th day of August, 2015.



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